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

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

for the transition period from _____ to

Commission file number: 001-38547

Autolus Therapeutics plc

(Exact name of Registrant as specified in its charter)

England and Wales	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

The Mediaworks
191 Wood Lane, London, W12 7FP
United Kingdom
(Address of principal executive offices)

(44) 20 3829 6230
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
American Depositary Shares, each representing one ordinary share, nominal value of $0.000042 per share	AUTL	The Nasdaq Global Select Market
Ordinary shares, nominal value $0.000042 per share*	*	The Nasdaq Stock Market LLC*

* *Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Stock Market LLC.*

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** ☒ **No** ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. **Yes** ☐ **No** ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
Yes ☐ **No** ☒

As of June 30, 2023, the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $279,466,250 based on the closing sale price on that date of $2.38 per ADS. Shares held by each executive officer and director and by each other person who may be deemed to be an affiliate of the Registrant have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of March 20, 2024, there were 265,926,305 of the registrant's ordinary shares (including in the form of ADSs), with a nominal value of $0.000042 per share, outstanding.

EXPLANATORY NOTE

Autolus Therapeutics plc (the "Company"), a corporation organized under the laws of England and Wales, qualifies as a "Foreign Private Issuer," as defined in Rule 3b-4 under the Securities Exchange Act of 1934 (the "Exchange Act") in the United States. The Company has voluntarily elected to file annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K with the United States Securities and Exchange Commission (the "SEC") instead of filing on the reporting forms available to foreign private issuers.

Although the Company has voluntarily chosen to file, periodic reports and current reports, as well as registration statements, on U.S. domestic issuer forms, the Company will maintain its status as a foreign private issuer. Accordingly, as a foreign private issuer, the Company remains exempt from the U.S. federal proxy rules pursuant to Section 14 of the Exchange Act and Regulations 14A and 14C thereunder, Regulation FD, and its officers, directors, and principal shareholders are not subject to the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

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GENERAL INFORMATION

All references in this Annual Report on Form 10-K ("the Annual Report") to "Autolus," the "Group," the "company," "we," "us" and "our" refer to Autolus Therapeutics plc and its consolidated subsidiaries, except where the context otherwise requires.

"AUTOLUS" is our registered trademark. All other brand names and service marks, trademarks and other trade names appearing in this Annual Report are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Exchange Act, that relate to future events or to our future operations or financial performance. Any forward-looking statement involves known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statement. In some cases, forward-looking statements are identified by the words "anticipate," "believe," "continue," "could," "estimate," "expect," "future," "goals," "intend," "likely," "may," "might," "ongoing," "objective," "plan," "potential," "predict," "project," "seek," "should," "strategy," "target," "will" and "would" or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these identifying words. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this Annual Report on Form 10-K are based upon information available to us as of the date of this Annual Report and, while we believe we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the development of our product candidates, including statements regarding the initiation, timing, progress and the results of clinical studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to advance our product candidates into, and successfully complete, clinical trials;
- our ability to obtain and maintain regulatory approval of our product candidates in the indications for which we plan to develop them, and any related restrictions, limitations or warnings in the label of an approved drug or therapy;
- the impacts of public health crises and their effects on our operations and business, including interruption of key clinical trial activities, such as clinical trial site monitoring, access to capital, and potential disruption in the operations and business of third-party manufacturers, clinical sites, contract research organizations ("CROs"), other service providers and collaborators with whom we conduct business;
- our ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreement;
- our plans to research, develop, manufacture and commercialize our product candidates;
- the potential benefits of our product candidates;
- the timing or likelihood of regulatory filings and approvals for our product candidates, along with regulatory developments in the United States, European Union ("EU"), the United Kingdom ("UK") and other foreign countries;
- the size and growth potential of the markets for our product candidates, if approved, and the rate and degree of market acceptance of our product candidates, including reimbursement that may be received from payors;
- our need for and ability to obtain additional funding, on favorable terms or at all, including as a result of worsening macroeconomic conditions, including changes inflation and interest rates and unfavorable general market conditions, and the impacts thereon of the war in Ukraine, the conflict between Hamas and Israel, and global geopolitical tension;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our plans to collaborate, or statements regarding our current collaborations with BioNTech SE ("BioNTech") and others;
- our license and option agreement with BioNTech, including our potential to receive milestone payments and royalties under the agreement;

- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify, recruit and retain qualified employees and key personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the scalability and commercial viability of our manufacturing methods and processes;
- the success of competing therapies that are or may become available;
- whether we are classified as a Passive Foreign Investment Company ("PFIC"), for current and future periods;
- additional costs and expenses related to our decision to voluntarily comply with certain U.S. domestic issuer reporting obligations before we are required to do so; and
- any other factors which may impact our financial results or future trading prices of our American Depositary Shares ("ADSs"), and the impact of securities analysts' reports on these prices.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors including, without limitation, risks, uncertainties and assumptions regarding the impact of worsening macroeconomic events, including changes inflation and interest rates and unfavorable general market conditions and the impacts of the war in Ukraine, the conflict between Hamas and Israel, and global geopolitical tensions, on our business, operations, strategy, goals and anticipated timelines, our ongoing and planned preclinical activities, our ability to initiate, enroll, conduct or complete ongoing and planned clinical trials, our timelines for regulatory submissions and our financial position that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You are urged to carefully review the disclosures we make concerning these risks and other factors that may affect our business and operating results in this Annual Report on Form 10-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. Except as required by law, we do not intend, and undertake no obligation, to update any forward-looking information to reflect events or circumstances.

RISK FACTOR SUMMARY

Our business is subject to a number of risks and uncertainties, including those risks discussed more fully in Part I, Item 1A., Risk Factors in this Annual Report. These risks include, among others, the following:

- We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We will need additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all.
- All of our product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our proprietary, next-generation T cell programming technologies, our modular approach for engineering T cells and our manufacturing platform for our programmed T cell product candidates, represent emerging approaches to cancer treatment that face significant challenges and hurdles.
- We collaborate with third parties in the research, development and commercialization of certain of our product candidates. If our collaborators do not perform as expected or if we are unable to maintain existing or establish additional collaborations, our ability to develop and commercialize our product candidates may be adversely affected.
- We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.
- Our future success is highly dependent on the regulatory approval of our current clinical-stage programmed T cell product candidates and our preclinical programs. All of our product candidates will require significant clinical or preclinical testing before we can seek regulatory approval for and launch a product commercially.

- Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, could limit the commercial profile of an approved label, or could result in significant negative consequences following any potential marketing approval.
- If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA") and the European Commission, or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We may not be able to successfully create our own manufacturing infrastructure for supply of our requirements of programmed T cell product candidates for use in clinical trials and for commercial sale.
- Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped.
- We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- If we are unable to obtain and maintain patent protection for our T cell programming technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- As an English public limited company, certain capital structure decisions will require shareholder approval, which may limit our flexibility to manage our capital structure.
- General market conditions and macroeconomic trends, including those driven by geopolitical tension, supply chain disruptions, market volatility, inflation, and fluctuations in foreign currency exchange rates, among other factors, could materially and adversely affect our business, results of operations and financial condition.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs of our products, limit their use or adoption, and otherwise negatively affect our operating results and business.

PART I

Item 1. Business

Business Overview

We are a biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer and autoimmune diseases. Using our broad suite of proprietary and modular T cell programming technologies, we are engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize target cells, break down their defense mechanisms and attack and eliminate these cells. We believe our programmed T cell therapies have the potential to be best-in-class and offer patients substantial benefits over the existing standard of care, including the potential for cure in some patients.

Our T cell programming technologies allow us to tailor our therapies to address the specific disease we are targeting and introduce new programming modules in to a patient's T cells to give those T cells improved properties to better recognize target cells and overcome fundamental disease defense mechanisms. Cancers in particular, thrive on their ability to fend off T cells by evading recognition by T cells and by establishing other defense mechanisms, such as checkpoint inhibition, and creating a hostile microenvironment. We believe our leadership in T cell programming technologies will provide us with a competitive advantage as we look to develop future generations of T cell therapies targeting both hematological cancers, solid tumors and autoimmune diseases, including potential products that could have a tolerability profile such to make them amenable to be used in outpatient settings..

Our current clinical-stage pipeline comprises five programs being developed in eight hematological and solid tumor indications and one autoimmune indication.

Our current clinical-stage programs are:

Obe-cel (AUTO1):

Obe-cel (obecabtagene autoleucel) is a CD19-targeting programmed T cell investigational therapy with a CD19 binder designed to improve the efficacy and safety profile, as compared to other CD19 CAR T therapies.

We initiated the FELIX study, a Phase 1b/2 clinical trial of obe-cel for the treatment of adult r/r B-Acute Lymphoblastic Leukemia ("ALL"), in 2020. This trial is intended to serve as a registrational trial and support regulatory licensure. In November 2023, we submitted a Biologics License Application ("BLA") to the U.S. FDA for obe-cel for the treatment of patients with r/r adult B-ALL. In January 2024, the FDA notified us that they had accepted the BLA filing for review and under the Prescription Drug User Fee Act ("PDUFA"), the FDA has set a target action date of November 16, 2024. The BLA submission is based on data from the Phase 2 cohort of FELIX study. The data were presented at the 2023 American Society of Clinical Oncology ("ASCO") Annual Meeting in June 2023, with updated data presented at the Annual Meeting of the American Society for Hematology ("ASH") in December 2023.

With the cut-off date of September 13, 2023, the data presented at the ASH 2023 meeting were from a pooled analysis of data from all patients across all cohorts in the FELIX Phase 1b/2 study (morphologic disease, minimal residual disease ("MRD"), isolated extramedullary disease ("EMD")) (n=127, median follow-up time from first obe-cel infusion to data cut-off of 16.6 months). Median vein-to-release time was 22 days. Across all patients, treatment with obe-cel resulted in a high response rate with complete response ("CR")/complete remission with incomplete recovery ("CRi") rate of 78% in evaluable patients. Additionally, obe-cel showed a favorable safety profile; grade ≥3 cytokine release syndrome ("CRS") was 2% and grade ≥3 immune effector cell-associated neurotoxicity syndrome ("ICANS") was 7%, with most severe cases of immunotoxicity occurring in patients with high leukemic burden in the bone marrow ("BM"). The event free survival estimate ("EFS") at 12-months was 50% across all patients, with only 17% of responders proceeding to stem cell transplant while in remission. Cellular kinetic data shows high expansion and long-term persistence of CAR T cells in most responders.

In collaboration with University College London ("UCL"), adult patients with r/r, B-ALL and treated with obe-cel continue to be monitored in the Phase 1 ALLCAR19 trial. A pooled analysis of long-term follow-up data from ALLCAR19 and FELIX Phase 1b Studies were presented at the ASH 2023 meeting. Data from the pooled analysis of r/r ALL patients (n=36) treated with obe-cel in the ALLCAR19 and FELIX 1b studies demonstrate high remission rates of 81% (29/36). After a median follow-up of 3 years and without subsequent transplant, 41% of patients continue in CR. The estimated EFS rate with censoring of subsequent transplant or new treatment was 45% at 36 months; all patients in ongoing remission were MRD negative at last assessment and median duration of response was not reached.

Patients continue to be enrolled into the Phase 1 ALLCAR19 extension trial. Data presented at the 2023 ASH meeting demonstrated the potentially best-in-class profile of obe-cel supported by the data observed in other B-cell malignancies, with continued high levels of durable remission paired with a favorable tolerability profile across patients with diffuse large B-cell lymphoma ("DLBCL"), mantle cell lymphoma ("MCL"), follicular lymphoma ("FL"), and chronic lymphocytic leukemia ("CLL").

Furthermore, obe-cel is being investigated for the treatment of primary CNS lymphoma, ("PCNSL"), in an exploratory Phase 1 clinical trial called CAROUSEL. UCL presented initial data at the 27th Congress of the European Hematology Association ("EHA") in 2022 and data is currently being prepared for publication. We have also initiated two Phase 1 studies, one in pediatric B-ALL and B-NHL and one in Systemic lupus erythematosus (SLE).

AUTO1/22: In collaboration with UCL, we commenced a Phase 1 clinical trial in pediatric patients with our academic partner at UCL in r/r B-ALL with our next-generation product candidate, AUTO1/22, in the fourth quarter of 2020. AUTO1/22 is a dual-targeting CAR T which builds on the obe-cel approach utilizing the same CD19 CAR, alongside a novel CD22 CAR designed to reduce antigen negative relapse of disease. In a publication in Blood in October 2023, we presented data demonstrating a high level of activity, with 83% of patients (10/12 patients evaluated) experiencing MRD negative complete remission, and a favorable tolerability profile in a very challenging patient population. Patients on study were high risk, with 4 patients who had failed prior CD19 CAR therapy, 3 patients with a CD19-negative disease component, 3 patients with non-CNS EMD and 6 patients who had received prior blinatumomab. Of 10 responding patients, 5 had emergence of MRD (2) or frank relapse (3) with CD19 and CD22 expressing disease associated with loss of CAR T cell persistence. Importantly, there were no cases of relapse due to antigen-negative escape, with a median follow-up of 8.7 months. Overall survival was 75% at 6 and 12 months. Six and 12-month EFS were 75% and 60% respectively. This study is no longer enrolling patients.

AUTO4: A programmed T cell investigational therapy for the treatment of peripheral T cell lymphoma targeting TRBC1. Unique targeting of TRBC1 potentially opens a new therapeutic approach. The preclinical study package suggested selective binding and anti-tumor activity of TRBC1 and TRBC2 CARs in vitro and in vivo. Data were presented at the International Conference on Malignant Lymphoma ("ICML") in June 2023 of the LibrA T1 Phase 1/2 study. At the cutoff date of April 28, 2023, 19 patients were enrolled into the study and 13 were dosed. Using manufacturing process A, 10 patients were dosed. Using manufacturing process B, 3 additional patients were dosed. Among the 13 patients dosed with AUTO4, the treatment was well tolerated with no dose limiting toxicities. Ongoing responses at 15 and 18 months post-dosing at the highest dose tested ($450x10^6$) are encouraging. Presence of CAR T cells in the lymph nodes of patients suggest fast homing of CAR T cells to the tumor site, despite absence in the blood. Efficacy data from Process B was not provided given median follow up is less than 3 months.

AUTO6NG: A programmed T cell investigational therapy targeting GD2 in development for the treatment of neuroblastoma utilizing a new binder designed to minimize on-target, off-tumor toxicity, humanized to reduce immunogenicity, including RQR8 safety switch. Findings from a Phase 1 clinical trial with AUTO6 were published in November 2020 and provide evidence that AUTO6 induces clinical activity in this solid tumor setting without inducing on-target off-tumor toxicity. We since developed a next-generation product candidate, AUTO6NG, which builds on this approach utilizing the same GD2 CAR alongside additional programming modules to enhance the activity and persistence. In June 2020, we presented preclinical data of AUTO6NG, including data from a tumor model in small cell lung cancer indicating that GD2 is an attractive target for programmed T cell therapies in that indication. The MAGNETO Phase 1 clinical trial of AUTO6NG in r/r neuroblastoma was initiated in December 2023.

AUTO8: A next-generation product candidate for multiple myeloma, which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. We have developed an optimized BCMA CAR which is designed for improved killing of target cell that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel. We believe that the design of AUTO8 has the potential to induce deep and durable responses and extend the durability of effect over other BCMA CARs currently in development. A Phase 1 clinical trial of AUTO8 was initiated in March 2022 with our academic partner UCL. The MCARTY Phase 1 study is an iterative, staggered design trial with two separate parallel cohorts for direct comparison of the BCMA CAR alone and AUTO8 (the BCMA CAR in combination with the CD19 CAR from obe-cel). As of November 13, 2023 (data cut-off), 11 patients have been infused with either BCMA CAR at 50 million (n=3) or 150 million (n=3) cells, or AUTO8 at 50 million (n=3) or 150 million (n=2). At a median follow-up of 6 months we observed 100% response rate ("ORR"), with 3 partial response ("PR"), 1 very good partial response ("VGPR"), 7 CR/ stringent complete response ("sCR") (all evaluable MRD negative). Two patients remained in ongoing sCR > 12 months. No cases of ICANS or CRS ≥ Gr 3 were observed across all subjects during the period. While persistence data from the dual targeting cohort is immature, it demonstrates expansion of three CAR populations and suggests a trend to increased persistence of D8 BCMA CAR expressing T cells. The study is ongoing and continues to recruit patients.

Our Pipeline

Our product pipeline is built on our core principles of modular innovation with protein-based cell programming focused on advanced targeting, pharmacological control and enhancement of activity. After identifying a target, we select the suite of programming modules that we believe is best suited to target that particular disease based on the latest clinical data and the results of our research. The particular modules selected may vary, and not every product candidate, including our current product candidates, contain all categories of modules. A viral vector is used to introduce combinations of these modules into the DNA of the T cells, as depicted in the graphic below.

The diagram below shows how our programming modules relate to our product candidates.

Our programs have been highly tailored and specifically engineered via our proprietary modules, and have the potential to be truly differentiated assets that could address limitations of current treatments and provide innovative options for patients.

Obe-cel has an optimized engagement of the CD19 target designed to enhance its persistence. We believe that these properties may enable obe-cel to be a suitable candidate for the treatment of adult patients with ALL, who tend to be less tolerant of severe toxicity compared with children with ALL. There is currently one CAR T cell therapy approved for the treatment of adult ALL. AUTO1/22 builds on the obe-cel approach utilizing the same CD19 CAR alongside a novel CD22 CAR designed to reduce antigen negative relapse of disease seen in cancer patients treated with CD19 CAR T cell therapies.

AUTO4, which we are developing for the treatment of peripheral T cell lymphoma, employs a novel and differentiated treatment approach. AUTO4 is designed to selectively kill cancerous T cells in a manner that we believe will preserve a portion of the patient's normal, healthy T cells to maintain immunity. It targets an antigen, TRBC1 found on approximately 40% of T cell lymphomas. Since our AUTO4 approach is a novel mechanism to target T cells, we have also programmed the product candidate with a "safety switch" in order to allow physicians to manage toxicity by eliminating the programmed T cells if a patient experiences severe adverse side effects from the treatment.

AUTO5 is a preclinical TRBC2 programmed T cell product candidate for the treatment of peripheral T cell lymphoma. TRBC2 is found on approximately 60% of T cell lymphomas. Plans to progress AUTO5 are subject to clinical data from the AUTO4 program.

We are developing AUTO6NG, which builds upon AUTO6 data by incorporating additional programming modules intended to enhance efficacy by aiming to extend persistence and to address the layers of defense that cancer cells deploy to evade T cell killing.

AUTO8 is our next-generation product candidate for multiple myeloma, which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. We have developed an optimized BCMA CAR which is designed for improved killing of target cell that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel. We believe that the design of AUTO8 has the potential to induce deep and durable responses and extend the durability of effect over other BCMA CARs currently in development.

Background on T Cells and Cancer

Cancers originate from individual cells that have developed mutations in essential cellular programs, driving increased cell division and growth. A key control mechanism to detect and eliminate such cells is the patient's own T cells. T cells are a type of white blood cells used by the human immune system to defend the body against infectious pathogens and cancerous cells. Using their T cell receptor like a molecular scanner, T cells are able to discriminate between normal human cells and ones that contain a mutation that alters their function. If the T cell recognizes an altered cell, it becomes activated and kills that particular cell. For a cancer to grow to the detriment of the patient, cancer cells evolve mechanisms to evade recognition by, or establish other defenses against, T cells.

Cancer Immunotherapy and T cell Therapies

In recent years we have seen the emergence of cancer immunotherapy, in which treatments harness the power of a patient's immune system to combat their disease.

Cancer immunotherapy treatment requires the activation and expansion of cancer-specific T cells, which kill cancer cells by recognizing antigen targets expressed on cancer cells. Studies have shown that tumors develop escape mechanisms that prevent T cell-mediated destruction through immune checkpoint proteins, which shut down anti-tumor immunity. Clinical trials have shown that treatment with immune checkpoint inhibitors can restore T cell activity and results in durable clinical responses. Several anti-PD1 and anti-PD-L1 antibodies are approved for the treatment of various solid tumors and Pembrolizumab is also approved in relapsed/refractory classical Hodgkin's disease or primary mediastinal B-cell lymphoma. However, none of the immune checkpoint inhibitors are currently approved in other hematologic indications. While these approaches collectively represented major advances in cancer treatment, they all lack active redirection of the patient's T cells to the cancer, eventually limiting clinical activity.

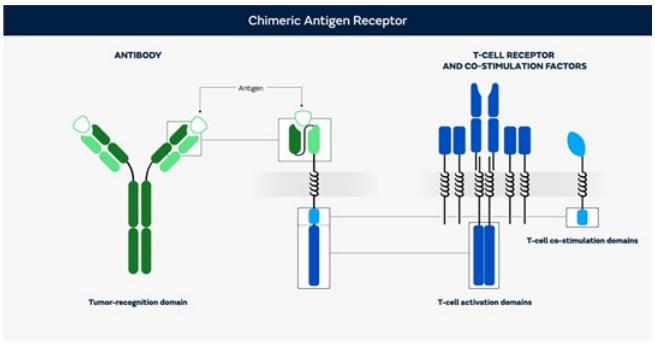
More recently, redirected T cell therapies that are designed to give the patient's T cells a new specificity to recognize cancer cells have been developed. The first approved product of this class is a bi-specific T cell engager called blinatumomab (Blincyto®) from Amgen Inc. Blinatumomab targets the CD19 antigen on the surface of B cells and cancers derived from B cells. Blinatumomab is approved for the treatment of B-ALL. More recently, genetically programmed redirected T cell therapies have been approved. These include the CD19 targeting therapies Kymriah®, Yescarta® and Tecartus®, and Breyanzi®, developed by Novartis AG, Kite Pharma, Inc. and Bristol Myers Squibb Inc., respectively, for the treatments of B-ALL and B-NHL. All four of these therapies showed high response rates and, in a subset of patients, prolonged treatment effects. For those patients experiencing a relapse, the common causes for relapse are insufficient survival of the programmed T cells, loss of the CD19 target on the cancer cells and upregulation of checkpoint inhibitor PD-L1 on the cancer cells.

In view of the limitations of current therapies, there remains a critical unmet medical need for improved T cell therapies. We believe that improving efficacy and durability over the products currently on the market or in development for the treatment of cancers requires addressing target antigen loss, countering checkpoint inhibition and adding novel targets to expand the range of indications amenable to programmed T cell therapy. We believe our clinical-stage product candidates and our approach to T cell programming have the potential to address these limitations.

Programmed T Cell Therapies

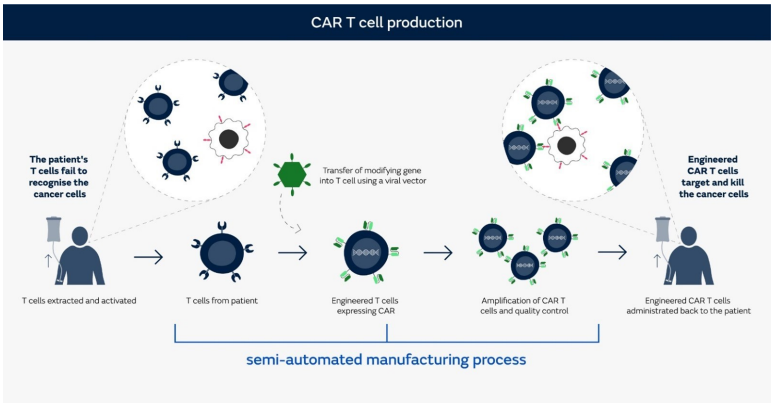
Chimeric Antigen Receptors ("CARs")

We use CARs to reprogram our T cell product candidates. These receptors combine the tumor recognition domain of an antibody with the activation and costimulatory domains from the T cell receptor to rearm a patient's T cells to recognize and kill their cancer cells.



CAR T Cell Production

We have developed our own proprietary viral vector and semi-automated cell manufacturing processes to engineer a patient's T cells with the CAR and other programming modules. We believe that this autologous approach has the potential to be both the safest and most therapeutically effective approach to manufacturing CAR T cells.



Limitations of Current T Cell Immunotherapies

Existing T cell immunotherapies, including CAR T therapies, have shown significant efficacy in hematological malignancies; however, the extent and duration of the treatment effects and disease remission are yet to be fully defined. Optimizing the targeting module of a programmed T cell may enhance its effect and safety. Also, in response to targeted therapies, cancer cells often mutate and cease to express the antigen the therapy was designed to recognize.

This loss of target antigen leads to patient relapse. Additionally, numerous challenges, including lack of T cell persistence and upregulation of checkpoint inhibitors, represent significant hurdles that need to be addressed by new therapies. T cell immunotherapies also have the capacity to elicit toxicities including CRS, neurologic toxicity and the elimination of normal cells via on-target off tumor recognition. Further, manufacturing T cells can be prohibitively costly if the manufacturing process is not appropriately designed to support parallel processing and automation. Finally, realization of the potential of this approach across a broad range of solid tumor types will require multiple technology solutions in order to address limitations of the current generation of therapies.

Emerging Promise of T Cell Immunotherapies for the Treatment Autoimmune Diseases

Autoimmune diseases are the result of an immune system that is overactive, causing it to attack and damage the patient's own tissues. Autoimmune diseases can affect multiple organs throughout the body and can in some cases be life threatening. The presence of autoreactive B cells that produce autoreactive antibodies, antibodies that attack the body's own tissues, are a common feature of these diseases. As such, therapeutic approaches that deplete B cells have had some clinical success. These B cell depletion approaches, such as the antibodies that target CD20 (Rituximab, Ocrelizumab and Ofatumumab,) and BAFF (Belimumab) are approved for the treatment of autoimmune diseases including systemic lupus erythematosus and multiple sclerosis. These antibody-based approaches have shown limited efficacy, typically limiting the progression of the autoimmune disease rather than ameliorating the disease completely. These therapies also require long-term administration and can have serious side effects.

Recently a small academic clinical trial conducted by Mackensen and colleagues from the University of Erlangen in Germany has shown that targeting CD19 with CAR T therapies can profoundly improve outcomes for patients with lupus and other autoimmune diseases. CD19 is a B cell specific antigen that is highly expressed on B cells including malignant B cells that cause cancers like B-ALL and autoreactive B cells that are a common feature of autoimmune disease. In this academic clinical trial, treatment of 15 autoimmune disease patients with a single dose of autologous CD19 CAR T cells resulted in rapid and durable responses in patients. These patients all had advanced disease, with multi-organ involvement and were refractory to current therapies. The treatment showed potential transformational clinical benefit, with all patients in remission or with major reductions in symptoms with a median follow up of 15 months. Toxic effects were manageable and mostly mild.

CD19 CAR T cell therapy shows the potential for superior efficacy compared to B cell depleting antibodies. It may be possible that CD19 is a better target than CD20 or BAFF, as it is expressed more broadly on the autoreactive plasma cells and plasma blasts as well as B cells. Additionally, CAR T cells may be better at depleting the B cells than the antibodies, as they can penetrate into all tissues including some that antibodies can't reach.

The future promise of CAR T cell therapy for autoimmune diseases will be driven by efficacy, safety and cost effectiveness. Existing CD19 CAR T cell therapies, are effective at treating B-cell malignancies; however, the extent and duration of the treatment effects and disease remission as well as the potential for toxicities including CRS and neurologic toxicity varies considerably between the different approved treatments. Differences in efficacy and safety are likely to be seen between different CD19 CAR T cell therapy approaches for Autoimmune diseases and optimizing the CD19 targeting module may be important for enhancing efficacy and safety. Further, manufacturing T cells can be prohibitively costly if the manufacturing process is not appropriately designed to support parallel processing and automation.

Our Solution: Advanced T Cell Programming

Our technological approach is the development of advanced T cell engineering components designed to directly address clinical challenges. A focus in our early-stage pipeline is incorporation of multiple components in a single product. The diagram in this section following the table summarizing our clinical programs shows how our programming modules relate to our product candidates.

Advanced Targeting Technologies

We have developed advanced antigen targeting technologies to improve the ability of our programmed T cell therapies to selectively identify and target cancer cells and to deliver a sustained anti-tumor effect. These targeting technologies include fast off-rate CARs, novel targets, high avidity spacers, dual-targeting and pattern recognition.

Fast Off-Rate CARs

We have designed programmed T cells with fast off-rate binders. These fast off-rate kinetics are similar to the behavior of naturally occurring T cells. Obe-cel has this enhanced kinetic profile, which, when compared to data reported for other CAR T cell product candidates in clinical development for ALL that use high affinity binders, appears to result in reduced Cytokine Release Syndrome and in increased T cell engraftment. We use Fast Off-Rate CARs targeting CD19 in our obe-cel, AUTO1/22 and AUTO8 programs.

Dual-Targeting CARs

Relapse due to target antigen loss or down regulation is a major cause of treatment failure in CAR T cell therapy. We have developed product candidates that target two antigens on a cancer cell and are designed to reduce the chances for relapse due to antigen escape. Evidence suggests that it may also improve a response in those patients with low levels of expression of a target antigen on their cancer cells. We use Dual Targeting CARs in our AUTO1/22 and AUTO8 programs.

Pharmacological Control of T Cell Activity

Management of toxicity is a critical step in the successful application of programmed T cell therapies. We have developed multiple technologies designed to pharmacologically control T cell activity in the event a patient suffers certain serious adverse events related to the T cell therapy. Safety switches are designed to selectively eliminate the programmed T cells following administration of a pharmacological agent, whilst tuneable or controllable CAR T cells allow the activity of T cell therapy to be dialed down following administration of a pharmacological agent.

Rituximab Safety Switch (RQR8)

The RQR8 safety switch is designed to selectively eliminate the programmed T cells by the administration of the commercially available monoclonal antibody rituximab. Once administered, rituximab binds to the engineered CD20 epitopes on the surface of the programmed T cell and triggers cell death. We use the RQR8 safety switch in our AUTO4, AUTO5 and AUTO6NG programs.

Rapamycin Safety Switch (RapaCasp9)

The RapaCasp9 safety switch is designed to selectively eliminate the programmed T cells by the administration of the commercially available drug rapamycin. Once administered, rapamycin heterodimerises caspase 9 via FRB and FKBP to activate a cell death cascade and selectively eliminate the programmed T cells.

Tetracycline Controllable CAR (TetCAR)

TetCAR is a controllable CAR T cell system designed to reversibly dampen the activity of the programmed T cells by the administration of the commercially available antibiotic tetracycline to a patient. Once administered, tetracycline temporarily dislocates the CAR signaling domain from the cancer antigen binding domain leading to deactivation of the T cell therapy. Activity is then restored on clearance of the pharmacological agent from the patient.

Tumor Microenvironment Shielding

Tumor cells and other cells in the tumor microenvironment can debilitate anti-tumor immune responses. Proteins expressed on tumor cells can trigger inhibitory receptors on T cells to block their ability to eliminate the tumor. Secretion of TGFβ by the tumor and other cells can shut down the activity of a T cell therapy. We have developed technologies designed to shield our programmed T cells from these immunosuppressive pathways.

Checkpoint Shielding (dSHP2)

Immune checkpoint receptors act through a common signaling pathway inside the T cell that prevents normal T cell activation. We have developed a modified version of an adaptor protein, SHP2, that in preclinical studies has been shown to efficiently counteract the inhibition of T cells resulting from the PD-L1/PD-1 interaction. In addition, it is designed to simultaneously disarm multiple inhibitory receptors on the cancer cell. We use the dSHP shielding module in our AUTO6NG program.

Enhanced Activity

One of the challenges of targeting some solid tumors is the lack of such easily accessible stimulation for programmed T cells, leading to poor persistence and a weak anti-tumor activity. Co-administration with cytokines can boost T cell activity and persistence. Certain cytokines can potentiate the anti-tumor of the T cell therapy by recruiting and activating other immune cells to kill the tumor.

However, systemic or local administration of cytokines can be toxic, therefore we have developed programming modules that are designed to harness the enhanced activity of cytokines whilst avoiding the potential for toxicities.

Chimeric Cytokine Receptors (CCRs)

The CCR is a programming module that is designed to deliver a cytokine signal directly inside T cells without administration or secretion of cytokines themselves. We use proteins from an antibody structure to stably heterodimerise two cytokine signaling domains together to deliver a proliferative and survival signal into our T cells. Preclinical data has demonstrated the potential for the CCR to improve the persistence and activity of CAR T cell therapy against solid tumors. We use the CCR enhanced activity module in AUTO6NG.

Host Immune System Recruitment (ssIL12)

IL-12 is a potent anti-tumor cytokine that mediates the activity of many different anti-tumor immune cells. The majority of clinical studies involving treatment of patients with IL-12 were associated with severe systemic side effects mediated by high levels of IFNγ. Our ssIL12 module is designed to secrete very low levels of IL-12 from our T cells and our preclinical data demonstrates the potential for ssIL12 to provide anti-tumor without systemic toxicity.

Engineering survival signal (Fas-TNFR)

CAR T cells have shown remarkable efficacy against hematological cancers, but their effectiveness in solid tumors has been limited by inhibitory factors expressed by the tumor or its microenvironment. One such inhibitory factor is Fas ligand ("FasL"), which binds to the Fas receptor (CD95) on the surface of an activated T cell and triggers the CAR T cell to die by apoptosis. Our Fas chimeras consist of the extracellular domain of Fas fused to the intracellular domain from different TNF receptor superfamily members. Expression of these chimeras in a CAR T cell not only blocks apoptosis triggered by FasL, but results in co-stimulation, which promotes CAR T cell survival and proliferation.

Our Product Candidates for the Treatment of Hematological Cancers and Autoimmune Diseases

Our clinical-stage product candidates targeting hematological cancers are obe-cel, AUTO1/22, AUTO4 and AUTO8. We have an additional hematological product candidate, AUTO5, in preclinical development. Additionally, obe-cel is also being explored as a potential therapeutic approach targeting certain autoimmune diseases.

Obe-cel: Our Programmed T Cell Therapy for the Treatment of ALL, other B-cell malignancies and autoimmune diseases

Introduction to Obe-cel

Obe-cel, formerly known as AUTO1, is a gene therapy product consisting of autologous T cells that are transduced with a lentiviral vector to express a novel anti-CD19 Chimeric Antigen Receptor (CD19 (CAT) CAR). The transduced T cells express second-generation CARs in which the CD19 CAR construct uses 41BB-ζ and CD3- ζ endodomains.

CD19 is an ideal target for a CAR T cell therapy as it is a cell surface marker for B-precursor cells and B-lymphocytes that is present on most B cell malignancies. CD19 is also a cell surface marker expressed broadly on the autoreactive B-cells and plasma cells that are associated with autoimmune diseases such as lupus. Upon CD19 directed CAR T cell therapies, it also leads to B-cell aplasia which can be used as a pharmacodynamic marker. CD19 CAR T cell therapies have proven effective in treating B-cell leukemias, B-cell lymphoma and early evidence suggest they are effective in treating b-cell mediated autoimmune diseases. Efficacy is dependent on engraftment and expansion of the CAR T cells. However, rapid activation and expansion of CAR T cells can result in CRS and/or ICANS, which in some cases can be life-threatening, particularly for elderly patients and patients with comorbidities that have a poor tolerance for toxicity. Furthermore, excessive activation of CAR T cells can lead to cell exhaustion and limit their engraftment and expansion, which may impact the initial efficacy and durability of therapeutic effect. Obe-cel is an investigational therapy in which a patient's T cells are genetically modified to express a novel CD19-specific binder designed to reduce side effects observed with this class of therapeutics.

Obe-cel has been designed to recognize CD19 and interact with the target with a fast off-rate enabled by the novel CAT scFv binding domain. This property allows the obe-cel cells to efficiently recognize target cells, inject cytotoxic proteins to initiate the natural self-destruction process present in all human cells and then rapidly disengage from them in order to engage the next target cell, a process also known as serial killing. Rapid disengagement from the target antigen is expected to minimize excessive activation of the programmed T cells, reduce toxicity and may also reduce T cell exhaustion.

Obe-cel is currently the subject of an ongoing Phase 1/2 trial (FELIX) in adult r/r B-ALL. We have also initiated a Phase 1 study in pediatric B-ALL and B-NHL.

Our academic partner, UCL, has conducted separate Phase 1 clinical trials evaluating the safety and efficacy of obe-cel. The first Phase 1 clinical trial in pediatric ALL patients is named the CARPALL trial, the second Phase 1 clinical trial in adult ALL patients is named the ALLCAR19 trial. The ALLCAR19 trial has been extended to include patients with DBCL, MCL, FL, and CLL. UCL has also conducted the CAROUSEL study in a small cohort of patients with primary central nervous system lymphoma.

We recently Autolus initiated a Phase 1 study (CARLYSLE) of obe-cel in patients with systemic lupus erythematosus ("SLE"), as described below.

Clinical Development of Obe-cel in Adult ALL

Background of Adult ALL

Obe-cel is currently being tested in a Phase 1b/2 clinical trial for the treatment of adult ALL, which according to the American Cancer Society is predicted to affect approximately 6,500 adults in the United States in 2023. Combination chemotherapy enables 90% of adult patients to experience complete remission ("CR"). However, the majority of these remissions are not long-lasting in adult patients. Despite this initial CR, and in contrast to pediatric ALL, the prognosis of adult ALL is still poor and has not changed significantly during the last two to three decades, with long-term remission rates limited to 30-40%. Approximately 50% of all adult ALL patients will relapse, and data from the Medical Research Council's UKALL12/ECOG 2993 study, published in 2007, found that five-year overall survival ("OS"), rate in adults who relapse following standard multi-agent chemotherapy is 7%. The only curative option for relapsed or refractory ALL consists of achieving a second CR by salvage therapy followed by an allogeneic hematopoietic stem cell transplant ("allo-HSCT"). Without allo-HSCT, a subsequent relapse occurs in nearly all patients. However, less than half of patients achieve a second CR, and therefore only a subset will be eligible for this procedure. Even then, less than one-third of patients receiving the transplant are expected to sustain long-term disease-free survival. Further, allo-HSCT is associated with severe morbidity and significant mortality. Many patients with relapsed or refractory ALL will have been maximally treated with chemotherapy, and often do not achieve a second CR with standard-of-care chemotherapy in order to be eligible for allo-HSCT.

Two targeted immunotherapies have been approved in a number of jurisdictions, including the United States and the EU, for the treatment of adult ALL: blinatumomab and inotuzumab ozogamicin. Both of these therapies achieve high CR rates, but durability is limited. In a randomized Phase 3 clinical trial of blinatumomab in heavily pretreated B-cell precursor ALL, the blinatumomab arm achieved a CR rate of 44%, of which 76% also achieved MRD-negative CR, and the median duration of remission was 7.3 months. The median OS in those patients, though significantly improved compared to chemotherapy, was still only 7.7 months. Similarly, in a Phase 3 clinical trial of inotuzumab ozogamicin, a higher percentage of patients achieved MRD-negative CR when treated with inotuzumab compared to standard-of-care chemotherapy, but the median duration of remission was 4.6 months and median OS was 7.7 months.

On October 1, 2021 the FDA approved the use of the CAR T cell therapy brexucabtagene autoleucel ("Tecartus") for adults with B-cell precursor ALL that has not responded to treatment (refractory) or has returned after treatment (relapsed). The European Commission approved Tecartus for adults aged 26 and over with relapsed or refractory B-cell precursor ALL in September 2022.

Obe-cel Phase 1b/2 Clinical Trial in Adult ALL (FELIX Trial)

The data were presented at the 2023 ASCO Annual Meeting in June 2023, with updated data presented at the Annual Meeting of the ASH in December 2023. With the cut-off date of September 13, 2023, the data presented at ASH were from a pooled analysis of data from all patients across all cohorts in the FELIX Phase Ib/II study (morphologic disease, MRD, isolated EMD) (n=127, median follow-up time from first obe-cel infusion to data cut-off of 16.6 months). Median vein-to-release time was 22 days. Across all patients, treatment with obe-cel resulted in a high ORR with CR/CRi rate of 78% in evaluable patients. Additionally, obe-cel showed a favorable safety profile; grade ≥3 CRS was 2% and grade ≥3 ICANS was 7%, with most severe cases of immunotoxicity occurring in patients with high leukemic burden in the BM. The EFS at 12-months was 50% across all patients, with only 17% of responders proceeding to stem cell transplant while in remission. Cellular kinetic data shows high expansion and long-term persistence of CAR T cells in most responders.

Obe-cel Phase 1 Clinical Trial in Adult ALL (ALLCAR19 Trial)

In the first quarter of 2018, our academic partner UCL initiated a single-arm, open label, multi-center Phase 1 clinical trial of obe-cel, named the ALLCAR19 trial, in patients aged 16 to 65 years with high-risk, relapsed or refractory CD19 positive B-lineage ALL. The clinical trial was conducted at sites in the United Kingdom. The trial enrolled patients with a high tumor burden; 45% of treated patients had 50% or greater bone marrow blasts. In the trial, 20 patients received obe-cel; product for 14 of those patients was manufactured using a semi-automated, fully-enclosed process. The therapy was well tolerated, with no patients experiencing Grade 3 or higher CRS. Three patients (15%), all of whom had high leukemia burden (>50% blasts), experienced Grade 3 ICANS that resolved swiftly with steroids. Of the 20 patients evaluable for efficacy, 17 patients (85%) achieved minimum residual disease ("MRD")-negative CR at one month.

A pooled analysis of long-term follow-up data from ALLCAR19 and FELIX Phase 1b Studies were presented at the ASH, meeting in December 2023. Data from the pooled analysis of r/r ALL patients (n=36) treated with obe-cel in the ALLCAR19 and FELIX Phase 1b studies showed high remission rates of 81% (29/36). After a median follow-up of 3 years and without subsequent transplant, 41% of patients continued in complete remission. The estimated EFS rate with censoring of subsequent transplant or new treatment was 45% at 36 months; all patients in ongoing remission were MRD negative at last assessment and median duration of response was not reached.

Development Strategy for Adult ALL

In 2020, we initiated a multi-center, single-arm Phase 1b/2 clinical trial of obe-cel in adult patients with relapsed or refractory ALL ("r/r ALL"), referred to as the FELIX trial. Recruitment in the Phase 2 Cohort A of the FELIX trial for morphological adult r/r ALL patients has been completed.

In January 2023, the FELIX trial completed screening patients for entry into the morphological cohort, as the pre-specified goal of approximately 90 patients enrolled had been reached. The Phase 2 Cohort A includes approximately 90 patients with morphological disease (at least 5% blasts in the BM at screening), with ORR (CR/CRi) as the primary endpoint; and the secondary endpoints include CR rate, EFS, duration of response ("DOR") and MRD negative remission rate. Smaller cohorts were also included in the Phase 2 portion of the FELIX trial, in which patients with MRD positive disease in morphological remission (Cohort B) as well as patients with isolated EMD (Cohort C) were be treated with obe-cel.

Obe-cel has received a number of designations from regulatory authorities, as follows: FDA orphan drug designation for the treatment of ALL (October 2019), EMA PRIME designation (March 2021), MHRA ILAP designation (June 2021), European Commission orphan drug designation (March 2022), and FDA RMAT designation (April 2022). In November 2023, we submitted a BLA to the U.S. FDA for obe-cel for the treatment of patients with r/r adult B-ALL. In January 2024, the FDA notified that they had accepted the BLA and the FDA has set a PDUFA target action date of November 16, 2024. The BLA submission is primarily based on data from the FELIX study. We plan to submit the marketing authorization application ("MAA") to the EMA in the first half of 2024.

Background of Pediatric ALL

According to the American Cancer Society, B-cell ALL is most common in childhood, peaking between two and four years of age. As per the National Cancer Institute Surveillance, Epidemiology and End Results statistics database, there are approximately 3,400 new cases of pediatric ALL diagnosed in the United States each year.

The current standard of care for both pediatric and adult B-cell ALL patients is a standard regimen of combination chemotherapy. Pediatric patients typically respond well to the complex first-line chemotherapy treatment. According to the American Cancer Society, the five-year survival rate for children with B-cell ALL is more than 85% overall. However, 10 to 20% of pediatric B-cell ALL patients relapse with chemotherapy-resistant disease. These patients are re-treated with intensive chemotherapy, and those that respond may proceed to receive an allogenic stem cell transplant ("SCT"). However, SCT can be associated with significant long-term morbidity due to the risk of developing graft-versus-host disease ("GVHD"), and treatment-related mortality, although the risk of death have declined with better post-transplant management.

Patients with high-risk clinical or genetic features including gene abnormalities, as well as those who have an inadequate response to initial chemotherapy, may not respond well with the current available treatments for B-cell ALL (including SCT), some of these patients will have a five-year OS rate of approximately 15%. Additionally, long-term survival rates are only approximately 10 to 20% among patients receiving a second SCT and negligible in those unable to proceed to a second transplant.

There is still a significant unmet medical need in pediatric patients with high-risk relapsed or refractory B-cell ALL. CD19 CAR T cell therapies have been developed for these patients. The approved CD19 CAR T therapy, Kymriah, has shown approximately 80% of complete molecular response rate. However, at six months after treatment, approximately 40% of the patients relapsed and the majority of the relapses were CD19 negative disease, with approximately two-thirds of relapses determined to have been due to loss of CD19 on the target cells in one study.

CD19 CAR T cell therapies have been tested in pediatric ALL patients and have shown sustained responses without allo-HSCT. In adult ALL, however, one of the major challenges has been severe toxicity, including death due to CAR T cell-mediated toxicity observed in the clinical trials of these products. Obe-cel has been designed to reduce toxicity but still sustain durable CRs, and we believe it has the potential to become a standalone therapy for adult ALL.

Obe-cel Phase 1 Clinical Trial in Pediatric ALL

The CARPALL trial was initiated by UCL in the second quarter of 2016 and is a single-arm, open label, multi-center Phase 1 trial enrolling patients aged 24 years or younger with high-risk relapsed or refractory CD19 positive B-lineage ALL. The main objective of the trial is to evaluate the safety and efficacy of obe-cel when administered at a single dose of 1 million cells/kg. The trial has completed enrollment with obe-cel. However, the extension arm is now open, and treating pediatric ALL patients with AUTO 1/22

As of the final data cut-off date of November 22, 2019, the obe-cel arm of the CARPALL trial had enrolled a total of 25 patients, in two cohorts; one cohort utilized a manual manufacturing process (cohort 1) and one cohort utilized a semi-automated fully enclosed manufacturing process (cohort 2). Product was generated for 14 of 17 patients in cohort 1 and the median follow-up for the 14 treated patients was 23 months. Seven patients were treated in cohort 2. The aim of cohort 2 was to increase feasibility of manufacture at scale; one patient died before infusion and product was generated for 100% of patients. Median follow-up for patients in cohort 2 was seven months.

None of the patients experienced Grade 3 or higher CRS and one patient out of 21 patients (5%) experienced Grade 4 neurotoxicity, which was deemed more consistent with fludarabine than CAR-associated neurotoxicity. Two patients experienced Grade 5 sepsis and death, one in the context of progressive disease and the second was considered related to obe-cel. This patient was in MRD-negative CR and had ongoing Grade 4 cytopenia associated with resistant HSV encephalitis. Thirteen patients experienced Grade 4 cytopenias that were ongoing at day 28. Nineteen of 21 treated patients (90%) achieved molecular CR at post-infusion.

Consistent with preclinical results, CAR T cell expansion and persistence was excellent and CARs were detectable by flow for up to 36 months in four patients in cohort 1 who had ongoing responses beyond 12 months. Persistence was noted in 15 of 21 patients at last follow-up, up to 36 months. All of the patients in cohort 2 achieved molecular CR at one month post-infusion.

For cohort 1, with a median follow-up of 23 months, the OS at six and 12 months was 86% and 71%, respectively, and event-free survival at six and 12 months was 71% and 54%, respectively. In cohort 2, at a median follow-up of 7 months, five patients remain in complete molecular remission and two patients relapsed. Five of eight evaluable relapses in cohort 1 and cohort 2 combined were due to CD19 negative escape.

In December 2023, Autolus initiated a phase 1 study to evaluate the safety and efficacy of obe-cel in pediatric patients with r/r B ALL and r/r B-NHL. This is a single-arm, open label, multi-center trial enrolling patients aged 18 and younger. The study is currently enrolling patients.

Obe-cel Phase 1 Clinical Trial in other B-cell malignancies (ALLCAR19 and CAROUSEL Trials)

The ALLCAR19 clinical trial has also been expanded to include three additional cohorts with a total of 40 patients:

- 10 patients with r/r DLBCL (including transformed FL, but not Richter's transformation);
- 10 patients with relapsed or refractory B-cell CLL / small lymphocytic leukemia; and
- 20 patients with relapsed or refractory indolent B-NHL (either FL, MCL or marginal zone lymphoma).

At the 2023 ASH meeting, updates were provided from the B-cell NHL/CLL cohorts. As of the data cut-off date of September 13, 2023, 23 r/r B-NHL and 5 B-CLL patients had received treatment with obe-cel. Obe-cel continues to display a favorable tolerability profile with no ICANS or Grade 3 or higher CRS across different indications. Of 28 patients with NHL/CLL evaluable for efficacy, the best ORR was 26/28 (92%). Obe-cel was observed to be well-tolerated and active in DLBCL, 8/9 evaluable patients entered CMR; 6 patients are in ongoing CMR with one relapse at 12 months and one unrelated death. . In CLL, four of the five treated patients achieved undetectable minimal residual disease ("uMRD") in the bone marrow, with all ongoing at the last follow-up date.

Notably, ongoing CAR T persistence appears to be important for ongoing response in FL. Longer follow-up and enrollment of additional MCL, DLBCL and CLL/SLL patients is ongoing.

UCL has also initiated a Phase 1 exploratory trial (CAROUSEL) of obe-cel in patients with relapsed or refractory PCNSL. CAROUSEL is evaluating the feasibility of generating obe-cel and safety of administration in this patient population. UCL presented initial data at the EHA meeting in June 2022. Expansion of obe-cel was observed in the peripheral blood by qPCR, with persistence in all treated patients at last follow-up. No Grade 3 or greater CRS was observed using intravenous ("IV") or intra-ventricular obe-cel administration. Two cases of Grade 3 ICANS were reported following IV infusion, whereby the first patient had several neurological deficits that evolved despite ICANS treatment and were compatible with progressive PCNSL, as confirmed with the month 1 MRI scan, and the second patient had neurological deficits that improved with steroids/anakinra. We observed encouraging response rates in six patients evaluable for efficacy following IV administration of obe-cel. The ORR was four out of six patients (67%), with 2 CRs and 2 PRs. These four responding patients are without disease progression at the last follow up date. Two patients died from progressive PCNSL while part of the study. We expect to report longer follow-up from this trial and enrollment of additional patients is ongoing.

Clinical Development of Obe-cel in Lupus and other Autoimmune diseases

Background of SLE

Systemic lupus erythematosus ("SLE") is an autoimmune disease characterized by the formation of autoantibodies and immune complex–mediated inflammation and organ damage, including the skin, joints, central nervous system, heart, lung, and kidneys. Disease severity changes over time with periods of no disease activity alternated by periods with disease flares/relapses. In some cases SLE can be life threatening. The disease onset is generally between the ages of 20 and 40, and it affects predominantly young women. The prevalent population of SLE patients in the United States, United Kingdom, Germany, France Spain, Italy and Japan is approximately 550,000 patients ~60% (330,000 patients) with moderate to severe disease. ~15% will be refractory to standard therapies; potentially addressable by CAR T therapy.

Currently available treatments are not curative and are associated with certain safety concerns. Many patients require life-long immunosuppression, often with high-dose corticosteroids, cyclophosphamide, or mycophenolate mofetil, non-specifically targeting the immune system to reduce inflammation. This results in low-level disease activity in only 25–44% of patients in the long term, while sustained complete remission is rare. Approximately 10% of patients with lupus nephritis ("LN"), a form of the disease associated with kidney organ damage, develop end-stage renal disease in 5 years. Side effects of the current treatment strategies include infections in the short term and risk for malignancy and cardiovascular disease in the long term, contributing to the reduced life expectancy of patients with SLE. This substantiates the need for developing better strategies to treat SLE.

Autoreactive B cells with autoantibody formation play a key role in the pathogenesis of SLE. However, B cell depleting agents, such as the anti-CD20 antibody rituximab, did not improve clinical outcomes compared to placebo in randomized studies in SLE and LN while two different biologics have recently been approved in SLE:

1. Belimumab, an anti-BAFF/BLyS monoclonal antibody, has been approved as add-on therapy in adult patients with active, autoantibody-positive SLE with a high degree of disease activity despite standard therapy.
2. Anifrolumab, a type I interferon ("IFN") receptor antagonist, has also been approved in the United States and EU and is indicated as an add-on for the treatment of adult patients with moderate to severe SLE who are receiving standard therapy.

Despite these approvals, some patients have insufficient response, lack of response, or lack of sustained response and are at risk for further organ damage despite standard therapy. Hence, challenges remain with treatment-resistant disease.

Another strategy to induce deeper depletion of the B cell compartment originates from the highly effective treatment of patients with B cell malignancies using CD19 CAR T cells. A clinical study by Mackensen and colleagues showed a deep depletion of CD19+ B cells and plasma blasts in SLE-affected tissues could trigger an immune reset that could allow the cessation of immunosuppressive treatment in patients with SLE. In this study, autologous T cells from 8 patients with SLE were transduced with a lentiviral anti-CD19 CAR vector, expanded and reinfused at a dose of 1×10x6 CAR T cells per kg body weight into the patients after lymphodepletion with fludarabine and cyclophosphamide. CAR T cells expanded in vivo and led to deep depletion of B cells with improvement of clinical symptoms and normalization of laboratory parameters including seroconversion of anti-ds DNA antibodies. Remission of SLE according to standard criteria was achieved in all patients after 3 months, and drug-free remission was maintained during longer follow-up after CAR T cell administration.

Based on the important role of B cells in the SLE disease pathogenesis and the preliminary evidence of safety and activity of CD19 CAR T cell therapy in this disease, it is hypothesized that treatment with a single infusion of obe-cel may have the potential to eliminate the malfunctioning autoreactive B cells and ameliorate disease in SLE patients in a similar fashion.

Clinical Development in SLE and other Autoimmune Diseases

The CARLYSLE trial is a single-arm, open-label, Phase 1 Study to determine the safety, tolerability, and preliminary efficacy of obe-cel in patients with severe, refractory SLE. Six patients are expected to receive a target dose of 50 x 10^6 CD19 CAR-positive T cells. Beyond this initial cohort, the study has the option to add further cohorts of patients. The first CARLYSLE trial was initiated in early 2024.

Depending on the outcome of the dose conformation study in SLE, we would plan to initiate further studies in SLE and LN. Furthermore, additional evidence of CD19 CAR T cell treatment in other autoimmune diseases has been shown by others, including efficacy in patients with idiopathic inflammatory myositis, systemic sclerosis, myasthenia gravis and multiple sclerosis. Depending on the outcome of the dose conformation study in SLE, we would plan to investigate obe-cel in additional autoimmune disease indications.

AUTO1/22 Our Programmed T Cell Therapy for the Treatment of ALL, other B-cell malignancies

Introduction to AUTO1/22

AUTO1/22 is a dual-targeting CAR T which builds on the obe-cel approach utilizing the same CD19 CAR, alongside a novel CD22 CAR designed to reduce antigen negative relapse of disease. Antigen negative relapse is a common cause of relapse in patients with pediatric ALL.

AUTO1/22 Phase 1 Clinical Trial in Pediatric ALL (CARPALL Trial)

We commenced a Phase 1 clinical trial in pediatric patients with relapsed or refractory ALL with our next-generation product candidate, AUTO1/22 in the fourth quarter of 2020. In a publication in Blood in October 2023, we presented data demonstrating a high level of activity, with 83% of patients (10 of 12 patients evaluated) experiencing MRD negative complete remissions, and a favorable tolerability profile in a very challenging patient population. Patients on study were high risk, with 4 patients who had failed prior CD19 CAR therapy, 3 patients with a CD19-negative disease component, 3 patients with non-CNS EMD and 6 patients who had received prior blinatumomab. Of 10 responding patients, 5 had emergence of MRD (2) or frank relapse (3) with CD19 and CD22 expressing disease associated with loss of CAR T-cell persistence. Importantly, there were no cases of relapse due to antigen-negative escape, with a median follow-up of 8.7 months. Overall survival was 75% at 6 and 12 months. Six and 12-month event free survival (EFS) were 75% and 60% respectively.

AUTO4: Our T Cell Lymphoma Program

Introduction to AUTO4

We are developing a programmed T cell product candidate, AUTO4, as a potential treatment for T-cell lymphomas. We are developing this product candidate with a unique targeting approach that is designed to avoid the severe immunosuppression typically associated with the current investigational CAR T-cell therapies which uses a pan t-cell antigen. for this disease.

T cells have one of two functionally identical genes, known as TRBC1 and TRBC2. A normal/healthy T cell population contains a mix of cells expressing either TRBC1 or TRBC2. Both forms are active and provide the body with natural immunity, including antiviral immunity. Because T-cell lymphomas are clonal tumors that develop from a single T cell, they are either entirely TRBC1-positive or entirely TRBC2-positive. Currently available products for the treatment of T-cell lymphoma indiscriminately target all T cells, leading to the severe immunosuppression associated with these treatments.

We have designed AUTO4 as a programmed T cell to specifically target and deplete cells expressing TRBC1, while preserving healthy T cells that express TRBC2. A normal T cell population consists of varying amounts of TRBC1-positive and TRBC2-positive T cells. Based on the typical distribution of TRBC1-positive and TRBC2-positive T cells, we believe that patients treated with AUTO4 should be left with a population of healthy, functional polyclonal T cells, which provides the immune system of these patients the ability to respond to bacterial and viral infections and other pathogens. In addition, this product candidate will have a built-in safety switch designed to eliminate the programmed CAR T cells in the event a patient suffers certain serious adverse events related to the CAR T cell therapy, such as CRS or neurotoxicity.

Background of T Cell Lymphoma

Mature T cell lymphomas are aggressive, treatment resistant malignancies that are associated with poor prognosis. Clinical application of immunotherapeutic approaches has been limited by a lack of target antigens that discriminate malignant from healthy/polyclonal T cells. T cell lymphoma is a rare and heterogeneous form of NHL, representing approximately 10 to 20% of NHL cases and 3 to 4% of all hematological malignancies. Most T cell lymphomas are peripheral T cell lymphomas, (PTCL), the initial indication for which we are developing AUTO4. PTCL generally involves high-grade tumors and occurs at a similar age as aggressive B cell lymphomas, with a relatively high proportion of patients becoming rapidly unwell. For the majority the PTCL subtypes, the five-year survival rate may range from 18% to 24%. The three most common subtypes of PTCL are peripheral T cell lymphoma not otherwise specified (“PTCL-NOS”), anaplastic large-cell lymphoma (“ALCL”), and angioimmunoblastic T cell lymphoma (“AITL”), together accounting for approximately 70% of all PTCLs in the United States.

The first-line treatment for PTCL consists of the combination chemotherapy (e.g. CHOP, consisting of cyclophosphamide, vincristine, doxorubicin and prednisolone). However, with CHOP chemotherapy, CR rates are low and disease relapse is common. In many treatment centers, CHOP chemotherapy may be consolidated with autologous or allogenic stem cell transplantation in selected patients.

Little is understood in terms of treatment guidance for the other PTCL subtypes and these lymphomas lack clear treatment guidelines. A large proportion of T cell lymphoma patients are refractory to or relapse following treatment with standard therapies and there remains a need to develop an effective therapy for this currently unmet medical need.

Unlike B cell lymphomas, T cell lymphomas have not benefited from advances in immunotherapeutic approaches. This is mainly due to the lack of therapeutic development in T cell lymphomas to identify suitable target antigens to distinguish malignant T cells from normal/polyclonal T cells. While a similar problem exists with B cell lymphomas, targeting a pan B cell antigen is an acceptable strategy, as the concomitant depletion of the normal B cell compartment is well tolerated, and some targeted approaches may be ameliorated by the administration of immunoglobulin. In contrast, targeting a pan T cell antigen would result in severe immunosuppression, where there is currently no available rescue medication. Some competitors that are pursuing this approach are planning to use CAR T cells therapy as a bridging to SCT. However, this approach would only benefit the transplant eligible patients who may not be the majority of the T cell lymphoma patients. There is currently no programmed T cell therapy that is being developed as a standalone treatment.

Clinical Development of AUTO4

In the fourth quarter of 2018, we began enrolling patients in a single-arm, open label, multi-center Phase 1/2 clinical trial, Libra T1, in patients with TRBC1 positive PTCL-NOS, AITL and ALCL, the three most common subtypes of PTCL, for which patients have failed, or have relapsed disease following, at least one prior therapy. We refer to this trial as the LibrA-T1 trial, which was initiated at sites in the UK and Spain in 2018 and 2020 respectively. Patients were screened for TRBC status of tumor cells using a CE-marked next-generation sequencing ("NGS") method prior to full enrollment in the trial.

The main objective of the Phase 1 portion of the trial was to evaluate the safety of AUTO4 and to determine a recommended dose for the Phase 2 portion of the trial. The main objective of the Phase 2 portion will be to further evaluate the safety of the treatment and evaluate efficacy endpoints, such as ORR and CR rate.

We designed the trial to evaluate up to five dose levels of AUTO4, beginning with a low dose of 25 million AUTO4 cells. If we do not observe any dose limiting toxicities ("DLT"), the dose escalation phase of the trial will continue to higher doses of 75 million AUTO4 cells, 225 million AUTO4 cells, 450 million and potentially 900 million AUTO4 cells.

Data from the first 13 patients dosed in the Libra T1 trial was presented at the ICML in June 2023. At the cutoff date of April 28, 2023, 19 patients were enrolled into the study and 13 were dosed. Using manufacturing process A, 10 patients were dosed. Using manufacturing process B, 3 additional patients were dosed. Among the 13 patients dosed with AUTO4, the treatment was well tolerated with no DLT. Ongoing responses at 15 and 18 months post-dosing at the highest dose tested (450x106) are encouraging. Presence of CAR T cells in the lymph nodes of patients suggest fast homing of CAR T cells to the tumor site, despite absence in the blood. Efficacy data from Process B was not provided given median follow up is <3 months.

AUTO8: Our Multiple Myeloma Program

Introduction to AUTO8

AUTO8 is a next-generation product candidate for multiple myeloma, which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. We have developed an optimized BCMA CAR which is designed for improved killing of target cell that express BCMA at low levels. This has been combined with fast off-rate CD19 CAR from obe-cel. We believe that the design of AUTO8 has the potential to induce deep and durable responses and extend the durability of effect over other approved BCMA CARs and those currently in development.

Background of Multiple Myeloma

According to data from the Global Burden of Disease Study 2020, there were approximately 156,000 new cases of multiple myeloma and 113,000 deaths in 2019. The American Cancer Society estimates that in the United States in 2024, approximately 35,780 new cases will be diagnosed and approximately 12,540 deaths are expected to occur from multiple myeloma. With currently available treatments the five-year survival rate is approximately 58%.

Treatment choices for multiple myeloma vary with the aggressiveness of the disease and related prognostic factors. Newly diagnosed patients in good physical health with active disease generally receive high-dose chemotherapy with autologous stem cell transplantation ("ASCT"). Eligibility for ASCT is established primarily by age and comorbidities. When transplantation is not an option, treatment traditionally consists of systemic chemotherapy, with adjunctive use of radiation.

The therapeutic landscape of multiple myeloma has changed significantly in the past decade with the introduction of novel immunomodulatory agents, such as lenalidomide, as well as monoclonal antibodies, such as daratumumab, and proteasome inhibitors, including bortezomib and carfilzomib. The past decade has also seen major progress in the understanding of the molecular oncogenesis of plasma cell neoplasms, which has significantly influenced the clinical management of multiple myeloma. Despite these major advances, most cases of multiple myeloma have remained incurable. A considerable number of multiple myeloma patients ultimately experience a final tumor relapse without any additional, effective treatment option. Patients with relapsed or refractory disease typically have a poor prognosis.

Recently approved therapeutic approaches include products that target BCMA on multiple myeloma cells, including redirected T cell therapies such as T cell engagers and CAR T cell therapies. Despite recent progress, there remains significant unmet clinical need among patients with multiple myeloma. We believe our programmed T cell product candidate, AUTO8, with its dual-targeting approach, has the potential to lead to higher levels of efficacy and durability of effect compared to other products and redirected T cell therapies that bind to BCMA alone.

Clinical Development of AUTO8

In collaboration with UCL, we commenced a Phase 1 clinical trial in patients with relapsed or refractory multiple myeloma in March 2022. The phase 1 study is an iterative, staggered design trial with two separate parallel cohorts for direct comparison of the BCMA CAR alone and AUTO8 (the BCMA CAR in combination with the CD19 CAR from obe-cel). As of November 13, 2023 (data cut-off), 11 patients have been infused with either BCMA CAR at 50 million (n=3) or 150 million (n=3) cells, or AUTO8 at 50 million (n=3) or 150 million (n=2). At a median follow-up of 6 months we observed 100% response rate (ORR), with 3 PR, 1 VGPR, 7 CR/sCR (all evaluable MRD negative). Two patients remained in ongoing sCR > 12 months. No cases of ICANS or CRS ≥ Gr 3 were observed across all subjects during the period. While persistence data from the dual targeting cohort is immature, it demonstrates expansion of three CAR populations and suggests a trend to increased persistence of D8 BCMA CAR expressing T cells. The study is ongoing and continues to recruit patients.

Our Solid Tumor Programs

Solid tumors present a particular challenge to CAR T cell therapies, since solid tumors tend to fend off T cells with upregulation of checkpoint inhibition and a hostile microenvironment. In addition, contrary to hematological cancer cells that are readily accessible to programmed T cells in the circulating blood of a patient, solid tumors are more difficult for programmed T cells to track down in sufficient numbers to impact the disease. In addition, the persistence of programmed T cells tends to be limited, which also leads to a reduced effect on solid tumor cells. In addition to the programs we are currently pursuing described below, we intend to continue to evaluate other possible solid tumor indications.

AUTO6: Our Neuroblastoma Program

Introduction to AUTO6 and AUTO6NG

Under our license agreement with University College of London Business Ltd. ("UCLB"), we have been granted an exclusive, worldwide license to AUTO6 (1RG-CART), a programmed T cell product candidate targeting the glycosphingolipid GD2. Cancer Research UK ("CRUK") has completed an exploratory Phase 1 clinical trial of AUTO6 in pediatric patients with neuroblastoma. We are developing a next-generation product candidate, which we refer to as AUTO6NG, incorporating additional programming modules designed to improve efficacy, safety and persistence of AUTO6.

Background of Neuroblastoma

Neuroblastoma is a cancer that develops from immature nerve cells found in several areas of the body, and most commonly arises in and around the adrenal glands, which have similar origins to nerve cells and sit atop the kidneys. However, neuroblastoma can also develop in other areas of the abdomen and in the chest, neck and near the spine, where groups of nerve cells exist. Neuroblastoma most commonly affects children age five or younger, though it may rarely occur in older children. According to the American Cancer Society, there are approximately 700 to 800 new cases of neuroblastoma each year in the United States.

Preclinical Studies of AUTO6/6NG

In preclinical *in vitro* studies, AUTO6 selectively, effectively and efficiently killed GD2-expressing tumor cells while sparing cells that did not express GD2. In addition, the RQR8 safety switch activation by rituximab was tested *in vitro*, where the addition of rituximab was shown to activate the safety switch and eliminate the programmed T cells from the culture, and residual cells did not possess any intrinsic anti-GD2 activity. This safety switch activation was also observed *in vivo* in a mouse model, where the murine analogue of rituximab was able to deplete the GD2-targeting programmed T cell product candidate from the bone marrow, blood, lymph node and spleen of animals that had previously been engrafted with programmed T cells.

In 2016, in collaboration with Cancer Research UK's Centre for Drug Development we initiated a single-arm Phase 1 dose escalation trial of AUTO6 in relapsed or refractory neuroblastoma at two pediatric cancer centers in the UK. The trial evaluated the safety and efficacy of AUTO6. In 2020 the data from the AUTO6 Phase 1 clinical trial was published in Science Translational Medicine. The results from the study showed that AUTO6 can induce rapid regression of bulky disease in a solid tumor setting without inducing on-target, off-tumor toxicity, despite dose dependent CAR T expansion. CAR T cell expansion was observed in all 6 patients treated at the higher cell dose cohorts in this Phase 1 study. Three of these six patients demonstrated evidence of transient CAR T cell activity, including CRS, and regression of soft tissue and BM disease activity.

The GD2 binder used in AUTO6 has been designed to minimize on-target, off-tumor neurotoxicity associated with GD2 expression at low levels in pain fibers and the brain. Despite the presence of clear CAR T cell activity, no neurotoxicity was observed. The publication also suggests that, whilst AUTO6 is a valid and safe strategy for targeting neuroblastoma, further modifications are required to promote CAR T cell persistence and induce deeper and more durable responses for these patients.

In November 2019, we reported preclinical data of AUTO6NG. Building on AUTO6, in AUTO6NG we introduced additional programming modules in order to help the programmed T cells persist in and withstand the hostile tumor microenvironment. AUTO6NG is a programmed T cell therapy incorporating the GD2-targeted CAR T and RQR8 safety switch from AUTO6 but also incorporating three additional programming modules: (i) an IL7 CCR designed to increase persistence, (ii) a dominant negative TGFbRII protein designed to block inhibitor signals from TGFb and (iii) a truncated SHP2 protein designed to block inhibitor signals from PD1. These modules are delivered, or transduced, into the T cells via two viral vectors. Both single- and dual-transduced CAR T cells were evaluated *in vitro* for anti-tumor activity, cytokine secretion, T cell proliferation, survival, and resistance to immunosuppressive pathways.

The addition of these three modules in the AUTO6NG product candidate significantly augmented its function by extending T cell persistence and rendering modified T cells resistant to TGFb- and PD1/PDL1-driven immune inhibition when compared to AUTO6 *in vitro*. Additionally, intravenous delivery of AUTO6NG in mice with established tumor burden exhibited potent anti-tumor activity and extended survival, whereas AUTO6 showed no activity in that model.

We presented new preclinical data for AUTO6NG in June 2020 at the AACR Virtual Annual Meeting 2020. GD2 was evaluated as a therapeutic CAR T target antigen in SCLC. We observed that AUTO6 alone has demonstrated efficacy in an in vitro SCLC model; however, successful tumor targeting alone was not sufficient to drive meaningful in vivo efficacy in the same SCLC model. We presented new preclinical data demonstrating the ability to target GD2 in SCLC cell line models in vitro, and the requirement for enhancing modules, designed to overcome TME suppressive mechanisms, to drive superior in vivo efficacy in a SCLC mouse model. The data suggests that AUTO6NG can overcome the immune suppressive mechanisms in the TME.

Clinical Development Strategy of AUTO6NG

GD2 is expressed in numerous pediatric and adult tumors including neuroblastoma, osteosarcoma, soft tissue sarcoma, melanoma, astrocytoma and small cell lung cancer (“SCLC”). A Phase 1 clinical trial of AUTO6NG in r/r neuroblastoma was initiated in December 2023 in collaboration with UCL.

Manufacture and Delivery of Programmed T Cell Therapies to Patients

We are devoting significant resources to process development and manufacturing in order to optimize the safety and efficacy of our product candidates, to ensure high quality and reliable product supply to patients, as well as to reduce our per unit manufacturing costs and time to market if we obtain regulatory approval for any of our programmed T cell product candidates.

The manufacture and delivery of programmed T cell therapies to patients involves complex, integrated processes, including harvesting T cells from patients, manufacturing viral vectors with nucleic acid content encoded with our programming modules, manufacturing programmed T cells using the viral vectors ex vivo, multiplying the T cells to obtain the desired dose, and ultimately infusing the T cells back into a patient’s body.

Commercial success in T cell therapies requires a manufacturing process that is reliable, scalable and economical. We have established a manufacturing process that is scalable and serves as a manufacturing platform designed to support rapid development of our programmed T cell therapy product candidates through clinical trial phases and regulatory approval processes. We are using a semi-automated, fully enclosed system for cell manufacturing, which is designed to provide a common platform suitable for manufacturing all of our product candidates. This platform allows for parallel processing having the ability to scale for commercial supply in a controlled environment at an economical cost. We have established reliable and consistent viral vector production and viral transduction processes further, also a key to our process reproducibility and reliability.

Our manufacturing and logistics process is designed to ensure that product integrity is maintained during shipment along with accurate tracking and tracing of shipments. We are expanding internal manufacturing and supply capabilities as well as the use of expert service providers on maturing our vein-to-vein logistics and our gradual capacity expansion in support of commercial operations. Chain of identity and chain of custody electronic systems are now in place to ensure transport and processing reliability and further adding to patient safety.

Our manufacturing and commercialization strategy requires a fully integrated vein-to-vein product delivery cycle. We believe having established manufacturing processes suitable for commercialization early in the development of our T cell therapies will allow us to focus on expanding manufacturing capacity during our clinical trials and early commercial launch needs. Over time, we expect to establish regional manufacturing hubs to meet projected near-, mid- and long-term commercial product requirements for commercialization. Our first purpose-built facility is located in Stevenage, UK. This facility, which has a global reach, can meet our near and mid-term clinical and commercial needs allowing ample time for expanding our manufacturing footprint. Our plan is to establish our manufacturing infrastructure in a manner that would minimize logistical complexities and costs for all regions going forward.

We believe our scalable closed-system manufacturing process, along with our proprietary and modular T cell programming technologies, would be challenging and costly for potential competitors to replicate.

Manufacturing Agreements

We have manufacturing agreements with King's College London for early phase vector manufacturing. Autolus also has an internal capability to produce vector for early and late-stage trials. Additionally, we have an agreement with AGC Biologics for late stage clinical and commercial supply of vector. All vector manufacturing is done in accordance with current Good Manufacturing Practice ("cGMP") in compliant manufacturing facilities. The manufacturing agreements governing the external supply arrangements also provide for access to services including quality management systems, qualified persons for product release, office space, frozen storage and warehousing services.

For clinical trial supply, we have established our initial cell and vector manufacturing capacity at the Cell and Gene Therapy Catapult in Stevenage, UK. We have a cell manufacturing suite capable of supporting clinical supply operations as well as a vector production suite capable of supplying clinical supplies.

In March 2018, we entered into a strategic, long-term supply agreement with Miltenyi Biotec GmbH ("Miltenyi"), for the supply of Miltenyi's CliniMACS Prodigy instruments, reagents and disposables for the manufacture of our programmed T cell therapies for preclinical and clinical use and, if approved, for commercial use, as well as support services. The supply agreement sets forth procedures to ensure continuity of supply to us of Miltenyi's products, both during the clinical phase and any future commercial phase of our product candidates. After the initial ten-year term of the agreement, we have two separate options to renew the agreement, each for an additional five-year term. The supply agreement contains customary termination provisions, allowing for termination by a party upon the other party's uncured material breach, upon the other party's bankruptcy or insolvency or upon the other party being subject to an extended period of force majeure events. We may also terminate the supply agreement upon advance written notice, if we decide to suspend or discontinue the development or commercialization of our product candidates. The supply agreement is governed under the laws of Germany.

Manufacturing Facilities

The licensure and commercial supply of our cell products will be from a new 70,000 square foot facility called the Nucleus. In March 2024, following the most recent GMP inspection by the MHRA in February 2024, the Nucleus facility obtained a Manufacturer's Importation Authorization (MIA) together with the accompanying GMP certificate. These licenses enable us to manufacture both commercial and clinical autologous drug products in the facility. The Nucleus provides multiple clean rooms, QC labs, warehouse and administrative space and is being fitted out in a phased manner as demand requires. At full capacity, we expect the Nucleus facility to provide manufacturing capacity for approximately 2,000 batches annually, Additional fallow space for the expansion of manufacturing capacity is available if required.

Manufacture and Delivery Performance

Data on manufacturing and delivery performance for obe-cel in the FELIX clinical trial were presented at the 2023 ASCO Annual Meeting in June 2023, with updated data presented at the ASH Annual Meeting in December 2023. The FELIX study successfully demonstrated the robust operability of obe-cel manufacturing, QC and logistics processes, meeting target V2C (time from leukapheresis to quality release) and V2D (time from leukapheresis to delivery of product to the hospital). Median V2C and V2D times were 21 and 24 days, respectively. All apheresis starting material was successfully processed despite the multitude of constraints posed by the COVID-19 pandemic. In total, 96% of manufactured obe-cel batches reached their target dose of 410 x 10^6 CAR T cells. Further optimization and improvements made during the study increased reliability, consistency, and precision of the manufacturing process, and supported the development of the Nucleus manufacturing facility with greater production capacity that aims to achieve a ≥95% manufacturing success rate with ≤15-day V2C times.

Commercialization

Based on the U.S. FDA acceptance of the BLA for obe-cel for patients with r/r Adult B-ALL, we are in the process of establishing our commercial infrastructure and distribution capabilities in preparation for a potential approval. Under PDUFA, the FDA has set a target action date of November 16, 2024, a standard review timeline consistent with recently approved CAR T therapies. We are developing our clinical-stage programs for the treatment of patients with late-stage or rare hematological cancers and solid tumors, most of whom are treated in specialized treatment centers or hospitals. With our experience in gene therapy, transplantation and oncology, we aim to provide high levels of service and scientific engagement at these treatment centers, and to pilot and establish systems necessary for product delivery by the time of launch. By focusing on these centers, we can begin to build our commercialization capabilities with limited resources.

We have retained worldwide commercial rights for certain of our product candidates. We currently plan to build our global commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. We may pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates. Under the terms of the License and Option Agreement with BioNTech, BioNTech has certain options to co-promote or co-commercialize AUTO1/22 and AUTO6NG. We generally expect to launch any of our products that receive regulatory approval in the United States first, followed by the EU and subsequently in other major markets. See "Risk Factors–Risks Related to our Intellectual Property–Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business."

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions and improvements that are commercially important to the development of our business by seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity and patent term extensions where available.

Our intellectual property estate, which includes in-licensed intellectual property and intellectual property that we own, is designed to provide multiple layers of protection. For example, we are pursuing patent protection for core constructs used in our product candidates, various methods of treatment for particular therapeutic indications using our approach, specific product candidates, innovative manufacturing processes, and constructs that may be used in future product candidates to improve the ability of our programmed T cells to better recognize and kill cancer cells. A portion of our patent portfolio is directed to certain current product candidates or technologies deployed in certain product candidates, and the remainder of the portfolio is directed to alternative approaches, technologies or modules that are not currently deployed in our current product candidates.

As of December 31, 2023, our patent portfolio is comprised of 81 patent families, of which 17 patent families originated from UCLB, the technology-transfer company of UCL, 3 patent families are in-licensed from Noile-Immune Biotech, Inc., and 61 patent families we own and have originated from our own research. Of the 17 live patent families that were originally in-licensed from UCL, 16 have been assigned to us. Because we have acquired or licensed certain of our patents from UCLB, and licensed certain of other patents from third parties, we must rely on their prior practices with regard to the assignment of such intellectual property. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

Commercially or strategically important non-U.S. jurisdictions in which certain patent applications that we have in-licensed are currently pending include: Europe, Australia, Canada, Japan, China, Brazil, Chile, Israel, India, Republic of Korea, Hong Kong, Mexico, New Zealand, Russian Federation, Singapore, South Africa, Colombia, Peru, Cuba, Indonesia, Malaysia and Philippines.

Our strategy is to develop and obtain additional intellectual property covering innovative manufacturing processes and methods for genetically engineering T cells expressing new constructs with properties that are designed to improve the ability of our programmed T cells to recognize and kill cancer cells. To support this effort, we have established expertise and development capabilities focused in the areas of T cell programming, preclinical and clinical research and development, and manufacturing and manufacturing process scale-up, and we expect that our ongoing research and development activities will yield additional patentable inventions and patent applications that will expand our intellectual property portfolio.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office ("USPTO") in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. The term of a patent that covers an FDA-approved drug may also be eligible for a patent term restoration of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term restoration is calculated based on the length of time the drug is under regulatory review. A patent term restoration under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be restored.

Moreover, a patent can only be restored once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. If and when possible, we expect to apply for patent term extensions for patents covering our product candidates or their methods of use.

Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents, if granted, will be commercially useful in protecting our commercial products and methods of manufacturing the same. Development and commercialization of products can be subject to substantial delays and it is possible that, at the time of commercialization, any patent covering the product has expired or will be in force for only a short period of time following commercialization.

Numerous third-party U.S. and non-U.S. issued patents exist in the area of programmed T cell therapies, including patents held by our competitors. We cannot predict with any certainty if any third-party U.S. or foreign patent rights, or other proprietary rights, will be deemed infringed by the use of our technology. Nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. Should we need to defend ourselves against any such claims, substantial costs may be incurred. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all our products in the United States, EU and other major markets.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our License and Option Agreement with BioNTech SE

In February 2024, we entered into a License and Option Agreement (the "BioNTech License Agreement") with BioNTech pursuant to which we granted to BioNTech an exclusive, worldwide, sublicensable license (the "License") to certain binders and to exploit products that express in vivo such binders (collectively, the "Binder Licensed Products").

In addition to the License we also granted BioNTech several time-limited options (the "*Options*") to acquire additional rights to specified clinical-stage product candidates, binders and technologies, described in more detail below. In the event that all Options are fully exercised, we would be eligible to receive maximum aggregate future payments of up to $582 million. This maximum amount includes the potential milestone payments for the Binder Licensed Products described below, all option exercise fees and potential milestone payments for licenses to optioned products and technologies, and additional payments that BioNTech may pay to us for an increased revenue interest with respect to obe-cel as described below.

License and Options

In consideration for the License and the Options, BioNTech made an initial payment to us of $10 million (which is part of the $50 million of total upfront payments received).

We are eligible to receive milestone payments of up to $32 million in the aggregate upon the achievement of specified clinical development and regulatory milestones for each Binder Licensed Product that achieves such milestones. We are also eligible to receive a low single-digit royalty on net sales of Binder Licensed Products, subject to customary reductions, which reductions are subject to specified limits. The royalty will be increased if BioNTech, its affiliates or sublicensees commercialize a Binder Licensed Product in an indication and country in which we or our affiliates or licensees also commercializes a product containing the same binders. Under the BioNTech License Agreement, BioNTech is solely responsible for, and has sole decision-making authority with respect to, at its own expense, the exploitation of Binder Licensed Products.

We also agreed to grant BioNTech the following time-limited Options:

- an option to obtain exclusive rights to co-fund development costs of our development-stage programs AUTO1/22 and AUTO6NG, in return for agreed upon economic terms, including an option exercise fee, milestone payments and a profit-sharing arrangement for each such product candidate, with additional options to co-promote or co-commercialize such product candidate;
- an option to obtain an exclusive worldwide license to exploit products that express certain additional binders in vivo or, with respect to certain binders, in an antibody drug conjugate ("Binder Option");
- an option to obtain a co-exclusive worldwide license to exploit products that express in vivo our modules for activity enhancement, with a non-exclusive right, in certain agreed instances, to exploit products that include our modules for activity enhancement but do not express in vivo such modules (the "Activity Enhancement Option"); and
- an option to obtain a non-exclusive worldwide license to exploit products that contain our safety switches (the "Safety Switch Option" and, together with the Binder Option and the Activity Enhancement Option, the "Technology Options").

The option exercise fee for each Technology Option is a low seven-digit amount. Each of the Activity Enhancement Option and the Safety Switch Option must be exercised with respect to a given biological target or combination of targets. There is a cap on the total option exercise fee if multiple options are exercised with respect to a given target.

There is also a cap on milestone payments across all agreements entered into as the result of BioNTech exercising one or more of the Technology Options and a cap on royalties payable on any given product for which multiple Options are exercised.

Obe-cel Product Revenue Interest

Under the BioNTech License Agreement, BioNTech has also agreed to financially support the expansion of the clinical development program for, and planned commercialization of, obe-cel. In exchange for the grant of rights to future revenues from the sales of obe-cel, BioNTech has made an upfront payment to us of $40 million (representing the remainder of the $50 million total upfront payment). We will pay BioNTech a low single-digit percentage of annual net sales of obe-cel, which may be increased up to a mid-single digit percentage in exchange for milestone payments of up to $100 million in the aggregate on achievement of certain regulatory events for specific new indications upon BioNTech's election.

Manufacturing and Commercial Agreement

Under the terms of the BioNTech License Agreement, we granted BioNTech the option to negotiate a joint manufacturing and commercial services agreement pursuant to which the parties may access and leverage each other's manufacturing and commercial capabilities, in addition to our planned commercial site network and infrastructure, with respect to certain of each parties' CAR T product candidates, including BioNTech's product candidate BNT211 (the "Manufacturing and Commercial Agreement"). The Manufacturing and Commercial Agreement, if entered into, would also grant BioNTech access to our planned commercial site network and infrastructure.

Termination

Unless earlier terminated, the BioNTech License Agreement will continue for so long as royalties are payable in respect of Binder Licensed Products and the revenue interest is payable in respect of obe-cel products. Subject to a cure period, either party may terminate the agreement in the event of the other party's uncured material breach or the insolvency of the other party. BioNTech may terminate the agreement, in whole or in part, for any or no reason upon a specified period of prior written notice.

Our License Agreement with UCL Business Ltd.

In September 2014, we entered into an exclusive license agreement with UCLB, the technology transfer company of UCL, for the development and commercialization rights to certain T cell programming modules (the "UCLB Agreement"). The UCLB Agreement was amended and restated in March 2016 to also include certain development and commercialization rights to improvements and new T cell programming modules. The UCLB Agreement was further amended and restated in March 2018 to include a license to AUTO1, for which UCL is conducting Phase 1 clinical trials in pediatric and adult ALL patients. The UCLB Agreement was further amended and restated in October 2020 to reflect our election to have various patent rights assigned to us, and to include a license to new technology and further licenses to obe-cel for which UCL is conducting Phase 1 clinical trials in PCNSL patients. Under the UCLB Agreement, subject to certain limitations, exceptions and retained rights of UCLB, we received an exclusive license of certain patent rights and know-how owned by UCLB covering T cell programming modules. The licensed rights cover obe-cel, AUTO4/5 and AUTO6 targeting modules, as well as additional T cell programming modules and technologies, including dual-targeting technology, pattern recognition technology, safety switches (including RQR8), tunable T cells, manufacturing processes as well as certain technology for evading tumor micro-environments. We also have option rights and rights of first negotiation to obtain an exclusive license for development and commercialization rights to certain new T cell programming modules.

In exchange for the rights under the original license agreement, we granted UCLB equity that was ultimately converted into 1,497,643 of our ordinary shares. We also agreed to pay a management fee, milestone payments and royalties upon future net sales of any products that use the in-licensed rights. The management fee of £120,000 was payable in equal installments on the first four anniversaries of our entry into the original license agreement. In exchange for the additional rights we received in March 2016 when the license agreement was amended, we issued UCLB additional equity that was ultimately converted into 313,971 of our ordinary shares, and we also made a one-time payment of £150,000. In exchange for the additional rights we received in March 2018 when the license agreement was further amended, we made an initial payment of £1.5 million and paid an additional £0.35 million in connection with UCLB's transfer of clinical data to us in December 2020.

Under the license agreement, as amended, we are obligated to pay UCLB milestone payments upon the initiation of certain clinical activities in an aggregate amount of £0.18 million, the receipt of specified regulatory approvals in an aggregate amount of £37.5 million, the start of commercialization in an aggregate amount of £18 million, and the achievement of net sales levels in an aggregate amount of £51 million. On a per-product basis, these milestone payments range from £1 million to £18.5 million, depending on which T cell programming modules are used in the product achieving the milestone. Under the terms of the license, we have the right to grant sub-licenses to third parties, subject to certain restrictions. If we receive any income in connection with such sublicenses, we must pay UCLB a percentage of the income allocable to the value of the sublicensed intellectual property rights ranging from low twenties to mid-single digits, decreasing based on the development expenses incurred by us and the passage of time. In 2023, $0.2 million was payable to UCLB by us relating to the income allocable to the value of the sublicensed intellectual property rights. UCLB has retained the right to use the licensed T cell programming modules for academic research purposes at UCL and with other academic institutions, subject to certain restrictions.

Upon commercialization of any of our products that use the in-licensed patent rights, we are obligated to pay UCLB a flat royalty for each licensed product ranging from the low- to mid-single digits, depending on which technologies are deployed in the licensed product, based on worldwide annual net sales of each licensed product, subject to certain reductions, including for the market entry of competing products and for loss of patent coverage of licensed products. We may deduct from the royalties payable to UCLB half of any payments made to a third party to obtain a license to such third party's intellectual property that is necessary to exploit any licensed products. Once net sales of a licensed product have reached a certain specified threshold, we may exercise an option to buy out UCLB's rights to the remaining milestone payments, royalty payments, and sublicensing revenue payments for such licensed product, on terms to be negotiated at the time.

As mentioned above, we acquired ownership of the majority of the licensed patent rights under the license agreement (with the exception of the RQR8 patent rights) by virtue of a Deed of Assignment from UCLB which was executed in October 2020. Our payment and diligence obligations remain unaffected by the assignment of the licensed patent rights to us.

Under the license agreement, we are solely responsible, at our expense, for developing the products that use the in-licensed patent rights and obtaining all regulatory approvals for such products worldwide. We are also solely responsible, at our expense, for commercializing the products worldwide after receiving regulatory approval. Further, we are obligated to use commercially reasonable efforts to develop certain products using the patent rights pertaining to the T cell programming modules we have licensed from UCLB. Failure to achieve diligence obligations may result in loss of exclusivity or termination of the license on a program-by-program basis.

The UCLB Agreement expires on a product-by-product and country-by-country basis upon the expiration of the royalty term with respect to each product in each country. We may unilaterally terminate the UCLB Agreement for any reason upon advance notice to UCLB. Either party may terminate the UCLB Agreement for the uncured material breach by the other party or for the insolvency of the other party. If UCLB terminates the UCLB Agreement following our insolvency or our material breach of the agreement, or if we terminate the agreement unilaterally, all rights and licenses granted to us will terminate, and all patent rights and know-how transferred, licensed or assigned to us pursuant to the agreement will revert back to UCLB. In addition, UCLB has the right to negotiate with us for the grant of an exclusive license to our improvements to the T cell programming modules we have licensed on terms to be agreed upon at the time.

Competition

The biotechnology and pharmaceutical industries put significant resources in developing novel and proprietary therapies for the treatment of cancer. Consequently, there are a number of different products available in the indications where Autolus is seeking to launch our products. These include in-class competitors, such as autologous CAR T cell therapies, and products from different classes, such as bispecific tumor engagers ("BiTEs"), anti-body drug conjugates ("ADC"), antibody treatments and classic small molecular entities ("SME") anti-tumor agents. These anti-tumor agents can be given as single agents or are often used in combination.

In oncology, it is customary to initially study and launch as a last line agent for use in relapse/refractory patients. Over-time, and based upon further clinical studies, it is then common for products to move earlier in the treatment paradigm, to earlier lines of care. Examples of this are the recent FDA approvals of Yescarta and Breyanzi for second-line treatment in DLBCL. Consequently, as product use is sequenced, physicians make treatment decisions in each line based upon a number of factors such as which products and combinations are registered and reimbursed, response to the treatments used in previous lines of care, the aggressiveness and speed of progression of the tumor and the general health status of the patient.

Consequently, many of the out of class agents will not be direct competitors to autologous CAR T cell therapies in the initial use after launch, as they are predominantly used earlier in the treatment course. However, as CAR T cell therapies move to earlier lines, this will require clinical data to displace the existing standard of care.

In the indications where autologous CAR T cell therapies are registered, due to their superior efficacy, they are poised to become standard or care. Several companies already have autologous CAR T cell therapies which have been registered by the FDA and/or European Commission. These are direct competitors, and a summary of the indications in which they are currently registered is given below:

Approved Autologous CAR T Cell Therapies*			
Product	**Targeting**	**Company**	**Indications**
Abecma (idecabtagene vicleucel)	BCMA	BMS	Adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy.
Breyanzi (lisocabtagene maraleucel)	CD19	BMS	Adult patients with large B-cell lymphoma ("LBCL"): • refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; • refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age • relapsed or refractory disease after two or more lines of systemic therapy
Carvykti (ciltacabtagene autoleucel)	BCMA	J&J / Janssen Biotech	Adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy.
Kymriah	CD19	Novartis	Patients up to 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse Adult patients with relapsed or refractory (r/r) LBCL after two or more lines of systemic therapy, including DLBCL Adult patients with relapsed or refractory FL after two or more lines of systemic therapy.

Tecartus	CD19	Kite Gilead	Adult patients with relapsed or refractory MCL. Adult patients with relapsed or refractory B-cell precursor ALL.
Yescarta (axicabtagene ciloleucel)	CD19	Kite Gilead	Adult patients with LBCL that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. Adult patients with relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL. Adult patients with relapsed or refractory FL after two or more lines of systemic therapy.

*Indication based on United States Prescribing Information (USPI)

Four of these products, Tecartus and Yescarta from Kite/Gilead, Kymriah from Novartis and Breyanzi from BMS are anti-CD19 CAR T cell therapies, the same class as obe-cel. However, only Tecartus is approved for use in adult ALL. We believe there will be a market for obe-cel in this indication due to its differentiated safety profile when compared to current approved therapies.

It is possible that companies could take other autologous CAR T cell products forward in adult ALL or allogeneic "off-the-shelf" CAR T cell therapies could be developed which would be considered direct competitors. Allogeneic products are in early development and, because these products are not made from the patient's own cells, they might be more convenient to deliver, without the need to wait for a product to be manufactured (typical manufacturing times for autologous products are currently 18-25 days). However, this class of product has not shown the same levels of durable activity and the products in clinical trials are therefore likely to require periodic repeat dosing as opposed to autologous products, which allow for the therapy to be given as a one-time treatment.

CAR T cell therapies are also being evaluated for treatment of autoimmune diseases. There are biotech and pharma companies in early stage clinical trials in SLE and LN, as well as other autoimmune diseases, including Myasthenia Gravis, Scleroderma, Myositis, Multiple Sclerosis. Initiated Phase 1 and 2 studies in SLE/LN include Cabaletta (CABA 201), Kyverna (KYV 101), Novartis (YTB323), Juno/BMS (CC-97540), Cartesian (Descartes-08).

Government Regulation and Product Approval

As a biopharmaceutical company, we are subject to extensive regulation. Our programmed T cell product candidates, if approved, will be regulated as biological medicines. With this classification, commercial production of our products will need to occur in registered and licensed facilities in compliance with GMPs for biologics.

Human immunotherapy products are a new category of therapeutics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA, for marketing authorization.

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

U.S. Government Regulation

Product Development Process

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

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practices ("GLPs"), and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as Good Clinical Practices ("GCPs"), and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation and submission to the FDA of a BLA, for marketing approval that includes substantive evidence of quality, efficacy, and safety from results of nonclinical testing and clinical trials;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP to assure that the facilities, methods and controls used in product manufacture are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current Good Tissue Practices ("GTPs") for the use of human cellular and tissue products;
- potential FDA inspection of the nonclinical study and clinical trial sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA; and
- FDA acceptance, review and approval, of the BLA, which might include review by an advisory committee, a panel typically consisting of independent clinicians and other experts who provide recommendations as to whether the application should be approved and under what conditions.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous the preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations as well as in vitro and animal studies to assess the potential safety and efficacy of the product candidate. After sufficient preclinical testing has been conducted, the conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit an IND to the FDA before clinical testing can begin in the United States. An IND must contain the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature, a proposed clinical protocol, an investigator's brochure, a sample informed consent form, and other materials.

Clinical trial protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Some preclinical testing, such as toxicity studies, may continue even after the IND is submitted.

The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials or places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB"), at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials involving recombinant or synthetic nucleic acid molecules also must be reviewed by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent.

Human clinical trials are typically conducted in three sequential phases, as follows:

- *Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition.
- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population, generally at geographically dispersed clinical trial sites. These clinical trials are intended to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk to benefit profile of the product and to provide an adequate basis for product labeling.

In some instances, these phases may overlap or even be combined into one study (*e.g.*, Phase 1/2 studies) particularly in case of high medical need and sufficient clinical efficacy and safety of the product phase 2 data may be sufficient for initial approval. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board, an independent group of experts that evaluates study data for safety and makes recommendations concerning continuation, modification, or termination of clinical trials, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

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

Review and Approval Processes

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

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

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

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

To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, recordkeeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the agency decides not to approve the BLA in its present form, the FDA will issue a Complete Response Letter, which generally outlines the specific deficiencies in the BLA identified by the FDA and may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Even with the submission of additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements that important safety information and material facts related to the product be disclosed. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative liability.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products and some intermediates in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

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

Marketing Exclusivity

The Biologics Price Competition and Innovation Act amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. Biosimilars are approved pursuant to an abbreviated pathway whereby applicants need not submit the full slate of preclinical and clinical data, and approval is based in part on the FDA's findings of safety, purity, and potency for the original biologic (i.e., the reference product). Original BLAs are eligible to receive 12 years of exclusivity from the time of first licensure of the product, which prevents the FDA from approving any biosimilars to the reference product through the abbreviated pathway, but does not prevent approval of BLAs that are accompanied by a full data package and that do not rely on the reference product. A biosimilar may be approved if the product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences with the reference product in terms of the safety, purity, and potency.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial. Similar regulations are in place in other jurisdictions.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in significant part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payers include federal and state healthcare programs, private managed care organizations, health insurers and other organizations. The process for determining whether a third-party payer will provide coverage for a product may be separate from the process of establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity of and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

Reimbursement may impact the demand for, and/or the price of, any product candidate which obtains marketing approval. Even if coverage and reimbursement is obtained for a given product candidate by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use a product, and physicians may be less likely to prescribe a product, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of the product. Therefore, coverage and adequate reimbursement is critical to new drug product acceptance.

Additionally, we are developing a proprietary diagnostic test for use with certain of our product candidates. The diagnostic test will require separate regulatory approval in addition to the regulatory approval of AUTO4 and AUTO5. Failure to obtain marketing approval for the diagnostic test could prevent us from commercializing either AUTO4 or AUTO5 unless another similar diagnostic test for distinguishing TRBC1-positive and TRBC2-positive T cell lymphomas is commercially available. We will be required to obtain coverage and reimbursement for this test separate and apart from the coverage and reimbursement we seek for AUTO4 and AUTO5, if approved. Similar challenges to obtaining coverage and reimbursement, applicable to our product candidates, will apply to this proprietary diagnostic test.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of additional clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The downward pressure on healthcare costs in general, particularly prescription drugs and biologics, has become very intense. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. As a result, increasingly high barriers are being erected to the entry of new products. The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Laws Governing Interactions with Healthcare Providers

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws restrict our business activities, including certain marketing practices. These laws include, without limitation, anti-kickback laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The U.S. federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item, good, facility or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. 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 hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the U.S. federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances.

Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the U.S. federal Anti-Kickback Statute has been violated. Additionally, the intent standard under the U.S. federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act ("ACA"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. federal False Claims Act.

Federal civil and criminal false claims laws and civil monetary penalties laws, including the U.S. federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, prohibit any person or entity from, among other things, 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. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, 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. Further, pharmaceutical manufacturers can be held liable under the U.S. federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims.

The U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the U.S. federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, impose certain requirements on "covered entities," including certain healthcare providers, health plans and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their covered subcontractors, relating to the privacy, security, transmission and breach of individually identifiable health information. Further, HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions.

Additionally, the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare and Medicaid Services ("CMS"), information related to certain payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (such as physicians assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members.

Additionally, similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the data privacy and security of certain protected information, such as the EU GDPR and the UK GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union and the United Kingdom (including health data).

Finally, the majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures.

Some states and local jurisdictions require the registration of pharmaceutical sales representatives. State and foreign laws also govern the data privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

Healthcare Reform Efforts

A primary trend in the United States healthcare industry and elsewhere is cost containment. Over the last several years, there have been federal and state proposals and legislation enacted regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, and making changes to healthcare financing and the delivery of care in the United States.

Recently, there have been a number of health reform measures by the Biden administration that we expect will have a significant impact on the pharmaceutical industry. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, U.S. Department of Health and Human Services ("HHS"), released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA"), into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

In addition, the IRA (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Further, there remains heightened Congressional scrutiny in the United States of pharmaceutical pricing practices designed to, among other things, bring more transparency in product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

In addition to the IRA, other federal health reform measures have been proposed and adopted in the United States that could impact cell therapy. Most notably, the previous administration supported and promulgated a rule related to value based payment alternatives in the Medicaid program. Medicaid is a jointly run federal and state program that provides health benefits coverage for low-income residents and children. In exchange for broad coverage in Medicaid, drug manufacturers are required to sign a Medicare Drug Rebate agreement which requires them to offer Medicaid programs the "best price" available for a particular product. This "best price" takes into consideration any rebates or concessions manufacturers offer, with some exceptions. The final rule would exempt value-based or outcomes-based payment arrangements from the definition of "best price" which provides manufacturers more flexibility to work with commercial payers and states on innovate payment mechanisms for high-cost cell and gene therapies. While Medicaid is not a significant driver of cell therapy sales it is a bellwether program and one we watch closely.

The U.S. Foreign Corrupt Practice Act, the UK Bribery Act 2010 and Other Anti-corruption Laws

The U.S. Foreign Corrupt Practice Act, as amended (the "FCPA") prohibits any U.S. individual or business, as well as their employees, officers, agents, and representatives, from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign, non-U.S. official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

Our operations are also subject to non-U.S. anti-corruption laws such as the UK Bribery Act 2010 (the "UK Bribery Act"). As with the FCPA, these laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the UK Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the UK and the United States and authorities in the EU, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as trade control laws.

Failure to comply with the UK Bribery Act, the FCPA and other anti-corruption laws and trade control laws could subject us to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses.

Data Privacy and Security Laws

In the ordinary course of our business, we process personal or sensitive data, including data we collect in connection with our clinical trial activities. Accordingly, we are subject to certain data privacy and security obligations, including U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Such obligations may include, without limitation, the Federal Trade Commission Act, HIPAA, as amended by the HITECH, the EU's General Data Protection Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of UK law by virtue of section 3 of the EU (Withdrawal) Act 2018 ("UK GDPR"), and the ePrivacy Directive. In the past few years, several states within the United States—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses. We may in the future become subject to these laws. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

See the risk factor captioned "We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences" In Part I, Item 1A. of this report for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

EU Regulation

Review and Approval of New Drug Products

In the EU, medicinal products, including advanced therapy medicinal products ("ATMPs"), are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic-cell therapy products and tissue engineered products, which are cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to regenerate, repair or replace a human tissue. We anticipate that our T cell therapy products will be regulated as ATMPs in the EU.

There is legislation at a EU level relating to the standards of quality and safety for the collection and testing of human blood and blood components for use in cell-based therapies, which could apply to our products. Additionally, there may be local legislation in various EU Member States, which may be more restrictive than the EU legislation, and we would need to comply with such legislation to the extent it applies.

Clinical Trials

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 ("CTR") which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 ("CTD").

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal" the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials, including ATMPs, must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections. Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization ("ICH"), guidelines on GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of ATMPs. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide "no fault" compensation to any study subject injured in the clinical trial.

During the development of a medicinal product, the EMA and national medicines regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EU level, developers of medicinal products can ask the EMA for scientific advice and protocol assistance at any stage of development and regardless of whether the medicinal product is eligible for the centralized authorization procedure or not. Assistance is given by the EMA's Committee for Medicinal Products for Human Use, or CHMP, on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure. Advice from the EMA is provided by responding to specific questions concerning, quality aspects (manufacturing, chemical, pharmaceutical and biological testing of the medicine), nonclinical testing (toxicological and pharmacological tests designed to show the activity of the medicine in the laboratory) and clinical aspects (appropriateness of studies in patients or healthy volunteers, selection of endpoints), methodological issues (statistical tests to use, data analysis, modelling and simulation), overall development strategy (conditional marketing authorization, bridging strategy for generics, safety database), significant benefit for maintaining orphan designation, and pediatric developments. In accordance with the EMA's policy, scientific advice will not be legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorizations

In order to market a new medicinal product in the EU, a company must submit and obtain approval from regulators of a marketing authorization application ("MAA"). The process for doing this depends, among other things, on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization ("MA"), granted by the European Commission that is valid throughout the EEA (i.e., the EU as well as Iceland, Liechtenstein and Norway). The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) products designated as orphan medicinal products and (iv) advanced-therapy medicines ("ATMPs"), such as gene therapy, somatic cell therapy or tissue-engineered medicines. 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, authorization through the centralized procedure is optional on related approval. Therefore, the centralized procedure would be mandatory for the products we are developing. As a result, the information in this section focuses solely on this procedure.

Under the centralized procedure in the EU, the EMA's Committee for Medicinal Products for Human Use ("CHMP") conducts the initial 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 MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this opinion is favorable, the European Commission may then adopt a decision to grant an MA. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

An MA has, in principle, an initial validity of five years. The MA 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 EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

The European Commission may grant an MA "under exceptional circumstances". Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may be because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information.

Like a conditional MA, an MA granted under exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

The EU medicines rules expressly permit the EU Member States to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products we have in development do not make use of embryonic stem cells, it is possible that the national laws in certain EU Member States may prohibit or restrict us from commercializing our products, even if they have been granted an EU marketing authorization.

Advanced Therapy Medicinal Products

ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. The grant of marketing authorization in the EU for products containing viable human tissues or cells such as gene therapy medicinal products is governed by Regulation (EC) No. 1394/2007 on ATMPs, read in combination with Directive (EC) No. 2001/83 of the European Parliament and of the Council. Regulation (EC) No. 1394/2007 establishes specific rules concerning the authorization, supervision and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the EMA which is required to provide an opinion regarding the application for marketing authorization.

The Committee for Advanced Therapies ("CAT") is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a marketing authorization application is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs. Although these guidelines are not legally binding, we believe that our compliance with them is likely necessary to gain and maintain approval for any of our product candidates.

Cell-based products must also comply with Directive (EC) No. 2004/23 of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (the "Tissues and Cells Directive"), as well as its technical implementing directives. The Tissues and Cells Directive describes the conditions and quality requirements which must be applied when sourcing the cells intended for manufacturing of the cell-based medicinal product. The EU Member States have transposed the Tissues and Cells Directive into their national laws. However, various interpretations of the Tissue and Cells Directive have occurred and are reflected in individual EU Member States national implementing legislation which have led to diverging approaches.

Data Exclusivity

MA applications for generic medicinal products do not need to include the results of preclinical and clinical trials, but instead can refer to the data included in the MA of a reference product for which regulatory data exclusivity has expired. If a MA is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic MAAs referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the European Union. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Pediatric Development

In the EU, companies developing a new medicinal product must agree to a Pediatric Investigation Plan ("PIP"), with the EMA's Pediatric Committee ("PDCO") during drug development and, at the latest, before submission of an MA, and must conduct pediatric clinical trials in accordance with that PIP, unless a deferral or waiver applies (e.g., because the relevant disease or condition occurs only in adults). The MAA for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a full or partial deferral has been granted. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Products that are granted an MA on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

In the United States, companies developing a new medicinal product must agree to a Pediatric Study Plan, or PSP, with the FDA during development (except for non-oncology medicinal product with an Orphan Drug Designation) and, at the latest, before submission of a marketing authorization application, and must conduct pediatric clinical trials in accordance with that PSP as agreed, unless a deferral or waiver applies (e.g., because the relevant disease or condition occurs only in adults). The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PSP, unless a waiver applies, or a full or partial deferral has been granted. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PSP are eligible for a six-month extension of marketing exclusivity (pediatric exclusivity).

Manufacturing Regulation

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Orphan Designation

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Approval Controls

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Pricing and Reimbursement

In the EU, pricing and reimbursement schemes vary widely from country to country. EU Member States will approve the gross price set by the manufacturer and attempt to negotiate discount schemes to manage product acquisitions costs and monitor and control prescription volumes and issue guidance to physicians to limit prescriptions to the label indication.

In addition, some EU Member States may require the submission of dossiers that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA") process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA Regulation") was adopted. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. When it enters into application in 2025, the HTA Regulation will be intended to harmonize the clinical benefit assessment of HTA across the EU. In light of the fact that the UK has left the EU, Regulation No 2021/2282 on HTA will not apply in the UK. However, the UK Medicines and Healthcare products Regulation Agency ("MHRA") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence ("NICE"), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products.

Regulation of Companion Diagnostics

In the EEA, companion diagnostics are deemed to be in vitro diagnostic medical devices ("IVDs") and are governed by Regulation 2017/746 ("IVDR"), which entered into application on May 26, 2022, repealing and replacing Directive 98/79/EC. The IVDR defines a companion diagnostic as a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.

The IVDR and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. IVDs, including companion diagnostics, must conform with the general safety and performance requirements ("GSPR") of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA.

To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, and obtain the right to affix the CE mark, IVD manufacturers must conduct a conformity assessment procedure, which varies according to the type of IVD and its classification. Apart from low risk IVDs (Class A which are not sterile), in relation to which the manufacturer may issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

Companion diagnostics must undergo a conformity assessment by a Notified Body. If the related medicinal product has, or is in the process of, been authorised through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have or are in the process of authorisation through any other route provided in EU legislation, the Notified Body must seek the opinion of the national competent authority of an EU Member State.

Brexit and the Regulatory Framework in the United Kingdom

The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency ("MHRA") is now the UK's standalone regulator for medicinal products and medical devices. Great Britain (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules for now.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation.

These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains within the scope of EU authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is implemented in Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedure. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in Great Britain.

Corporate Information

We are a public limited company, originally incorporated pursuant to the laws of England and Wales in February 2018 as a private company with limited liability called Autolus Therapeutics Limited. Autolus Limited was originally incorporated under the laws of England and Wales in July 2014. Pursuant to the terms of a corporate reorganization carried out in June 2018, the shareholders of Autolus Limited exchanged each of the shares held by them in Autolus Limited for the same number and class of newly issued shares of Autolus Therapeutics Limited and, as a result, Autolus Limited became a wholly owned subsidiary of Autolus Therapeutics Limited. On June 18, 2018, Autolus Therapeutics Limited re-registered as a public limited company and was renamed Autolus Therapeutics plc. On June 22, 2018, the different classes of our issued share capital were converted into a single class of ordinary shares and various classes of deferred shares, and we completed our IPO on the Nasdaq Global Select Market ("Nasdaq"). Our ADSs trade on Nasdaq under the symbol "AUTL". Our ordinary shares are not listed.

Our registered office and principal executive offices are located at the Mediaworks, 191 Wood Lane, White City, London W12 7FP, United Kingdom and our telephone number is +44 20 3829 6230. Our agent for service of process in the United States is Autolus Inc., 15810 Gaither Drive, Gaithersburg, Maryland, 20877.

Available Information

Our website address is www.autolus.com. Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

Copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments, if any, to those reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website and on the website of the SEC at www.sec.gov.

Employees and Human Capital Resources

As of December 31, 2023, we had 463 full-time employees as shown in the table below:

	At December 31,		
	2023	2022	2021
Function:			
Administration	80	56	51
Research and development	383	343	273
Total	**463**	**399**	**324**
Geography:			
UK	391	362	295
Switzerland and Germany	13	8	4
United States	59	29	25

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of equity-based compensation awards.

Item 1A. Risk Factors

An investment in our ADSs involves a high degree of risk. You should carefully consider the risks and uncertainties described below, and all other information appearing elsewhere in this Annual Report, including our consolidated financial statements and the related notes hereto, before making an investment decision regarding our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects.

Risks Related to Our Financial Position and Need For Capital

We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history, and we have incurred significant net losses since our inception in 2014. We have incurred losses of $208.4 million, $148.8 million and $142.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we had an accumulated deficit of $878.6 million. We have funded our operations to date primarily with proceeds from the sale of our equity securities, including ADSs, licensing and collaboration arrangements and strategic financing.

We currently have no products approved for commercial sale, and while we have generated revenue from licensing, we are devoting substantially all of our financial resources and efforts to research and development of our programmed T cell product candidates and T cell programming technologies, as well as to building out our commercial and manufacturing infrastructure. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront operating and 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.

The FDA has accepted our BLA for obe-cel for patients with relapsed/refractory (r/r) Adult B-Cell ALL, and has set a target PDUFA action date of November 16, 2024. Should the FDA not grant us marketing approval, we are unsuccessful in our commercialization efforts or the market does not accept our product, we may not generate revenue. We expect that it could take several years until any of our other product candidates receive marketing approval and are commercialized, and we may never be successful in obtaining marketing approval and commercializing any of our product candidates, including obe-cel. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our shareholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned research and development of our current programmed T cell product candidates for the treatment of hematological cancers, solid tumors and autoimmune diseases;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, including our planned development of additional T cell therapies for the treatment of hematological cancers, solid tumors and autoimmune diseases;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up internal and external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- make required milestone and royalty payments to UCLB or other third parties, under license agreements pursuant to which we were granted some of our intellectual property rights;
- make required sales milestone and royalty payments to BXLS V Autobahn LP ("Blackstone") under our collaboration and financing agreement relating to obe-cel, our lead product, and other collaboration products for B cell malignancies;
- make required milestone payments to Miltenyi under our sublicense agreement relating to certain proprietary technologies incorporated in certain of our manufacturing processes;
- make required revenue share interest payments to BioNTech relating to obe-cel under our license and option agreement;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;

- hire additional clinical, quality control and manufacturing personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in the United States, Europe and other geographies; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, preparing a satisfactory filing package for regulatory authorities, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development, manufacturing, delivery and commercialization of complex autologous cell therapies, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our ADSs and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our ADSs could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. As an organization, we have not demonstrated an ability to successfully obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our limited history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer.

We will need additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all.

We will require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our product development programs or commercialization efforts.

Since our inception, we have devoted substantially all of our resources to fund the operating expenses and capital expenditure requirements associated with the research and development of our product candidates. These programs are described in greater detail in the “Business” section of this Annual Report. Our current funding may only be sufficient to fund obe-cel through initial commercial launch, assuming certain timelines on successful regulatory approval, and we will need to raise additional capital to reach profitability as well as to complete the development and commercialization of our other programmed T cell product candidates, and in connection with our continuing operations, strategy and other planned activities. Our future capital requirements will depend on many factors, including:

- the progress, results and costs of laboratory testing, manufacturing, and preclinical and clinical development of our current and future product candidates;
- the timing and amounts of any milestone or royalty payments we may be required to make under current or future license or collaboration agreements;
- the costs of leasing, building out, equipping, and operating the facilities necessary to research, develop, manufacture and commercialize our product candidates, as well as to support our continuing operations;
- the costs of hiring additional clinical, quality control and manufacturing personnel;
- the costs, timing and outcome of regulatory review of our product candidates;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our product revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available until late 2024 at the earliest, in the case of our existing lead program and, with respect to other pipeline programs, for up to several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders may experience substantial dilution. We may sell ordinary shares or ADSs, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares or ADSs, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders. In February 2024, we issued an aggregate of approximately 91.7 million ADSs in an underwritten offering and a private placement, resulting in substantial dilution for existing shareholders. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our shareholders and may cause the market price of our ADSs to decline.

We have incurred substantial obligations under license and collaboration agreements, which could impair our flexibility and access to other capital and adversely affect our financial position, and our business would be adversely affected if we were unable to meet our obligations under these and similar future agreements.

In November 2021, we entered into a collaboration agreement with Blackstone (the "Blackstone Collaboration Agreement") pursuant to which Blackstone has agreed to pay us up to $150 million to support the continued development and, following approval, commercialization of obe-cel and next-generation product candidates (obe-cel and such next-generation products, collectively, the "Collaboration Products") in exchange for our agreement to make substantial payments to Blackstone following approval of such products. These payments include a single-digit percentage payment on worldwide net sales of (i) the Collaboration Products in any indication and (ii) AUTO3 for the treatment of B-cell leukemias and lymphomas, by us and any of our licensees, as well as sales milestone payments relating to such net sales. Such payments to Blackstone could increase our cash requirements and could impair our liquidity. As of December 31, 2023, Blackstone has paid $120 million to us under the terms of the Blackstone Collaboration Agreement.

Under the BioNTech License Agreement with BioNTech entered into in February 2024, we have agreed to pay BioNTech a low single-digit percentage of annual net revenue of obe-cel which may be increased up to a mid-single digit percentage in exchange for milestone payments of up to $100 million in the aggregate on achievement of certain regulatory events for specific new indications upon BioNTech's election. Such payments to BioNTech could increase our cash requirements and could impair our liquidity.

In connection with the Collaboration Agreement, Blackstone was granted a security interest in substantially all of our assets. The Collaboration Agreement also contains negative covenants that restrict us from (a) granting liens on certain of our assets, including liens on the intellectual property relating to the Collaboration Products, except for certain permitted liens, (b) making distributions or dividends, except for certain permitted distributions, (c) entering into development or commercialization license transactions with respect to the Collaboration Products, except that we are permitted to enter into any such development or commercialization license transactions with certain pharmaceutical companies, including those companies that have annual sales in excess of an agreed threshold, (d) consummating certain change in control transactions, (e) selling royalties or entering into similar financials transactions involving the sale of revenues or royalties, or (f) acquiring subsidiaries without joining such subsidiary as a party to the Blackstone Collaboration Agreement. These restrictions could inhibit our ability to pursue our business strategies and may limit our ability to, among other things, incur secured indebtedness, encumber assets, pay dividends or make other distributions to holders of our capital stock, license-out the Collaboration Products, complete mergers or acquisitions, or sell royalties.

If we default under our obligations under the Blackstone Collaboration Agreement, we will be obligated to pay Blackstone liquidated damage payments in excess of the development payment paid by Blackstone. If we fail to make such payments, Blackstone could elect to exercise its remedies in respect of the security interest, which would seriously harm our business and ability to continue as a going concern.

Risks Related to the Development of Our Product Candidates

All of our product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have established clinical proof-of-concept for only one of our product candidates. There is no assurance that our current or any other future clinical trials of our product candidates will be successful or will generate positive clinical data, and we may not receive marketing approval from the FDA, or other regulatory agencies, including the European Commission, for any of our product candidates. In order to commence a clinical trial in the United States, we must submit an IND to the FDA and have the IND application go into effect. Trials in the United States must be conducted pursuant to an active IND. An investigator may not administer a drug candidate to human subjects until the IND goes into effect. Similar requirements apply to our conduct of trials in the UK and EU. We are sponsoring active, recruiting clinical trials for two of our product candidates, obe-cel (AUTO1), and AUTO4. We are also collaborating with our academic partner UCL to support clinical trials sponsored by them of our product candidates (obe-cel, AUTO1/22, AUTO6NG and AUTO8). In addition, patients who have received an investigational product developed by us will be evaluated for long-term safety and disease response in a long-term follow-up protocol. There can be no assurance that the FDA, the competent authorities of EU Member States or other regulatory agencies will permit any future clinical trial application to go into effect in a timely manner or at all.

U.S. and EU regulations require parties seeking regulatory approval for product candidates in adult indications to define a development plan for such candidate in pediatric indications, commonly referred to as a PSP in the United States. and a PIP in the EU. Similar requirements apply in other jurisdictions. If these requirements are not met, a submission for marketing authorization cannot be submitted. A pediatric development plan must be approved by U.S., EU and other regulators, and the conduct of the respective pediatric studies, typically in parallel with the adult clinical development, must be conducted in the time frame described in the plan. Failure to comply with these requirements can lead to penalties and reputational damage. There can be no assurance that the FDA, EMA or other regulatory agencies will permit a pediatric development plan to go into effect in a timely manner, or at all.

If we are unable to agree upon appropriate pediatric development plans with these regulatory agencies, or if we are unable to perform the activities described in an agreed plan, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates.

The success in the development of our programmed T cell product candidates will depend on many factors, including:

- completing preclinical studies and receiving regulatory approvals or clearance for conducting clinical trials for our preclinical-stage programs;
- obtaining positive results in our clinical trials demonstrating efficacy, safety, and durability of effect of our product candidates;
- establishing pediatric development plans with respect to product candidates for which we seek regulatory approval;
- receiving approvals for commercialization of our product candidates from regulatory authorities;
- manufacturing our product candidates at an acceptable cost; and

- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our products and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which would materially harm our business.

Our proprietary, next-generation T cell programming technologies, our modular approach for engineering T cells and our manufacturing platform for our programmed T cell product candidates, represent emerging therapeutic approaches that face significant challenges and hurdles.

We have concentrated our research and development efforts on our T cell technology platform using our expertise in disease biology and cell programming, and our future success is highly dependent on the successful development and manufacture of our programmed T cell product candidates. We do not currently have any approved or commercialized products. Some of our product candidates employ a dual-targeting mechanism. By targeting two separate antigens on the cancer cell surface, we believe these product candidates have the potential to improve durability of treatment response and reduce the frequency of cancer relapse as compared to other currently available single-targeting T cell therapies. AUTO4, our product candidate for the treatment of T cell lymphoma, employs a novel approach to killing malignant T cells that aims to preserve approximately half of the normal, healthy T cells. Some of our product candidates include a "safety switch" that is designed to allow for the elimination of the engineered T cells if a patient experiences severe adverse side effects from the treatment. However, this "safety switch" technology has not been activated to date in our clinical studies, and we do not know whether it would have the intended effect if used. Additionally, as with other targeted therapies, off-tumor or off-target activity could delay development or require us to re-engineer or abandon a particular product candidate. Because programmed T cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment and autoimmune diseases generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- obtaining regulatory approval for our product candidates, as the FDA, the European Commission and other regulatory authorities have limited experience with programmed T cell therapies for cancer;
- sourcing clinical and, if approved, commercial supplies of the materials used to manufacture our product candidates;
- developing programming modules with the desired properties, while avoiding adverse reactions;
- creating viral vectors capable of delivering multiple programming modules;
- developing a reliable and consistent vector and cell manufacturing process;
- establishing manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical studies and our projected commercial requirements;
- achieving cost efficiencies in the scale-up of our manufacturing capacity;
- developing protocols for the safe administration of our product candidates;
- educating medical personnel regarding our programmed T cell therapies and the potential side effect profile of each of our product candidates, such as potential adverse side effects related to CRS;
- establishing integrated solutions in collaboration with specialty treatment centers in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies;
- establishing sales and marketing capabilities to successfully launch and commercialize our product candidates if and when we obtain any required regulatory approvals, and risks associated with gaining market acceptance of a novel therapy if we receive approval; and
- obtaining coverage and adequate reimbursement from third-party payors for our novel and personalized therapies in connection with commercialization of any approved product candidates.

We may not be able to successfully develop our programmed T cell product candidates or our T cell programming technologies in a manner that will yield products that are safe and effective, scalable or profitable.

Additionally, because our technology involves the genetic modification of patient cells *ex vivo*, we are subject to additional regulatory challenges and risks, including regulatory requirements governing genetically modified organisms that have changed frequently and will likely continue to change in the future, and that may limit or delay our ability to import our product candidates into certain countries for use in clinical trials or for commercial sale even if we receive applicable marketing approvals.

Moreover, public perception and awareness of T cell therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of programmed T cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Our future success is highly dependent on the regulatory approval of our current clinical-stage programmed T cell product candidates and our preclinical programs. All of our product candidates will require significant clinical or preclinical testing before we can seek regulatory approval for and launch a product commercially.

We do not have any products that have gained regulatory approval. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our programmed T cell product candidates. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates in countries outside of the United States without obtaining regulatory approval from comparable regulatory authorities in relevant jurisdictions, such as the European Commission in the EU (granted on the basis of a positive opinion from the CHMP of the EMA). Additionally, to file for licensure in any jurisdiction outside of the UK we must first receive GMP certification from the MHRA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, if approved, we must demonstrate with substantial evidence gathered in preclinical and clinical studies, that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate. The obe-cel Regenerative Medicine Advanced Therapy ("RMAT") designation was submitted to FDA in February 2022 and was granted in April 2022. Similarly, in the UK, Autolus utilized the MHRA Innovative Licensing and Access Pathway ("ILAP") and applied for 'Innovative Passport' designation ("Innovation Passport") which aims to accelerate the timeline to regulatory approval. The UK ILAP designation in r/r adult B-ALL was granted in June 2021. Additionally, EMA PRIME designation in r/r B-ALL was obtained in March 2021. Moreover, Orphan Designation in B-ALL was granted by the FDA in November 2019 and by the European Commission in March 2022. To date, we have had only limited interaction with the FDA, MHRA, the EMA and the European Commission, regarding our product candidates. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA, MHRA, the EMA and other regulatory authorities regarding the design of our clinical trials and the type and amount of clinical data necessary to seek and gain approval for our product candidates.

The time required to obtain approval by the FDA, MHRA, the European Commission and other regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA, MHRA, the European Commission or other regulatory authorities and, consequently, fail to achieve suitable commercial success for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or our facilities;
- failure to receive timely handover of our planned commercial launch facility to enable on-time completion of all operational qualification activities;
- failure to achieve timely acceptance of Technical Transfer and Performance Qualification of our commercial manufacturing facility;
- augmentation of the requirements to satisfy facility qualification or licensure submission by the regulating authorities, thus delaying time to submission and licensure of;

- failure to achieve a competitive value proposition in terms of product release specifications and our vein-to-vein delivery time;
- failure to achieve approval of state of the art in-process and release assays critical to optimizing intent to treat and achieving a competitive vein to vein time;
- failure to have adequate funding to sustain the full complement of staff required to facilitate targeted product launch volumes;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

The FDA, the EMA or the European Commission, or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we change our manufacturing processes or manufacturing facilities, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications) or for different indications from those obtained in other territories, may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Furthermore, the indication granted by health authorities may vary from region to region, which may impair our commercialization plans. Finally, even with licensures in the relevant regions we initially do not have production redundancy. Due to this, we are at higher risk of supply disruptions to regional factors that could impair our supply chains. Examples of this include an expanded conflict in Eastern Europe and severe volcanic activity in Iceland, either of which has the potential to disrupt international air traffic for weeks.

Even if a product candidate were to successfully obtain approval from the FDA, the European Commission or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn. See the risk factor titled "—Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate."

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to use our expertise in tumor biology and cell programming and our proprietary and modular T cell programming technologies to develop what we believe are safer and more effective T cell therapies. Our initial focus is on the development of a pipeline of product candidates for the treatment of hematological cancers and the progression of these product candidates through clinical development. We also intend to develop follow-on, or next-generation, product candidates with additional elements of programming built into the programmed T cell product candidate to offer enhanced characteristics as compared to the earlier product generation, such as pharmacological control or insensitivity to checkpoint inhibition. However, we may not be able to develop product candidates that are safe and effective, or which compare favorably with our existing product candidates.

Even if we are successful in continuing to build our pipeline and developing next-generation product candidates or expanding into solid tumor indications or autoimmune diseases, the potential product candidates that we identify may not be suitable for clinical development, including as a result of lack of safety, lack of tolerability, lack of anti-tumor activity, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our ADSs.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or to commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Many of our product candidates are in the preclinical development stage. The risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on IND applications in effect in the United States and clinical trial applications ("CTAs") in the EU and other European countries. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the competent authorities of EU Member States or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA, the competent authorities of EU Member States or other regulatory authorities allowing clinical trials to begin.

Clinical trials are difficult to design and implement, involve uncertain outcomes and may not be successful.

Human clinical trials are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for biologic products proceeding through clinical trials, which may be higher for our product candidates because they are based on new technology and engineered on a patient-by-patient basis. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.

Results from preclinical studies are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. For example, we have treated only a small number of patients in some of our ongoing clinical trials. For that reason, we do not know whether these candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. This failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates.

We depend on enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size and nature of the patient population required for analysis of the trial's primary and secondary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving T cell-based immunotherapy;
- our ability to obtain and maintain patient consents;

- disruptions to healthcare systems caused by global disease pandemics;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment; and
- other public health factors.

In particular, some of our clinical trials will look to enroll patients with characteristics which are found in a very small population. For example, our clinical trial for AUTO4 seeks to enroll patients with peripheral T cell lymphoma, a rare and heterogeneous form of non-Hodgkin lymphoma ("NHL"). Other companies are conducting clinical trials with their redirected T cell therapies in multiple myeloma, pediatric or adult relapsed or refractory acute B lymphoblastic leukemia ("B-ALL"), or pediatric or adult ALL, and relapsed or refractory DLBCL, relapsed or refractory MCL and seek to enroll patients in their studies that may otherwise be eligible for our clinical trials, which could lead to slow recruitment and delays in our clinical programs. In addition, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites.

Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment and autoimmune diseases, potential study participants and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than participate in our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect.

For instance, cancer therapies are sometimes characterized as first line, second line or later lines, and the FDA often approves new therapies initially only for later line use. When blood cancers are detected, they are treated with the first line of therapy with the intention of curing the cancer. This generally consists of chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. In addition, sometimes a bone marrow transplantation can be added to the first line therapy after the combination chemotherapy is given. If the patient's cancer relapses, e.g. a B-cell malignancy, then they are given salvage therapies which can consist of more chemotherapy, radiation, CAR T cell products, antibody drug conjugates, tumor-targeted small molecules, or a combination of these, or a bone marrow transplant. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy in the treatment of lymphoma and myeloma is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations.

We are currently developing obe-cel for treatment of relapsed / refractory adult patients with B-ALL. As a next step, obe-cel could be developed in newly diagnosed patients with B-ALL as a consolidation strategy in first complete remission in order to replace or avoid allogeneic transplantation. AUTO4 is currently being developed as a treatment option for relapsed / refractory TRBC1-positive T cell lymphoma patients. If AUTO4 is eventually approved as a second line therapy, we may seek to initiate a trial to position it as a consolidation therapy after first line chemotherapy in T cell lymphoma. There is no guarantee that any of our product candidates, even if approved in later lines, would be approved for an earlier line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers.

The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, in our clinical trial for AUTO4, we are initially targeting a small patient population that suffers from peripheral T cell lymphoma, a rare and heterogeneous form of NHL. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenues without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following any potential marketing approval.

In clinical trials conducted by other companies involving CAR T cells, the most prominent acute toxicities included symptoms thought to be associated with CRS, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, or neurotoxicity, such as confusion, tremor, cranial nerve dysfunction, seizures and speech impairment. CAR T cell associated neurotoxicity is also known as ICANS. Adverse events with the worst grades and attributed to CAR T cells were severe and life threatening in some patients. The life-threatening events were related to cardiac dysfunction, kidney dysfunction and neurotoxicity. Severe and life-threatening toxicities occurred mostly in the first two weeks after cell infusion and generally resolved within three - four weeks, but several patients died in clinical trials involving CAR T cells developed by other companies and academic institutions. For example, at the ASH Annual Meeting in December 2023 we presented safety data from a pooled analysis of 127 patients treated in the FELIX trial, where we observed that 2% of patients, had equal to or greater than Grade 3 CRS and that 7% of patients, had equal to or greater than Grade 3 ICANS. In addition, the FDA recently announced a requirement that approved BCMA-directed or CD19-directed autologous CAR T cell immunotherapies carry a boxed warning in their labeling for the risk of developing secondary T cell malignancies.

There can be no assurance that patients in ongoing or future trials of obe-cel, AUTO4 or any of our other product candidates will not experience more severe CRS, unacceptable levels of neurotoxicity or other serious adverse events.

Our clinical trials include cancer patients who are very sick and whose health is deteriorating, and we expect that additional clinical trials of our other product candidates will include similar patients with deteriorating health. It is possible that some of these patients may experience similar adverse side effects as were observed in clinical trials conducted by other companies and academic institutions involving CAR T cells, and that additional patients may die during our clinical trials for various reasons, including as a result of receiving our product candidates, because the patient's disease is too advanced, or because the patient experiences medical problems that may not be related to our product candidate. Even if the deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidate.

Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our therapeutic candidates, could result in the delay, suspension, clinical hold or termination of clinical trials by us, the FDA, the competent authorities of EU Member States or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA and the European Commission or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA, the European Commission or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict accurately when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. The potential label for the same product may differ in different territories based on the approval by different health authorities. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA, the EMA, the European Commission or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical development of our product candidates may be greater than we anticipate;
- the FDA, the competent authorities of EU Member States or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, particularly given their novel, first-in-human application, such as cytokine-induced toxicity and T cell aplasia, causing us or our investigators, regulators or IRBs to suspend or terminate the clinical trials; and
- the approval policies and related requirements of the FDA, the EMA of the European Commission, or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA, the EMA, the European Commission, or regulatory authorities in other countries or jurisdiction to approve our BLA, MAA, or other comparable application, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We may not be able to successfully create our own manufacturing infrastructure for supply of our, or our current or future collaborators', requirements of programmed T cell product candidates for use in clinical trials and for commercial sale.

Our manufacturing and commercialization strategy is based on establishing a fully integrated vein-to-vein product delivery cycle. We have constructed and use a new facility (which we call "The Nucleus") in Stevenage, UK which we believe will support our clinical manufacturing capacity and potential commercial manufacturing needs. Although we have received approval and licensure from health authorities to enter into operations at this facility, we may not be able to maintain ongoing licensure requirements. At present, we currently also use facilities and equipment at the Cell and Gene Therapy Catapult, as well as third party vendors, for vector and cell manufacturing. Over time we can add additional manufacturing sites in the United States and in Europe as needed. The implementation of this plan is subject to many risks. For example, the establishment of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals. Creating an internal manufacturing infrastructure will rely upon finding personnel with an appropriate background and training to staff and operate the facility. Should we be unable to find these individuals, we may need to rely on external contractors or train additional personnel to fill the needed roles. There are a small number of individuals with experience in cell therapy and the competition for these individuals is high.

We expect that the establishment of our own commercial cell manufacturing facilities will provide us with enhanced control of product supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term cost margins. However, we have limited experience as a company in designing and operating a commercial cell therapy or vector manufacturing facility and may never be successful in developing our own manufacturing facility or capability. We may establish additional manufacturing sites as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing operations could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors, or we may not be successful in establishing sufficient capacity to produce our product candidates in sufficient quantities to meet the requirements for the potential launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

We may not be successful in achieving cost of goods at commercial scale that provide for an attractive margin.

We believe that our current, enclosed manufacturing processes are fit for commercial scale and we anticipate they will enable commercial supply at an economical cost. However, we have not yet established manufacturing capacity at commercial scale and may underestimate the cost and time required to do so, or overestimate cost reductions from economies of scale that can be realized with our manufacturing processes. We may ultimately be unable to manage the cost of goods for our product candidates to levels that will allow for a margin in line with our expectations and return on investment if and when those product candidates are commercialized.

Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped.

We have developed a process for manufacturing programmed T cells in a fully enclosed system designed to minimize the risk of contamination, and we have improved the viral transduction process to help eliminate processing inconsistencies. We believe that our current processes are suitable for commercialization. While we have established a process which we believe is scalable for commercial production, each manufacturing process must be validated through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. We have not yet manufactured or processed our product candidates on a commercial scale and may not be able to do so for any of our product candidates.

We, like other manufacturers of biologic products, may encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process. These problems include delays or break-downs in logistics and shipping, difficulties with production costs and yields, quality control, and product testing, operator error, lack of availability of qualified personnel, as well as failure to comply with strictly enforced federal, state and foreign regulations, which are updated regularly.

Furthermore, if microbial, viral or other contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any of these or other issues relating to the manufacture of our product candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

The manufacture and delivery of programmed T cell therapies to patients involves complex, integrated processes, including harvesting T cells from patients, programming the T cells *ex vivo*, multiplying the T cells to obtain the desired dose, and ultimately infusing the T cells back into a patient's body. As a result of the complexities, the cost to manufacture biologics in general, and our programmed T cell product candidates in particular, is higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult and costly to reproduce. In addition, our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of white blood cells from the patient, shipping such patient material to the manufacturing site, storing and processing such patient material, shipping the patient material with the programmed T cells back to the patient, and infusing the patient with the final product. Other manufacturing issues include the differences in patient starting materials, inconsistency in cell growth, variability in product characteristics, interruptions in the manufacturing process, equipment or reagent failure, improper installation or operation of equipment, and vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. For example, in the FELIX clinical trial of obe-cel reported at the ASH Annual Meeting in December 2023, 7 patients out of the 153 patients enrolled on to the clinical trial did not receive an infusion of obe-cel due to manufacturing related reasons. If we lose, destroy or otherwise impair the patient materials at any point in the vein-to-vein supply chain, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome due to the risk of disease progression.

In addition, because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Our manufacturing facilities also require commissioning and validation activities to demonstrate that they operate as designed, and are subject to government inspections by the FDA, the MHRA, the competent authorities of EU Member States and other comparable regulatory authorities. If we are unable to reliably produce products to specifications acceptable to the regulatory authorities, we may not obtain or maintain the approvals we need to manufacture our products. Further, our facilities may fail to pass government inspections prior to or after the commercial launch of our product candidates, which would cause significant delays and additional costs required to remediate any deficiencies identified by the regulatory authorities. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Prior treatments can alter the patient's disease and negatively impact chances for achieving clinical activity with our programmed T cells.

Patients with hematological cancers receive highly toxic lympho-depleting chemotherapy as their initial treatments. These therapies can impact the viability of the T cells collected from the patient and can contribute to highly variable responses to programmed T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended programmed T cell product candidate and thereby lead to a selection of cancer cells with low or no expression of the target. As a result, our programmed T cell product candidates may not recognize the cancer cell and may fail to achieve clinical activity. Our most advanced product candidate, obe-cel, may face this challenge. For example, ALL patients could have received currently approved therapies such as Blincyto or Kymriah or Tecartus, or a CD19 ADC, or a CD22 targeting CAR T, or CD22 ADC, like Besponsa, or similar products or product candidates prior to receiving obe-cel. Similarly, patients with autoimmune diseases receive multiple types of treatment including toxic lympho-depleting chemotherapies, these may also have an impact of the viability of T cells collected from a patient and may also contribute to highly variable responses to programmed T cell therapies. If any of our product candidates do not achieve a sufficient level of clinical activity, we may discontinue the development of that product candidate, which could have an adverse effect on the value of our ADSs.

We may expend our resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We plan to seek, but may fail to obtain breakthrough therapy designation or RMAT designation from the FDA and PRIME designation from the EMA, and may pursue accelerated approval for some or all of our programmed T cell product candidates, which may prolong the regulatory approval process for our product candidates.

In 2012, the FDA established a breakthrough therapy designation which is intended to expedite the development and review of product candidates 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 product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; 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. The frequency of communication from the FDA is intended to allow for questions and issues to be resolved quickly, which often leads to earlier drug approval and access by patients.

RMAT was introduced as a new designation under the 21st Century Cures Act for the development and review of certain regenerative medicine therapies. To receive RMAT designation, a regenerative medicine product candidate must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition with preliminary clinical evidence indicating that the drug has the potential to address unmet medical need. RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over available therapies, as breakthrough designation requires. In February 2019, the FDA released guidance that clarified that gene therapies, including genetically modified cells, that lead to a durable modification of cells or tissues, may meet the definition of a regenerative medicine therapy for RMAT designation.

Similar to breakthrough designation, an RMAT product candidate receives: intensive guidance on an efficient drug development program; intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and a rolling review. Regenerative medicine therapies that qualify for RMAT designation may also qualify for other FDA expedited programs, if they meet the criteria for such programs.

Similarly, the EMA has established the PRIME scheme to expedite the development and review of product candidates that show a potential to address to a significant extent an unmet medical need, based on early clinical data. Likewise, the MHRA has established the ILAP scheme to expedite the development and review of product candidates that show a potential to address to a significant extent an unmet medical need, based on early clinical data.

We intend to seek breakthrough therapy designation, RMAT designation, ILAP or PRIME designation for some or all of our programmed T cell product candidates that may qualify. There is no assurance that we will obtain breakthrough therapy designation or RMAT designation, or that we will obtain access to PRIME or ILAP for any of our product candidates.

Breakthrough therapy designation, RMAT designation ILAP and PRIME eligibility do not change the standards for product approval, and there is no assurance that such designation or eligibility will result in expedited review or approval. Additionally, breakthrough therapy designation, RMAT designation and access to PRIME or ILAP can each be revoked if the criteria for eligibility cease to be met as clinical data emerges.

We may also seek accelerated approval for certain of our product candidates. 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 indication approved under the accelerated approval pathway if, for example:

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

Risks Related to Our Business Operations

As a company based outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business outside of the United States, as our company is based in the UK and conducts operations internationally. Many of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the pound sterling, U.S. dollar, euro and currency controls;
- changes in a specific country's or region's political or economic environment, including the implications of the UK's withdrawal from the EU;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our share option schemes or equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters, including earthquakes, typhoons, floods and fires, or health epidemics, such as the coronavirus pandemic.

The United Kingdom's withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our ordinary shares.

Following Brexit, the UK and the EU signed an EU-UK Trade and Cooperation Agreement ("TCA"), which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards however there are still uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a "third country," a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland continues to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

As it relates to marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU Member States no longer encompasses Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market in Great Britain. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission.

On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so-called "Windsor Framework". The Framework is intended to revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. If the changes are adopted in the form proposed, medicinal products to be placed on the market in the UK will be authorized solely in accordance with UK laws. Northern Ireland would be reintegrated back into a UK-only regulatory environment under the authority of the MHRA with respect to all medicinal products. The implementation of the Windsor Framework would occur in stages, with new arrangements relating to the supply of medicinal products into Northern Ireland anticipated to take effect in 2025.

A significant proportion of the regulatory framework in the UK applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for UK legislation to diverge from EU legislation following Brexit could materially impact the regulatory regime with respect to the development, manufacture, import, approval, and commercialization of our product candidates in the UK or the EU. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Our functional currency and that of our subsidiaries is the pound sterling, the U.S. dollar, the euro and Swiss franc and our reporting currency is the U.S. dollar. Given that our functional currency and that of our subsidiaries differ from our reporting currency, fluctuations in currency exchange rates between the U.S. dollar and the functional currencies of our subsidiaries could materially and adversely affect our business. There may be instances in which costs and revenue will not be matched with respect to currency denomination. Currently, we do not have any exchange rate hedging arrangements in place.

Additionally, although we are based in the UK, we source research and development, manufacturing, consulting and other services from the United States and other countries. Further, potential future revenue may be derived from the United States, countries within the euro zone, and various other countries around the world. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the euro, swiss franc, and other currencies, which may have a significant impact on our results of operations and cash flows from period to period. As a result, to the extent we continue our expansion on a global basis, we expect that increasing portions of our revenue, cost of revenue, assets and liabilities will be subject to fluctuations in currency valuations. We may experience economic loss and a negative impact on earnings or net assets solely as a result of currency exchange rate fluctuations.

We will need to manage the size of our organization, and we may experience difficulties.

As of December 31, 2023, we had 471 employees, 463 of whom are full-time. As our development and commercialization plans and strategies develop, and as we further develop as a public company, we may need additional managerial, operational, financial and other personnel, including personnel to support our product development and commercialization efforts. 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, FDA and EMA review processes for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in cell therapy and the competition for these individuals is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and 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 these growth activities.

If we are not able to effectively manage the size of our organization, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

In addition to expanding our organization, we are building out our development and manufacturing capabilities, which requires significant capital expenditures. If these capital expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the availability of manufacturing capacity is delayed, it may limit our ability to rapidly expand the size of our organization in order to meet our corporate goals.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. We are highly dependent on our management, scientific and medical personnel. Each member of our senior management may terminate their employment with us at any time. We do not maintain ‘‘key person’’ insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. 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, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may also evaluate various acquisitions and strategic collaborations, including collaborating with respect to our product candidates, or licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration, such as the Blackstone Collaboration Agreement and the BioNTech License Agreement, may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- negative covenants that may affect our ability to develop and commercialize our product candidates;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials and sensitive third-party data (collectively, sensitive data). As a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence ("AI"), telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations (including our clinical trial activities), ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party research collaborators, CROs, contract manufacturers, and suppliers for many aspects of our business, including research and development in connection with our clinical trial activities. Our reliance on such third-party service providers, technologies and collaborators could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, be able to detect and remediate all such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon which we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon which we rely) to provide our products and services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon which we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including in connection with our clinical trial activities); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our products and services, deter new customers from using our products and services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We maintain cybersecurity insurance coverage for claims related to cyber crime (up to £250,000 per occurrence) and other cybersecurity incidents (up to £6,000,000 per occurrence). However, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, and data we collect about trial participants in connection with clinical trials. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

An increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU GDPR and the UK GDPR impose strict requirements for processing personal data. Under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, the processing of "special category personal data", such as health information, may also impose heightened compliance burdens under the EU GDPR and the UK GDPR and is a topic of active interest among relevant regulators.

The EU GDPR provides that European Economic Area ("EEA") Member States may make their own further laws and regulations to introduce specific requirements related to the processing of "special categories of personal data", including personal data related to health.

This fact may lead to greater divergence on the law that applies to the processing of such data types across the EEA and/or UK, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such country-specific regulations could also limit our ability to collect, use and share data in the context of our EEA and/or UK operations, and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA, the UK, and Switzerland have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA, the UK, and Switzerland to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, the Swiss-U.S. Data Privacy Framework (once officially recognized as a valid data transfer mechanism by the Swiss government), and the EU-U.S. Data Privacy Framework and the UK Extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, Switzerland, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by the HITECH, imposes specific requirements relating to the privacy, security and transmission of protected health information. Additionally, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive data, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example the CCPA provides fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages.

Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these state laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

In addition to data privacy and security laws, we are subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies, marketing materials, and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties upon whom we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Business disruptions, including those caused by the ongoing geopolitical conflicts, could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our vendors and suppliers, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters, geopolitical conflict or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

The global economy has experienced volatility and disruptions from the impacts of the international conflicts, terrorism and other geopolitical events, including the ongoing war in Ukraine and the current Israel-Hamas conflict in Gaza. Although the length and impact of the ongoing military conflict is highly unpredictable, the war in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which contributed to record inflation globally. In addition, global markets may experience additional disruptions as a result of the current Israel-Hamas conflict, with Israel having declared war on Hamas, a U.S. designated Foreign Terrorist Organization, due to recent attacks. Although, to date, our business has not been materially impacted by the events described above, it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of the conflicts in Ukraine and Gaza, geopolitical tensions, record inflation and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks we face.

As a public company with operations in the EU, we may be subject to the sustainability disclosure requirements set out in the EU Corporate Sustainability Reporting Directive.

A growing number of investors, regulators, self-regulatory organizations and other stakeholders have expressed an interest in Environmental, Social and Corporate Governance ("ESG") matters, and are requiring more robust ESG disclosures. The related legislative landscape in the EU has been evolving accordingly. For example, EU Directive No 2464/2022 on Corporate Sustainability Reporting ("CSRD") was adopted and entered into force on January 5, 2023, amending the current EU Accounting Directive No 2013/34. The CSRD introduces new mandatory reporting obligations that will require the publication of audited sustainability information. The CSRD is supplemented by EU Delegated Regulation No 2023/2772 which establishes the first set of European Sustainability Reporting Standards ("ESRS"), which are applicable to in-scope EU entities. Further reporting standards are due to be adopted by June 2026, including for in-scope non-EU entities.

The CSRD and ESRS require certain mandatory disclosures, as well as disclosures of certain "material" sustainability matters in the company's own operations, those of their subsidiaries and those of their value chain. The identification of material sustainability matters requires a "double materiality" assessment. This means that in-scope entities will have to assess both financial materiality, which are sustainability matters which generate risks or opportunities that affect, or could reasonably be expected to affect, the company's financial position, financial performance, cash flows, access to finance or cost of capital over the short-, medium- or long-term, and impact materiality, which are the company's material actual or potential, positive or negative impacts on people or the environment over the short-, medium- and long-term.). Sustainability matters are material if they satisfy one or both of these materiality tests.

The CSRD applies to entities with securities admitted to trading on an EU regulated market, as well as large EU companies, EU parents of a "large group", and to listed EU small or medium-sized enterprises, amongst others. It will also apply to non-EU companies that have a certain threshold of EU-generated turnover and an in-scope EU subsidiary or EU branch meeting the turnover thresholds. Companies subject to the CSRD are required to fulfil their reporting obligations in accordance with a staggered timeline depending on the category of company. The first reports are expected in 2025 for the 2024 financial year, predominantly for entities with securities admitted to trading on an EU regulated market, and in 2026 for the 2025 financial year for many other EU companies (including EU subsidiaries of non-EU parents) that are not listed on an EU regulated market but meet the relevant size thresholds.

In response to new ESG initiatives and regulations we may voluntarily elect, or be required, to adopt strategies, policies, or procedures related to ESG matters and report on these. Reporting on ESG goals and objectives may cause us to expend significant capital and human resources, and could divert management's attention from central operational matters. Reports could also lead to the disclosure of information that which may have a negative impact on our operations and reputation which may lead to additional exposure. Failure to accurately comply with any ESG reporting obligations may result in enforcement actions, sanctions, reputational harm or private litigation.

Risks Related to Our Dependence on Third Parties

We are dependent on intellectual property obtained or licensed from third parties, and if we were to fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose intellectual property rights that are important to our business and we may not be able to continue developing or commercializing our product candidates, if approved.

We are party to an exclusive intellectual property license agreement with UCLB, the technology-transfer company of UCL, which is important to our business and under which we have acquired or licensed patent rights related to 17 patent families and other intellectual property related to our business. We expect to enter into additional license agreements in the future. Our existing license agreement with UCLB imposes, and we expect that future license agreements will impose, various due diligence, milestone payment, royalty, insurance and other obligations on us. Any uncured, material breach under the UCLB license agreement could result in our loss of rights to practice the patent rights (including those that have been assigned to us from UCLB) and other intellectual property licensed to us, and could compromise our development and commercialization efforts for our current or any future product candidates.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. For example, under our license agreement with UCLB, our exclusive rights under certain of the patents is subject to specified exclusions. Our right to enforce any patents that may issue from such patent rights similarly excludes enforcing them in such excluded fields, and obligates us to coordinate our enforcement efforts with a third-party licensee, if any, with rights in that excluded field. If a third party-licensee has the right to enforce those patents in their field, it could put a patent that may issue from this family at risk of being invalidated or construed narrowly, in which case we would no longer have the benefit of the patents for our own exclusivity.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our obligations to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us;
- our right to transfer or assign the license; and
- the effects of termination.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. See the section of this Annual Report titled "Business - Our License Agreement with UCL Business Ltd." for a more detailed description of our license agreement with UCLB, as well as our rights and obligations under the agreement.

We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical and clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as GLP and GCP, for conducting, recording and reporting the results of preclinical and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (the "ICH").

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA or comparable foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidates or any future product candidates.

We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored databases, such as ClinicalTrials.gov and foreign equivalents, within specified timeframes. Failure to do so by us or third parties can result in FDA or comparable foreign regulatory authority refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for access to facilities and supply of certain materials and equipment used in the manufacture of our product candidates. For example, we currently use facilities and equipment at the Cell and Gene Therapy Catapult, as well as third party vendors, for vector and cell manufacturing. In addition, we purchase equipment and reagents critical for the manufacture of our product candidates from Miltenyi and other suppliers on a purchase order basis. Some of our suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers, and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may not be able to obtain key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we may need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

We operate a manufacturing facility to manufacture materials for our CAR T product candidates, which requires significant resources. A failure to successfully operate our manufacturing facility could lead to substantial delays and adversely affect our research and development efforts, including clinical trials, and the future commercial viability, if approved, of our CAR T product candidates. We are also obligated to share some of the capabilities of the manufacturing facility with BioNTech under the BioNTech License Agreement.

Our clinical and commercial manufacturing facility, The Nucleus, must be periodically inspected and licensed by the appropriate authorities. While we will continue to source raw materials from external CMOs, we plan to make the transition from external CMOs to our manufacturing facility and we expect our manufacturing facility to be the sole source supplier of clinical materials for our clinical trials and for commercial products, once approved. This sole source reliance increases the risk that we will not have sufficient quantities of our CAR T product candidates at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts, if approved.

In addition, under the terms of the BioNTech License Agreement, we granted BioNTech the option to negotiate a joint Manufacturing and Commercial Agreement pursuant to which the parties may access and leverage each other's manufacturing and commercial capabilities, in addition to Autolus' commercial site network and infrastructure, with respect to certain of each parties' CAR T products, including BioNTech's product candidate BNT211 (the "Manufacturing and Commercial Agreement"). The Manufacturing and Commercial Agreement, if entered into, would also grant BioNTech access to our commercial site network and infrastructure. If required under the Manufacturing and Commercial Agreement, we may need to subordinate production of our CAR T products in order to BioNTech's products. Sharing The Nucleus facility with BioNTech increases the risk that we will not have sufficient quantities of our CAR T product candidates at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts, if approved.

In either case, if we are unable to manufacture sufficient clinical or commercial materials at our manufacturing facility, we may be forced to contract with external CMOs, which we may not be able to do on commercially reasonable terms, if at all. Even if commercially reasonable terms are available, any transition of manufacturing from our manufacturing facility to an external CMO could be time-consuming and require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our CAR T product candidates may be unique or proprietary and we may have difficulty transferring such skills or technology to another CMO and a feasible alternative may not exist. If we fail to manufacture at our manufacturing facility, or obtain from a CMO, a sufficient supply of clinical materials for our clinical trials in accordance with applicable specifications on a timely basis, our research and development efforts, including clinical trials, the future commercial viability, if approved, of our CAR T product candidates, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

We collaborate with third parties in the research, development and commercialization of certain of our product candidates. If our collaborators do not perform as expected or if we are unable to maintain existing or establish additional collaborations, our ability to develop and commercialize our product candidates may be adversely affected.

We have collaboration and license agreements with, for example, BioNTech SE, Cabaletta Bio Inc., Moderna Inc., Bristol-Myers Squibb Company, and investee of Syncona Portfolio Limited. These agreements provide us with important funding for our programs. If our therapeutic programs and related collaborations do not result in the successful development and commercialization of products or if one of our collaborators or licensees terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments associated with such collaboration or license arrangement. In addition, any termination of an agreement by the relevant collaborators could affect our ability to develop further such product candidates or adversely affect how we are perceived in scientific and financial communities. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our program collaborators.

In our collaboration arrangements, we depend on the performance of our collaborators. Our licensees have the right to make decisions regarding the development and commercialization of product candidates under the collaborations without consulting us and may make decisions with which we do not agree. Our collaborators may fail to perform their obligations under the collaboration agreements or may not perform their obligations in a timely manner. If conflicts arise between our collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Furthermore, our collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. In addition, we cannot control the amount and timing of resources our collaborators may devote to our product candidates. They may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Even if our collaborators continue their contributions to the strategic collaborations, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Additionally, if our collaborators pursue different clinical or regulatory strategies with their product candidates based on similar technology as used in our product candidates, adverse events with their product candidates could negatively affect our product candidates. Any of these developments could harm our product development efforts.

If our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. Furthermore, if our collaborators do not prioritize and commit sufficient resources to our product candidates, we or our partners may be unable to develop or commercialize these product candidates, which would limit our ability to generate revenue and become profitable.

We do not and will not have access to all information regarding the product candidates we license to our collaboration partners. Consequently, our ability to inform our shareholders about the status of such product candidates, and to make informed operational and investment decisions about the product candidates to which we have retained development and commercialization rights, may be limited.

We do not and will not have access to all information regarding the product candidates being developed and potentially commercialized by BioNTech, including potentially material information about clinical trial design and execution, regulatory affairs, process development, manufacturing, marketing and other areas known by BioNTech. In addition, we have confidentiality obligations under our agreement with BioNTech. Thus, our ability to keep our shareholders informed about the status of product candidates under our collaboration will be limited by the degree to which BioNTech keeps us informed and allows us to disclose such information to the public.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Additionally, although we intend to develop product candidates through our own internal research, we may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership regardless of the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, the EU and other comparable regulatory authorities in other jurisdictions. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third-party CROs, to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and efficacy.

Securing marketing approval also requires the submission of information about the product manufacturing process demonstrating the products quality to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or the European Commission or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, 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. Regulatory authorities have discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies including further manufacturing process or quality control data. In addition, varying interpretations of the data obtained from manufacturing procedures, quality control, preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be impaired.

In order to market and sell our products in the EU and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all.

Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but 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 product candidate, comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional manufacturing quality controls, or additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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 products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, pharmacovigilance oversight, storage, advertising, promotion, sampling, and recordkeeping, including the potential requirements to implement a REMS program in the United States or comparable foreign strategies, or similar schemes in other countries, or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs 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 products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive regulatory requirements of the FDA, the EU and national competent authorities of EU Member States and other regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP and other comparable regulations and standards, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We or our suppliers could be subject to periodic unannounced inspections by the FDA, the competent authorities of EU Member States, or other regulatory authorities to monitor and ensure compliance with cGMP. Failure to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if approved, and significantly harm our business, financial condition, results of operations and prospects.

Accordingly, if we receive marketing approval for one or more of our product candidates, we and suppliers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

The FDA and other federal and state agencies, including the U.S. Department of Justice ("DOJ"), closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of products in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Similar legislation or provisions may also apply in other jurisdictions. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, or if other of our marketing claims are deemed false or misleading, we may be subject to enforcement action. Physicians, on the other hand, may prescribe products for off-label uses. The FDA and other regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment. However, companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the U.S. federal False Claims Act and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Similar legislation or provisions may also apply in other jurisdictions. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled 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 revenues;
- suspension, variation or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties and reputational damage. Similarly, failure to comply with regulatory requirements regarding the protection of personal data can also lead to significant penalties and sanctions.

Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal data can also lead to significant penalties and sanctions.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners, and vendors, could include failures to comply with regulations of the FDA, the EU, EU Member States and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct.

It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, National Health Service in the UK, or other government supported healthcare in other jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval, and foreign equivalents. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the U.S. federal government and by the states and foreign jurisdictions in which we conduct our business.

The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term ‘‘remuneration’’ has been broadly interpreted to include anything of value. 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 hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the U.S. federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the U.S. federal Anti-Kickback Statute has been violated;
- U.S. federal civil and criminal false claims laws, including the U.S. federal False Claims Act, which can be enforced though civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, 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. Further, pharmaceutical manufacturers can be held liable under the U.S. federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims;
- HIPAA, which created new federal criminal statutes that prohibit 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 of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Additionally, HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal Physician Payments Sunshine Act, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “ACA”), and its implementing regulations, created annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions), to annually report to the CMS, information related to certain payments and “transfers of value” provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous state laws and regulations and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign 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; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the data privacy and security of certain protected information, such as the EU GDPR and UK GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU and UK (including health data).

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Further, the ACA, among other things, amended the intent requirement of the U.S. federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. federal False Claims Act.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that our business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of significant investigations, prosecutions, convictions and settlements in the healthcare industry.

Efforts to ensure that our internal operations and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

Our product candidates are subject to government price controls in certain jurisdictions that may affect our revenue.

There has been heightened governmental scrutiny in the UK, United States, EU and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in the United States, at the federal level in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, on August 16, 2022, President Biden signed the IRA, into law, which among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Outside of the United States, particularly in the UK and EU, the pricing of prescription pharmaceuticals is subject to governmental control by individual EU Member States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In the EU, EU Member States may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Current and future legislation in the United States and other countries may affect the prices we may obtain for our product candidates and increase the difficulty and cost for us to commercialize our product candidates.

In the United States and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which has resulted in a number of changes to laws and regulations, and may result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, the ACA was enacted in the United States in March 2010 with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare, and includes measures to change healthcare delivery, increase the number of individuals with insurance, ensure access to certain basic healthcare services, and contain the rising cost of care. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how additional changes, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other federal health reform measures have been proposed and adopted in the United States. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year until 2032 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program ("Quality Payment Program"), under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. The Quality Payment Program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models ("APMs"), and the Merit-based Incentive Payment System ("MIPS"). Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

The combination of healthcare cost containment measures, increased health insurance costs, reduction of the number of people with health insurance coverage, as well as future legislation and regulations focused on reducing healthcare costs by reducing the cost of or reimbursement and access to pharmaceutical products, may limit or delay our ability to generate revenue, attain profitability, or commercialize our products.

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. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR provides a three-year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials in relation to which an application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

We are subject to the U.K. Bribery Act, the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the UK Bribery Act, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The UK Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls.

Under the UK Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We and those acting on our behalf operate in a number of jurisdictions that pose a high risk of potential UK Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the UK Bribery Act, FCPA or local anticorruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. 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.

Compliance with the UK Bribery Act, the FCPA and these other laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, anti-corruption laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

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

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the UK Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the UK 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 UK Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United States, UK or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. Further, the failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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

Although we maintain insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We have identified a material weakness in our internal control over financial reporting. If our remediation of the material weakness is not effective or if we fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial information or comply with Section 404 of the Sarbanes-Oxley Act of 2002 could be impaired, which could have a material adverse effect on our business and the trading price of our ADSs.

As a public company, we are subject to the reporting requirements of the Exchange Act, as well as the requirements of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), and the listing standards of the Nasdaq Stock Market.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. It also requires management to perform an annual assessment of the effectiveness of our internal control over financial reporting and disclosure of any material weaknesses in such controls. In connection with the audit of our financial statements for the year ended December 31, 2023, we have identified a material weakness in our internal control over financial reporting in connection with the historic misinterpretation and application of ASC 740 - *Income Taxes*, resulting in our UK small and medium enterprise (SME) tax credits being incorrectly presented in income tax benefit (expense). Refer to Note 3, Restatement of Previously Issued Consolidated Financial Statements, in the Consolidated Financial Statements in Part II, Item 8 of this report for additional information.

Any failure to remediate the identified material weakness, or to develop or maintain effective controls, or any difficulties encountered in the implementation or improvement of such controls, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods, such as the restatement of our previously issued consolidated financial statements described in more detail in this Annual Report on Form 10-K.

Any failure to remediate the identified material weakness, or to implement and maintain effective internal control over financial reporting also could adversely affect the results of management evaluations and, to the extent they are required in the future, attestations of our independent registered public accounting firm with respect to our internal control over financial reporting. We can provide no assurance that the measures we are taking and plan to take in the future will remediate the material weakness identified in connection with the restatement described in this report, or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements. We continue to evaluate steps to remediate the material weakness. Any failure to maintain effective internal control over financial reporting could adversely impact our ability to report our financial position and results from operations on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the Nasdaq, the SEC or other regulatory authorities, or other potential claims or litigation. Ineffective internal control over financial reporting could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs.

Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which may have a negative effect on the trading price of our ADSs. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Select Market.

Risks Related to the Commercialization of Our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

We currently plan to build our global commercialization capabilities internally so we are able to commercialize obe-cel or any other product candidate, subject to obtaining regulatory approval. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to build a sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, in any territory, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenues and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or elsewhere.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations.

Due to their promising clinical therapeutic effect in clinical exploratory trials, engineered T cell therapies, redirected T cell therapies in general and antibody-drug conjugates are being pursued by multiple biotechnology and pharmaceutical companies, including Novartis AG ("Novartis"), Gilead Sciences, Inc. ("Gilead"), Bristol-Myers Squibb ("BMS"), Janssen Biotech Inc., Bluebird bio, Inc. ("Bluebird bio"), Roche Holding AG, Seattle Genetics, and Amgen Inc. Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates non-competitive and obsolete.

We are developing our lead program, obe-cel, a CD19-targeting programmed T cell product candidate for the treatment of adult ALL. Novartis, Gilead and BMS have received marketing approval for anti-CD19 CAR T cell therapies. Gilead's therapy was approved for the treatment of adult ALL in October 2021. Obe-cel is expected to compete directly with these companies and therapies. In addition, some companies, such as Cellectis, Inc., Les Laboratoires Servier SAS and Allogene Therapeutics Inc., are pursuing allogenic T cell products that could compete with our programmed T cell product candidates.

Novartis, Gilead and BMS may be successful in establishing a strong market position for their CD19-targeted CAR T cell products, and we may not be able to compete effectively against these therapies once they have been established.

In addition, our competitors with development-stage programs may obtain marketing approval from the FDA, the European Commission or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors.

These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA, European Commission or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA, the European Commission or other comparable regulatory authorities and are able to initiate commercialization of our clinical-stage product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. FDA's investigation into secondary malignancies associated with CAR T cell therapies and other similar actions could result in increased government regulation, unfavorable public perception and publicity, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement, and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, 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 our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

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

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective.

Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop.

Additionally, we are developing a proprietary diagnostic test for use with certain of our product candidates. We will be required to obtain coverage and reimbursement for this test separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. There is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for this proprietary diagnostic test for reasons similar to those applicable to our product candidates.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold £10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of £10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. 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.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our T cell programming technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States, the EU, the UK and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications related to our technology and product candidates in the major pharmaceutical markets, including the United States, major countries in Europe and Japan. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary positions, we file patent applications in the United States and other countries related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

Prosecution of our owned and in-licensed patent portfolio is at an early stage for some of our patent families. We currently have 39 patents that have been issued from our pending applications in the United States, and 16 patents that have been issued from our pending applications in Europe. Some of our patent portfolio consists of pending priority applications that are not examined and pending applications under the Patent Cooperation Treaty ("PCT").

Neither priority applications nor PCT applications can themselves give rise to issued patents. Rather, protection for the inventions disclosed in these applications must be further pursued by applicable deadlines via applications that are subject to examination. As applicable deadlines for the priority and PCT applications become due, we will need to decide whether and in which countries or jurisdictions to pursue patent protection for the various inventions claimed in these applications, and we will only have the opportunity to pursue and obtain patents in those jurisdictions where we pursue protection.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could threaten our ability to commercialize our product candidates. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the protections offered by laws of different countries vary. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation.

As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, whether owned or in-licensed, are highly uncertain. Furthermore, recent changes in patent laws in the United States, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening 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 U.S. federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Similarly, should we own or in-license any patents or patent applications in the future, we may not be certain that we or the applicable licensor were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could significantly harm our business and results of operations.

Our pending and future patent applications, whether owned or in-licensed, may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents, should they issue, by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary and modular T cell programming technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including in the area of programmed T cell therapies and including patents held by our competitors. If any third-party patents cover our product candidates or technologies, we may not be free to manufacture or commercialize our product candidates as planned.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights and claims may also come from competitors against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization. There are and may in the future be additional third-party patents or patent applications with claims to, for example, materials, compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of any one or more of our product candidates. For example, we are aware of third-party U.S. patents that claim technology related to obe-cel. These U.S. patents will expire between 2023 and 2025, and there are no counterpart patents in Europe or the rest of the world that extend beyond the earliest expected regulatory approval date of obe-cel. If regulatory approval is received for obe-cel, unless we are able to obtain a license or licenses to the third-party U.S. patent or patents on commercially reasonable terms or any applicable patent or patents are invalidated, held to be unenforceable, or deemed uninfringed by our activities. As a result, the future commercial opportunity of obe-cel in the United States could be adversely impacted.

Moreover, we may fail to identify relevant third party patents or patent applications, or we may incorrectly conclude that the claims of an issued patent are invalid or are not infringed by our activities. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that any of our product candidates may infringe, or which such third parties claim are infringed by our technologies.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required or may choose to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if successful, the defense of any claim of infringement or misappropriation is time-consuming, expensive and diverts the attention of our management from our ongoing business operations.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, if issued, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products.

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, and our founder and Chief Scientific Officer, Dr. Martin Pulé, is currently employed both by us and UCL. Although we try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

As of December 31, 2023, our patent portfolio is comprised of 81 patent families, of which 17 patent families originated from UCLB, the technology-transfer company of UCL, 3 patent families are in-licensed from Noile-Immune Biotech, Inc., and 61 patent families we own and have originated from our own research. Of the 17 live patent families that were originally in-licensed from UCL, 16 have been assigned to us. Because we have acquired or licensed certain of our patents from UCLB and licensed certain other patents from third parties, we must rely on their prior practices with regard to the assignment of such intellectual property. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

We may be subject to claims challenging the inventorship or ownership of our owned or in-licensed patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, disputes may arise from conflicting obligations of consultants or others who are involved in developing our technology and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. The owners of intellectual property in-licensed to us could also face such claims. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property.

Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates. For each selected trademark, we will need to apply to register them and our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection 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 pursued and 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 product candidates and preclinical programs 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 biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and patent agencies outside the United States in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents.

If we or our licensors fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in-licensed from a third party, any failure on our part to maintain the in-licensed rights could jeopardize our rights under the relevant license and may expose us to liability.

Risks Related to Ownership of Our Securities and Our Status as a Public Company

The trading price of our ADSs has been and may continue to be highly volatile and may fluctuate due to factors beyond our control.

The trading price of our ADSs continues to be volatile. The stock market in general, and the market for biopharmaceutical and pharmaceutical companies in particular, has 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, including economic conditions and other adverse effects or developments relating to geopolitical instability, may negatively affect the market price of our ADSs, regardless of our actual operating performance.

As a result of this volatility, you may not be able to sell your ADSs at or above the price paid for the ADSs. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Annual Report, the trading price for our ADSs may be influenced by the following:

- the commencement, enrollment or results of our planned or future clinical trials of obe-cel and any other product candidates;
- the clinical or commercial success of competitive drugs, therapies or technologies;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States, UK and other countries;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes to our relationships with collaborators, manufacturers or suppliers;

- concerns regarding the safety of our product candidates or programmed T cells in general;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our ADSs on Nasdaq;
- sales of our ADSs or ordinary shares by us, members of our senior management and directors or our shareholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or the UK;
- price and volume fluctuations of the listed securities comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their ADSs and may otherwise negatively affect the liquidity of our ADSs. In addition, the stock market in general, 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.

Some companies that have experienced volatility in the trading price of their securities have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our ADSs.

Our ADSs are thinly traded and our shareholders may be unable to sell their ADSs quickly or at market price.

Although we have had periods of high volume daily trading in our ADSs, generally our ADSs are thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of ADSs by our shareholders may disproportionately influence the price of those ADSs in either direction. The price for our ADSs could, for example, decline significantly in the event that a large number of ADSs are sold on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on the price of the security.

Future sales of our ADSs in the public market could cause our share price to decline, even if our business is doing well.

As of March 20, 2024, approximately 265.8 million of our ordinary shares (including ordinary shares in the form of ADSs) were issued and outstanding. Sales of a substantial number of shares of our ADSs in the public market, or the perception that these sales might occur, could depress the market price of our ADSs and could impair our ability to raise capital through the sale of additional equity securities.

We have filed registration statements on Form S-8 under the Securities Act to register ordinary shares (including in the form of ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans, and we have also filed an automatic shelf registration statement on Form S-3 under the Securities Act to register an unspecified number of securities. In addition, in the future, we may issue ordinary shares, ADS or other securities if we need to raise additional capital. The number of new ordinary shares or ADSs, or securities convertible into our ordinary shares or ADSs, issued in connection with raising additional capital could represent a material portion of our then-outstanding ordinary shares. For example, in February 2024, we sold ADSs representing 58.3 million ordinary shares in an underwritten offering resulting in gross proceeds of $350.0 million, and we also sold ADSs representing 33.3 million ordinary shares to BioNTech in a private placement, resulting in gross proceeds of $200.0 million.

We are contractually obligated to file a resale registration statement, on form S-3, to register the ADSs we sold to BioNTech in February 2024. Upon the effectiveness of that registration statement, those ADSs will be freely tradeable. Additionally, in 2022, we filed two "resale" registration statements on Form F-3 under the Securities Act to register a total of approximately 33.4 million of our ordinary shares, or securities convertible into our ordinary shares, held by certain of our investors, allowing these shares or ADSs to be sold in the public market. If these shares or ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

Our senior management, directors and principal shareholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to our shareholders for approval.

Members of our senior management, directors and current beneficial owners of 5% or more of our ordinary shares and their respective affiliates beneficially own, in the aggregate, a majority of our outstanding ordinary shares (including ordinary shares in the form of ADSs). As a result, if these shareholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may harm the market price of our ADSs by:

- delaying, deferring, or preventing a change in control;
- entrenching our management and/or the board of directors;
- impeding a merger, scheme of arrangement, consolidation, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, some of these persons or entities may have interests different than yours. For example, because many of these shareholders purchased their shares at prices substantially lower than our current trading price and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of our ADSs, are governed by English law, including the provisions of the U.K. Companies Act 2006 (the "Companies Act"), and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

Holders of our ADSs may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise their right to vote.

Holders of the ADSs do not have the same rights as our shareholders and in accordance with the provisions of the deposit agreement, will not be able to exercise voting rights attaching to the ordinary shares evidenced by the ADSs on an individual basis. The Depositary or its nominee will act as the representative for the holders of the ADSs and will exercise the voting rights attached to the ordinary shares represented by the ADSs. Holders of our ADSs may not receive voting materials in time to instruct the Depositary to vote, and it is possible that they, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the Depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise voting rights and may lack recourse if their ADSs are not voted as requested. In addition, holders of our ADSs will not be able to call a shareholders' meeting.

Holders of our ADSs may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

Although we do not have any present plans to declare or pay any dividends, in the event we declare and pay any dividend, the Depositary for the ADSs has agreed to pay to holders of our ADSs the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. Holders of our ADSs will receive these distributions in proportion to the number of our ordinary shares their ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of the ADSs. We have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that holders of our ADSs may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have an adverse effect on the value of the ADSs.

Because we do not anticipate paying any cash dividends on our ADSs in the foreseeable future, capital appreciation, if any, will be our ADS holders' and shareholders' sole source of gains and they may never receive a return on their investment.

Under current English law, a company's accumulated realized profits must exceed its accumulated realized losses (on a non-consolidated basis) before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, on our ADSs will be our ADS holders' sole source of gains for the foreseeable future, and they will suffer a loss on their investment if they are unable to sell their ADSs at or above the price at which they purchased the ADSs.

If we are a PFIC, there could be adverse U.S. federal income tax consequences to U.S. Holders.

Under the Internal Revenue Code of 1986, as amended, (the "Code"), we will be a PFIC, for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income, including cash (other than certain cash held in non-interest bearing accounts for short-term working capital needs). For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U.S. holder holds our ADSs, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including 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.

Based on our analysis of our income, assets, activities and market capitalization, we believe we were not a PFIC for our taxable year ended December 31, 2023. However, the determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service ("IRS"), will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ended December 31, 2023, or any future taxable year.

If a United States person is treated as owning at least 10% of our ordinary shares, including ordinary shares represented by ADSs, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder is treated as owning (directly, indirectly or constructively through the application of attribution rules) at least 10% of the value or voting power of our ordinary shares, including ordinary shares represented by ADSs, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes at least one U.S. subsidiary (Autolus Inc.), certain of our non-U.S. subsidiaries may be treated as controlled foreign corporations (regardless of whether Autolus Therapeutics plc is treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries, if any, are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations.

Further, we cannot provide any assurances that we will furnish to any U.S. shareholder information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ADSs.

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

Our business and our ADSs and ordinary shares are subject to changes in tax laws, regulations and treaties, or the interpretation thereof, and tax policy initiatives and reforms under consideration or being implemented by tax authorities in the jurisdictions in which we operate, including in connection with the Base Erosion and Profit Shifting, or BEPS, Project of the Organization for Economic Co-Operation and Development, or OECD, and initiatives of the European Commission.

Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid, or the stamp duty or stamp duty reserve tax treatment of our ADSs or ordinary shares. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

The IRA enacted in the United States introduced, among other changes, a 15% corporate minimum tax on certain United States corporations and a 1% excise tax on certain stock redemptions by United States corporations (which the U.S. Treasury indicated may also apply to certain stock redemptions by a foreign corporation funded (or deemed funded) by certain United States affiliates. In addition, effective in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures in the current period and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Internal Revenue Code Section 174.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, His Majesty's Revenue & Customs ("HMRC"), the U.S. IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a ''permanent establishment'' under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

We may be unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments or benefits from favorable UK tax legislation.

As a UK resident trading entity, we are subject to UK corporate taxation. Due to the nature of our business, we have generated losses since inception. As of December 31, 2023, we had cumulative carryforward tax losses of $418.1 million. Subject to any relevant utilization criteria and restrictions (including those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half the ordinary shares of the company and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits.

Research and development expenditure is presented net of reimbursements from reimbursable tax and expenditure credits from the UK government. As a company that carries out extensive research and development activities, we benefit from the UK research and development tax credit regime under the scheme for small or medium-sized enterprises, or SMEs, and also claim a Research and Development Expenditure Credit, or RDEC, to the extent that our projects are grant funded.

The SME Program has been particularly beneficial to us, as under such program the trading losses that arise from our qualifying R&D activities can be surrendered for a cash rebate of up to 33.35% of qualifying expenditure incurred prior to April 1, 2023 and decreasing to 18.6% after April 1, 2023. Additionally, the U.K Government enacted further changes to the SME regime on March 4, 2024 which include the introduction of a new rate for R&D intensive companies of 27% (which we may qualify for) and comes into effect for expenditures incurred after April 1, 2024. Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects for which we do not receive income. 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 our subsidiary Autolus Limited, are eligible for inclusion within these tax credit cash rebate claims.

Under the RDEC Program, tax credits for qualifying R&D expenditure incurred prior to April 1, 2023 are granted at a headline rate of 13% and can generate cash rebates of up to 10.5% of qualifying R&D expenditure. The headline rate of RDEC increased to 20% on April 1, 2023 and can generate cash rebates of up to 15% on qualifying R&D expenditure incurred from this date.

Amendments to the current SME and RDEC programs that are contained in the Finance Bill currently proceeding through the UK Parliament will take effect from periods on or after April 1, 2024 and will (i) (unless limited exceptions apply) introduce restrictions on the tax relief that can be claimed for expenditure incurred on sub-contracted R&D activities or externally provided workers, where such sub-contracted activities are not carried out in the UK or such workers are not subject to UK payroll taxes, and (ii) merge the SME Program and the RDEC Program into a single scheme which would generate net cash benefit of up to 15% of the qualifying expenditure for profit making companies and up to 16.2% for loss making companies. We currently meet the conditions of the SME regime, but also can make claims under the RDEC regime to the extent that our projects are grant funded. In addition, it is also expected that we will meet the conditions of the R&D intensive scheme and would be able to make claims under merged SME R&D intensive regime. We may not be able to continue in the future to qualify as a small or medium-sized enterprise under the SME program, based on size criteria concerning employee headcount, turnover and gross assets. If we cease to qualify under the SME regime, we may make a claim under the RDEC regime for periods ending December 31, 2024 or the merged R&D regime from period ending December 31, 2025. It should be noted, however, that the types of qualifying expenditure in respect of which we may make claims under the RDEC regime are more restricted than under the SME regime (for example, it may be the case that certain subcontracted costs in respect of which claims may be made under the SME regime do not qualify for relief under the RDEC regime).

We may benefit in the future from the UK's "patent box" regime, which allows certain profits attributable to revenues from patented products (and other qualifying income) to be taxed at an effective rate of 10% by giving an additional tax deduction.

We are the exclusive licensee or owner of one patent and several patent applications which, if issued, would cover our product candidates, and accordingly, future upfront fees, milestone fees, product revenues and royalties could be eligible for this deduction. When taken in combination with the enhanced relief available on R&D expenditures, we expect a long-term rate of corporation tax lower than statutory to apply to us. If, however, there are unexpected adverse changes to the UK R&D tax credit regime or the "patent box" regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments then our business, results of operations and financial condition may be adversely affected. This may impact our ongoing requirement for investment and the timeframes within which additional investment is required.

To date, Autolus Limited has recovered all of the VAT incurred on its expenditure in the UK on the basis of having an intention to solely make taxable supplies. In recent months we have been working with our advisers in relation to the appropriate VAT treatment that should be applied in the UK in relation to Autolus Limited's primary income stream. Our advisors are still finalizing their understanding of the full facts which underpin our CAR T therapy and will provide a more conclusive VAT opinion in due course but it has been mentioned during initial discussion that some products which include human blood can be exempt from a UK VAT perspective. If the conclusion is that this activity is exempt from a UK VAT perspective, this may result in a retrospective restriction in terms of VAT recovered on a proportion of our UK expenditure (with this restriction likely being based on the UK market turnover as a percentage of global turnover). We currently expect revenue from UK customers to only represent a small proportion of our overall activity.

We have incurred, and will continue to incur, significant costs and demands upon management as a result of being a public company, and our management have devoted, and will continue to devote, substantial time to existing and new compliance initiatives.

As a public company listed in the United States, we incur significant legal, accounting and other expenses. These expenses will likely become even more significant now that we no longer qualify as an emerging growth company under SEC rules effective as of December 31, 2023. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to maintain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

As a foreign private issuer, we are permitted to and follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards applicable to public companies organized in the United States. These practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.

We are entitled to rely on a provision in Nasdaq's corporate governance rules that allows us to follow English corporate law with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to domestic issuers listed on Nasdaq.

We are not subject to Nasdaq Listing Rule 5605(b)(2) because English law does not require that independent directors regularly have scheduled meetings at which only independent directors are present. Similarly, we have adopted a compensation committee, but English law does not require that we adopt a compensation committee or that such committee be fully independent. As a result, our practice varies from the requirements of Nasdaq Listing Rule 5605(d), which sets forth certain requirements as to the responsibilities, composition and independence of compensation committees. English law requires that we disclose information regarding compensation of our directors for services as a director of an undertaking that is our subsidiary undertaking and as a director of any other undertaking of which a director is appointed by virtue of our nomination (directly or indirectly) but not other third-party compensation of our directors or director nominees. As a result, our practice varies from the third-party compensation disclosure requirements of Nasdaq Listing Rule 5250(b)(3). In addition, while we have a compensation committee, English law does not require that we adopt a compensation committee or that such committee be fully independent. Additionally, we are not subject to Nasdaq Listing Rule 5605(e) because, under English law, director nominees are not required to be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors.

Furthermore, English law does not have a regulatory regime for the solicitation of proxies applicable to us, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies. In addition, we have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements.

To this extent, our practice will vary from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. In addition, while we have adopted a code of business conduct and ethics, English law does not require us to publicly disclose waivers from this code that have been approved by our board within four business days. We expect to report any such waivers on our website in lieu of any SEC filing. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

As a result, our practice varies from the requirements for domestic issuers pursuant to Nasdaq Listing Rule 5610.

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act and Rule 10A-3 of the Exchange Act, both of which are also applicable to Nasdaq listed U.S. companies. Because we are a foreign private issuer, however, our audit committee is not subject to additional requirements applicable to Nasdaq listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer, subject to certain phase-in requirements permitted by Rule 10A-3 of the Exchange Act.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, 2024. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the United States and we fail to meet additional requirements necessary to maintain our foreign private issuer status.

If we lose our foreign private issuer status on this determination date, we would have to comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders would become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq listing rules. As a U.S. listed public company that is not a foreign private issuer, we would incur significant additional legal, accounting and other expenses that we do not currently incur as a foreign private issuer, as well as increased accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange. If we lose our foreign private issuer status and are unable to devote adequate funding and the resources needed to maintain compliance with U.S. securities laws, while continuing our operations, we could be forced to deregister with the SEC. A deregistration would substantially reduce or effectively terminate the trading of our securities in the United States. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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

The U.K. City Code on Takeovers and Mergers (the "Takeover Code"), applies to an offer for, among other things, a public company whose registered office is in the UK if the company is considered by the Panel on Takeovers and Mergers (the "Takeover Panel"), to have its place of central management and control in the UK (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 UK tax authorities.

Under the Takeover Code, the Takeover Panel will determine whether we have our place of central management and control in the UK by looking at various factors, primarily where the directors are resident.

In June 2019, the Takeover Panel Executive 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 UK.

You may face difficulties in protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited, because we are incorporated under the laws of England and Wales, conduct most of our operations outside the United States and most of our directors and senior management reside outside the United States.

We are incorporated and have our registered office in, and are currently existing under the laws of, England and Wales. In addition, most of our tangible assets are located, and most of our senior management and directors reside, outside of the United States. As a result, it may not be possible to serve process within the United States on certain directors or us or to enforce judgments obtained in U.S. courts against such directors or us based on civil liability provisions of the securities laws of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

The United States and the UK do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the UK. In addition, uncertainty exists as to whether English courts would entertain original actions brought in the UK against us or our directors or senior management predicated upon the securities laws of the United States or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by English courts as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met.

Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is subject to determination by the court making such decision. If an English court gives judgment for the sum payable under a U.S. judgment, the English judgment will be enforceable by methods generally available for this purpose. These methods generally permit the English court discretion to prescribe the manner of enforcement.

As a result, U.S. investors may not be able to enforce against us or certain of our directors any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

As an English public limited company, certain capital structure decisions will require shareholder approval, which may limit our flexibility to manage our capital structure.

On June 18, 2018, we altered the legal status of our company under English law from a private limited company by re-registering as a public limited company and changing our name from Autolus Therapeutics Limited to Autolus Therapeutics plc. English law provides that a board of directors may only allot shares (or rights to subscribe for or convertible into shares) with the prior authorization of shareholders, such authorization stating the aggregate nominal amount of shares that it covers and valid for a maximum period of five years, each as specified in the articles of association or relevant shareholder resolution.

We obtained authority from our shareholders at our Annual General Meeting held on June 28, 2022 to allot additional shares (or to grant rights to subscribe for or to convert any security into our shares) for a period of five years from June 28, 2022, up to a maximum nominal amount of $8,400, which authorization will need to be renewed upon expiration (i.e., at least every five years) but may be sought more frequently for additional five-year terms (or any shorter period).

English law also generally provides shareholders with preemptive rights when new shares are issued for cash. However, it is possible for the articles of association, or for shareholders to pass a special resolution at a general meeting, being a resolution passed by at least 75% of the votes cast, to disapply preemptive rights. Such a disapplication of preemptive rights may be for a maximum period of up to five years from the date of adoption of the articles of association, if the disapplication is contained in the articles of association, or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years). We obtained authority from our shareholders at our Annual General Meeting held on June 28, 2022 to disapply preemptive rights for a period of five years from June 28, 2022 up to a maximum nominal amount of $8,400, which disapplication will need to be renewed upon expiration (i.e., at least every five years) to remain effective, but may be sought more frequently for additional five-year terms (or any shorter period).

English law also generally prohibits a public company from repurchasing its own shares without the prior approval of shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, and other formalities. Such approval may be for a maximum period of up to five years.

Our articles of association provide that the courts of England and Wales are the exclusive forum for the resolution of all shareholder complaints other than complaints asserting a cause of action arising under the Securities Act and the Exchange Act, and that the U.S. District Court for the Southern District of New York will be the exclusive forum for the resolution of any shareholder complaint asserting a cause of action arising under the Securities Act or the Exchange Act.

Our articles of association provide that the courts of England and Wales are to be the exclusive forum for resolving all shareholder complaints (i.e., any derivative action or proceeding brought on behalf of us, any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees, any action or proceeding asserting a claim arising out of any provision of the Companies Act or our articles of association or any action or proceeding asserting a claim or otherwise related to the affairs of our company) other than shareholder complaints asserting a cause of action arising under the Securities Act or the Exchange Act, and that the U.S. District Court for the Southern District of New York will be the exclusive forum for resolving any shareholder complaint asserting a cause of action arising under the Securities Act or the Exchange Act. In addition, our articles of association provide that any person or entity purchasing or otherwise acquiring any interest in our shares is deemed to have notice of and consented to these provisions.

This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. The enforceability of similar exclusive forum provisions (including exclusive federal forum provisions for actions, suits or proceedings asserting a cause of action arising under the Securities Act) in other companies' organizational documents has been challenged in legal proceedings, and there is uncertainty as to whether courts would enforce the exclusive forum provisions in our articles of association. Additionally, our shareholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find either choice of forum provision contained in our articles of association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our results of operations and financial condition.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our ADSs could decline.

The trading market for our ADSs is influenced by the research and reports that equity research analysts publish about us and our business. We currently have research coverage by several equity research, industry or financial analysts. The price of our ADSs could decline if one or more analysts covering our business downgrade our ADSs or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our ADSs could decrease, which in turn could cause the trading price or trading volume of our ADSs to decline.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

Our information security function is led by our Executive Director of Global IT Operations ("Head of IT"), whose team is responsible for leading enterprise-wide cybersecurity strategy, policy, standards, architecture, and processes.

The information security function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and our risk profile using various methods including, for example, manual tools and automated tools, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, internal and external audits, leveraging third party threat assessments, and conducting vulnerabilities assessments. In addition, our employees and contractors receive periodic training under our IT security policies, including simulated intrusion attempts, and are required to certify compliance with our cybersecurity practices.

Depending on the environment or system, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an information security policy, access management procedures, data back-up and restoration policy, cyberattack response procedure, network security controls, data segregation for certain data, encryption of certain data, access controls, physical controls, systems monitoring, penetration testing, employee training, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity consultants, cybersecurity service providers, and penetration testing services. The results of those assessments and reviews are reported to senior management and the board of directors, including the Audit Committee, by the Head of IT, as appropriate.

In addition, updates on our cyber risks and threats, the status of projects to strengthen our information security systems, assessments of the information security program, and the emerging threat landscape may also be reported to senior management and the board of directors, including the Audit Committee, by the Head of IT, as appropriate. Our senior management team and board of directors include several members with operational experience overseeing IT operations, including risk assessment and implementation of security measures. As of the date of this report, we are not aware of any material risks from cybersecurity threats, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

We use third-party service providers to perform a variety of functions throughout our business, such as CROs, contract manufacturing organizations, and other distributors, including those who process clinical trial data on our behalf. Depending on the nature of the services provided, the sensitivity of the critical systems, information and assets at issue, and the identity of the provider, our third-party risk management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider, including, for example, a review of security assessments and imposition of contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report, including "If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences."

Governance

Management is responsible for identifying and assessing cybersecurity risks on an ongoing basis, establishing processes designed to ensure that such potential cybersecurity risk exposures are monitored, putting in place appropriate mitigation and remediation measures, and maintaining cybersecurity programs. Our cybersecurity programs are managed under the direction of our Head of IT and monitors the prevention, detection, mitigation, and remediation of cybersecurity risks. Management regularly updates the board of directors on the Company's cybersecurity programs, material cybersecurity risks and mitigation strategies and provides regular cybersecurity updates.

Our board of directors has overall oversight responsibility for our risk management and is charged with oversight of our cybersecurity risk management program. The board is responsible for ensuring that management has policies and processes in place designed to identify, monitor, assess and respond to cybersecurity, data privacy and other information technology risks to which the Company is exposed and implement processes and programs to manage cybersecurity risks and mitigate cybersecurity threats and incidents.

Item 2. Properties

Our corporate headquarters are located at the MediaWorks, 191 Wood Lane, White City, London W12 7FP, United Kingdom, where we lease 32,673 square feet of office and laboratory space. We entered the lease in November 2018 with a rent-free period at the beginning of the lease term until August 2020. In addition, we have the option to terminate the lease in November 2026.

In September 2017, we executed an arrangement with Cell Therapy Catapult Limited to lease a manufacturing suite at the Cell and Gene Therapy Catapult manufacturing center in Stevenage, UK (the "Catapult") for a term through May 2021, at which time we renewed the lease. The lease had a six-month rent-free period. In July 2022, we and Cell Therapy Catapult Limited mutually agreed to reduce the lease term of this manufacturing suite from July 2024 to June 2023. In March 2023, we and Cell Therapy Catapult Limited mutually agreed to extend the lease term of this manufacturing suite from June 2023 to August 2024.

In October 2018, we entered into a sublease for 27,502 square feet of office space in Rockville, Maryland. On February 27, 2020, we terminated the sublease of this office space and concurrently entered into a direct lease with the building owner for the same premises. The lease is non-cancellable and is scheduled to terminate in March 2025.

In December 2018, we executed an additional lease arrangement with Cell Therapy Catapult Limited for additional manufacturing space at the Catapult for a term through September 2023, at which time we have the option to renew or terminate the lease. In March 2023, we and Cell Therapy Catapult Limited mutually agreed to extend the lease term of this manufacturing suite from September 2023 to August 2024.

In February 2019, we entered into a lease for a manufacturing facility, consisting of approximately 39,558 square feet, in Enfield, UK. The lease term is 15 years, commencing in February 2019, with an option to terminate the lease in February 2029. We initially planned on initiating manufacturing activities at this facility in 2020; however, following a strategic review of our manufacturing plan, we chose to discontinue the fit-out of manufacturing capability at the Enfield facility in December 2019. In March 2021, one of the units was split in two separate units and we surrendered one of those units back to the landlord. In October 2021, we subleased a portion of the facility to third party tenants over lease terms from October 2021 to February 2029 and October 2026, respectively.

In addition, in May 2020, we executed an arrangement with Cell Therapy Catapult Limited to lease a third manufacturing suite at the Catapult for a term through April 2024. In July 2022, we and Cell Therapy Catapult Limited mutually agreed to extend the lease term of a manufacturing suite leased by us from April 2024 to February 2025.

In September 2021, we entered into an arrangement for lease with the landlord, Forge Life Sciences Nominee, an affiliate of the Reef Group, for the design, construction and lease of a new 70,000 square foot commercial manufacturing facility in Stevenage, UK. Under this arrangement, the landlord leased the facility, which is called "The Nucleus," to us on agreed terms, upon satisfaction of certain conditions and completion of construction. Since November 2022, the landlord handed over various portions of the facility to us until its practical completion on July 31, 2023. We were required to pay a pro-rated license fee for each portion of the facility which we had been granted access until the execution of the lease agreement. On September 19, 2023, we entered into a 20 year lease agreement with the landlord for The Nucleus. This new manufacturing facility will have a GMP cell manufacturing capacity of approximately 2,000 batches a year. We anticipate that the size and layout of the new facility will allow for further increases in this capacity.

In September 2021, we also entered into a lease agreement for 2,762 square feet of laboratory and office space in Gaithersburg, Maryland, with a term until March 2024. In September 2023, we extended the original lease term to March 2027.

In order to commence the scale up of our manufacturing capability, an administrative office and training facility was set up at Unit 10, Gateway 1000, Arlington Business Park in Stevenage, UK adjacent to the Catapult facility. This office and training space was used to support the fit out and commencement of manufacturing activities at the Nucleus facility. During November 2023, we vacated this facility and relocated to The Nucleus. The current lease expires in 2025.

In order to support local activities, we hold a short-term office rolling lease in Munich, Germany which has a three month notice period. Similarly, in December 2023, we have entered in a lease agreement for an office in Weil am Rhein, Germany to support our regional activities and commercial presence.

We anticipate leasing additional office and manufacturing space as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosure

Not applicable

PART II

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

Our ADSs have been listed on Nasdaq since June 22, 2018 and are traded under the symbol "AUTL". Each ADS represents one ordinary share. Our ordinary shares are not listed.

Stockholders

As of March 20, 2024, we had approximately 35 holders of record of our ordinary shares (including shares in the form of ADSs). The actual number of holders of our ordinary shares is greater than this number of record holders and includes shareholders who are beneficial owners, but whose shares or ADSs are held in street name by brokers or held by other nominees. The number of holders of record also does not include shareholders whose shares or ADSs may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our ordinary shares and do not expect to pay dividends on our ordinary shares for the foreseeable future.

Sales of Unregistered Securities

Except as disclosed in our previous filings with the SEC, we did not sell any unregistered securities during the year ended December 31, 2023.

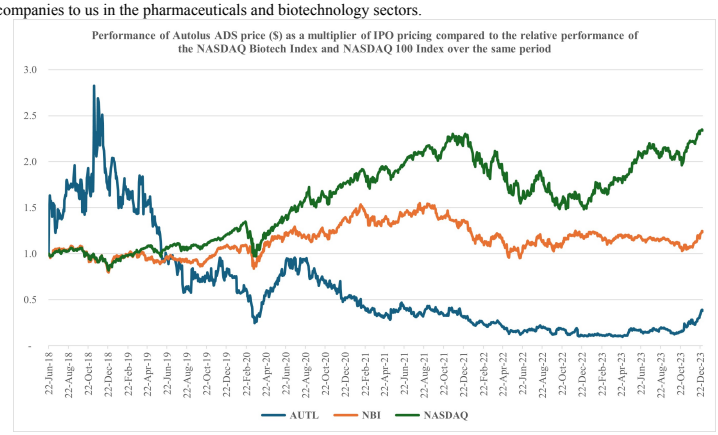
Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2023.

Stock Performance Graph

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

The following graph compares the cumulative total shareholder return on our ADSs with that of the Nasdaq Biotechnology Index ("NBI") and Nasdaq 100 Index for the five years ended December 31, 2023. The NBI has been chosen as an appropriate comparator as it comprises similar companies to us in the pharmaceuticals and biotechnology sectors.



Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. 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 and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth in the Item 1A. "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. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

We maintain our books and records in pounds sterling, our results are subsequently translated to U.S. dollars and we prepare our consolidated financial statements in accordance with U.S. GAAP. All references in this Annual Report to "$" are to U.S. dollars and all references to "£" are to pounds sterling. Our Consolidated Balance Sheets as of December 31, 2023 and 2022 have been translated from pounds sterling into U.S. dollars at the rate of £1.00 to $1.2730 and £1.00 to $1.2090, respectively. Our Consolidated Statements of Operations and Comprehensive Loss and Cash Flows for the years ended December 31, 2023, 2022 and 2021 have been translated from pounds sterling to U.S. dollars at the rate of £1.00 to $1.2433, £1.00 to $1.2374 and £1.00 to $1.3755, respectively. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

Overview

We are a biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer and autoimmune diseases. Using our broad suite of proprietary and modular T cell programming technologies, we are engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize cancer cells, break down their defense mechanisms and attack and kill these cells. We believe our programmed T cell therapies have the potential to be best-in-class and offer cancer patients substantial benefits over the existing standard of care, including the potential for cure in some patients.

Since our inception, we have incurred significant operating losses. For the years ended December 31, 2023, 2022, and 2021, we incurred net losses of $208.4 million, $148.8 million, and $142.1 million, respectively. As of December 31, 2023, we had an accumulated deficit of $878.6 million.

Based on our current clinical development plans, we believe our existing cash and cash equivalents of $239.6 million at December 31, 2023, together with the proceeds received in February 2024 from our private placement transaction with BioNTech and our underwritten registered offering of ADSs, as described below, we will be able to fund our current and planned operating expenses and capital expenditure requirements through at least the next twelve months from the date of this Annual Report. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses, which we have based on assumptions that may prove to be wrong and could prove to be significantly higher than we currently anticipate, could vary materially and adversely as a result of a number of factors. Management does not know whether additional financing will be on terms favorable or acceptable to us when needed, if at all. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our product candidates, management may need to curtail its development efforts and planned operations.

Recent Developments

Obe-cel updates:

Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL – FELIX Study

- Obe-cel BLA for r/r B-ALL submitted to the FDA in November 2023; PDUFA target action date of November 16, 2024. An MAA to the EMA was just submitted and an MAA submission to the MHRA in the UK is planned for the second half of 2024.
- Pooled analysis of the FELIX Phase 1b/2 study presented at ASH in December 2023 demonstrated prolonged EFS and low overall immunotoxicity across all cohorts in r/r B-ALL, and particularly in patients with low leukemic burden at lymphodepletion. Additionally, data from a pooled analysis from the ALLCAR19 study and FELIX Phase 1b in r/r B-ALL showed durable remissions with obe-cel as a stand-alone therapy in a subset of patients after a median follow up of longer than three years. Further long-term data from the FELIX study is anticipated at medical conferences in 2024.

Obe-cel in B-cell mediated autoimmune diseases

- The Phase 1 dose confirmation study in refractory SLE patients has the first site open for enrollment; initial clinical data expected in late 2024.

Pipeline clinical trials, in collaboration with UCL, updates and anticipated milestones:

- *AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study*
  - AUTO8 is a next-generation product candidate for multiple myeloma, which includes two CARs for the multiple myeloma targets, BCMA and CD19. Initial data from the MCARTY Phase 1 study in multiple myeloma presented at ASH in December 2023 showed AUTO8 was well tolerated, with responses observed in all patients. Further updates from the MCARTY study are anticipated during 2024.
- *AUTO6NG in Neuroblastoma – Phase 1 MAGNETO Study*
  - AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. A Phase 1 clinical study in children with r/r neuroblastoma was opened for enrollment in the fourth quarter of 2023.

On February 6, 2024, we, through our wholly owned subsidiaries, Autolus Limited and Autolus Holdings (UK) Limited entered into a License and Option Agreement (the "License Agreement") with BioNTech SE ("BioNTech") pursuant to which we granted to BioNTech an exclusive, worldwide, sublicensable license (the "License") to certain binders and to exploit products that express in vivo such binders (collectively, the "Binder Licensed Products").

In addition to the License, under the License Agreement we granted to BioNTech several time-limited options (the "Options") to acquire additional rights to specified clinical-stage product candidates, binders and technologies, described in more detail below. In the event that all Options are fully exercised, we would be eligible to receive future maximum aggregate payments of up to $582.0 million pursuant to the License Agreement. This maximum amount includes the potential milestone payments for the Binder Licensed Products described below, all option exercise fees and potential milestone payments for licenses to optioned products and technologies, and additional payments that BioNTech may pay to us for an increased revenue interest with respect to obe-cel as described below.

License and Options

In consideration for the License and the Options, BioNTech has made an initial payment to us of $10.0 million. We are eligible to receive milestone payments of up to $32 million in the aggregate upon the achievement of specified clinical development and regulatory milestones for each Binder Licensed Product that achieves such milestones. We are also eligible to receive a low single-digit royalty on net sales of Binder Licensed Products, subject to customary reductions, which reductions are subject to specified limits. The royalty will be increased if BioNTech, its affiliates or sublicensees commercialize a Binder Licensed Product in an indication and country in which we or our affiliates or licensees also commercialize a product containing the same binders. Under the License Agreement, BioNTech is solely responsible for, and has sole decision-making authority with respect to, at its own expense, the exploitation of Binder Licensed Products.

Under the terms of the License Agreement, we have agreed to grant BioNTech the following time-limited Options:

- an option to obtain exclusive rights to co-fund development costs of our development-stage programs AUTO1/22 and AUTO6NG, in return for agreed upon economic terms, including an option exercise fee, milestone payments and a profit-sharing arrangement for each such product candidate, with additional options to co-promote or co-commercialize such product candidate;
- an option to obtain an exclusive worldwide license to exploit products that express certain additional binders in vivo or, with respect to certain binders, in an antibody drug conjugate (the "Binder Option");
- an option to obtain a co-exclusive worldwide license to exploit products that express in vivo our modules for activity enhancement, with a non-exclusive right, in certain agreed instances, to exploit products that include our modules for activity enhancement but do not express in vivo such modules (the "Activity Enhancement Option"); and
- an option to obtain a non-exclusive worldwide license to exploit products that contain our safety switches (the "Safety Switch Option" and, together with the Binder Option and the Activity Enhancement Option, the "Technology Options").

The option exercise fee for each Technology Option is a low seven-digit amount. Each of the Activity Enhancement Option and the Safety Switch Option must be exercised with respect to a given biological target or combination of targets. There is a cap on the total option exercise fee if multiple options are exercised with respect to a given target.

There is also a cap on milestone payments across all agreements entered into as the result of BioNTech exercising one or more of the Technology Options and a cap on the royalty rate payable on any given product for which multiple Options are exercised.

Obe-cel Product Revenue Interest

Under the License Agreement, BioNTech has also agreed to financially support the expansion of the clinical development program for, and planned commercialization of obe-cel. In exchange for our grant of rights to future revenues from the sales of obe-cel products, BioNTech made an upfront payment to us of $40 million. We will pay BioNTech a low single-digit percentage of annual net sales of obe-cel products, which may be increased up to a mid-single digit percentage in exchange for milestone payments of up to $100 million in the aggregate on achievement of certain regulatory events for specific new indications upon BioNTech's election.

Manufacturing and Commercial Agreement

Under the terms of the License Agreement, we have granted BioNTech the option to negotiate a joint manufacturing and commercial services agreement pursuant to which we and they may access and leverage each other's manufacturing and commercial capabilities, in addition to our commercial site network and infrastructure, with respect to certain of each parties' CAR T products, including BioNTech's product candidate BNT211 (the "Manufacturing and Commercial Agreement").

Securities Purchase Agreement, Registration Rights Agreement and Letter Agreement

Concurrently with the execution of the License Agreement, we and BioNTech entered into a Securities Purchase Agreement (the "Purchase Agreement") pursuant to which we issued and sold 33.3 million ADSs to BioNTech at $6.00 per ADS for aggregate gross proceeds of $200.0 million.

In the event that we and BioNTech enter into the Manufacturing and Commercial Agreement described above within 18 months of the initial closing under the Purchase Agreement, BioNTech will purchase additional ADSs, not to exceed 15.0 million ADSs, for an aggregate purchase price of up to $20 million. The total number of ADSs that may be issued to BioNTech is subject to additional limitations and restrictions. BioNTech also has the right to purchase equity securities sold by us in bona fide financing transactions in amounts that are based on BioNTech maintaining specified ownership thresholds following such financing transactions.

Operational Updates

In March 2024, following the most recent GMP inspection by the MHRA in February 2024, The Nucleus manufacturing facility in Stevenage, UK obtained a Manufacturer's Importation Authorization (MIA), together with the accompanying GMP certificate. This authorization enables us to manufacture products for global commercial and clinical supply at The Nucleus, effective as of March 18, 2024.

Internal Control Over Financial Reporting

In connection with the audit of our financial statements for the year ended December 31, 2023, our management identified a material weakness in our internal control over financial reporting. The material weakness related to the historic misinterpretation and application of ASC Topic 740 - *Income Taxes*, resulting in our UK small and medium enterprise (SME) tax credits being incorrectly presented in income tax benefit (expense). Refer to Note 3, Restatement of Previously Issued Consolidated Financial Statements, in the Consolidated Financial Statements in Part II, Item 8 of this report for additional information.

We have commenced measures to remediate the material weakness; however, there can be no assurance that these measures will significantly improve or fully remediate the material weakness. There is also no assurance that we have identified all of our material weaknesses or that we will not in the future have additional material weaknesses. See "Risk Factors— We have identified a material weakness in our internal control over financial reporting. If our remediation of the material weakness is not effective or if we fail to develop and maintain effective internal controls over financial reporting, our ability to produce timely and accurate financial information or comply with Section 404 of the Sarbanes-Oxley Act of 2002 could be impaired, which could have a material adverse effect on our business and the trading price of our ADSs."

Financial Operations Overview

Grant Income

Grant income consists of proceeds from government research grants used to perform specific research and development activities. We recognize grant income over the period in which we recognize the related costs covered under the terms and conditions of the grant. We have received grants from the UK government, which are repayable under certain circumstances, including breach or noncompliance with the terms of the grant. For grants with refund provisions, we review the grant to determine the likelihood of repayment. If the likelihood of repayment of the grant is determined to be remote, then the grant is recognized as grant income. We have concluded that the likelihood of any repayment events included in our current grants is remote.

License Revenue

We account for our revenue pursuant to the provisions of Accounting Standards Codification ("ASC") Topic 606*, Revenue from Contracts with Customers*. We have no products approved for commercial sale and have not generated any revenue from commercial product sales. The total revenue to date has been generated principally from license agreements. During the year ended December 31, 2023, we entered into various license agreements which included non-refundable upfront license fees, options for future commercial licenses, payments based upon achievement of clinical development and regulatory objectives, payments based upon achievement of certain levels of product sales, and royalties on licensed product sales.

In determining the appropriate amount of revenue to be recognized in relation to each license agreement, we perform the following steps: (i) identify the promised goods or services in the contract; (ii) determine whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measure of the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations based on estimated selling prices; and (v) recognize of revenue when (or as) we satisfy each performance obligation.

License Fees and Multiple Element Arrangements

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license at such time as the license is transferred to the licensee and the licensee is able to use, and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligations to determine whether the combined performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Appropriate methods of measuring progress include output methods and input methods. In determining the appropriate method for measuring progress, we consider the nature of service that we promise to transfer to the customer. When we decide on a method of measurement, we will apply that single method of measuring progress for each performance obligation satisfied over time and will apply that method consistently to similar performance obligations and in similar circumstances.

Customer Options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. We evaluate the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on any identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Contingent Research Milestone Payments

ASC Topic 606 constrains the amount of variable consideration included in the transaction price in that either all, or a portion, of an amount of variable consideration should be included in the transaction price. The variable consideration amount should be included only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The assessment of whether variable consideration should be constrained is largely a qualitative one that has two elements: the likelihood of a change in estimate, and the magnitude thereof. Variable consideration is not constrained if the potential reversal of cumulative revenue recognized is not significant, for example.

If the consideration in a contract includes a variable amount, we will estimate the amount of consideration in exchange for transfer of promised goods or services. The consideration also can vary if our entitlement to the consideration is contingent on the occurrence or non-occurrence of a future event. We consider contingent research milestone payments to fall under the scope of variable consideration, which should be estimated for revenue recognition purposes at the inception of the contract and reassessed ongoing at the end of each reporting period.

We assess whether contingent research milestones should be considered variable consideration that should be constrained and thus not part of the transaction price. This includes an assessment of the probability that all or some of the milestone revenue could be reversed when the uncertainty around whether or not the achievement of each milestone is resolved, and the amount of reversal could be significant.

U.S. GAAP provides factors to consider when assessing whether variable consideration should be constrained. All of the factors should be considered, and no factor is determinate. We consider all relevant factors.

Royalty Revenue

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and Development Expenses

Research and development expenses consist of costs incurred in connection with the research and development of our product candidates, which are partially offset by research and development tax credits, including tax credits arising from the UK small and medium enterprise (SME) regime and research and development expenditure credit (RDEC) regime provided by HMRC. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials;
- employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- expenses incurred for outsourced professional scientific development services;
- costs for laboratory materials and supplies used to support our research activities;
- allocated facilities costs, depreciation and other expenses, which include rent and utilities; and
- upfront, milestone and management fees for maintaining licenses under our third-party licensing agreements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants and CROs in connection with our preclinical development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under license agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee research and development as well as for managing our preclinical development, process development, manufacturing and clinical development activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next few years as we increase personnel costs, initiate and conduct additional clinical trials and prepare regulatory filings related to our product candidates. We also expect to incur additional expenses related to milestone, royalty payments and maintenance fees payable to third parties with whom we have entered into license agreements to acquire the rights related to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from sales of any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with development and commercialization activities, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities, including establishing an appropriate safety profile with IND-directed studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial manufacturing;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;

- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- significant competition and rapidly changing technologies within the biopharmaceutical industry.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the EMA, the FDA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. Commercialization of our product candidates will take several years and millions of dollars in development costs.

UK Research and Development Tax Credits

Research and development expenditure is presented net of reimbursements from reimbursable tax and expenditure credits from the UK government. As a company that carries out extensive research and development activities, we benefit from the SME regime and, to the extent that our projects are grant funded, the RDEC regime.

The benefits from UK research and development tax credits are recognized in the statements of operations and comprehensive loss as a reduction of research and development expenses and represents the sum of the research and development tax credits recoverable in the UK.

The SME program has been particularly beneficial to us, as under such program the trading losses that arise from our qualifying R&D activities can be surrendered for a cash rebate of up to 33.35% of qualifying expenditure incurred prior to April 1, 2023 and decreasing to 18.6% after April 1, 2023. Additionally, the UK Government enacted further changes to the SME regime on March 4, 2024 which include the introduction of a new rate for R&D intensive companies of 27% (which we may qualify for) and comes into effect for expenditures incurred after April 1, 2024. Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects for which we do not receive income. 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 our subsidiary Autolus Limited, are eligible for inclusion within these tax credit cash rebate claims.

Under the RDEC program, tax credits for qualifying R&D expenditure incurred prior to April 1, 2023 are granted at a headline rate of 13% and can generate cash rebates of up to 10.5% of qualifying R&D expenditure. The headline rate of RDEC increased to 20% on April 1, 2023 and can generate cash rebates of up to 15% on qualifying R&D expenditure incurred from this date.

Amendments to the current SME and RDEC programs that are contained in the Finance Bill currently proceeding through the UK Parliament will take effect from periods on or after April 1, 2024 and will (i) (unless limited exceptions apply) introduce restrictions on the tax relief that can be claimed for expenditure incurred on sub-contracted R&D activities or externally provided workers, where such sub-contracted activities are not carried out in the UK or such workers are not subject to UK payroll taxes, and (ii) merge the SME and RDEC programs into a single scheme which would generate net cash benefit of up to 15% of the qualifying expenditure for profit making companies and up to 16.2% for loss making companies.

We currently meet the conditions of the SME regime, but we also can make claims under the RDEC regime to the extent that our projects are grant funded. In addition, we may meet the conditions of the R&D intensive scheme and may be able to make claims under merged SME R&D intensive regime. We may not be able to continue in the future to qualify as a small or medium-sized enterprise under the SME program, based on size criteria concerning employee headcount, turnover and gross assets. If we cease to qualify under the SME regime, we may make a claim under the RDEC regime for periods ending December 31, 2024, or the merged R&D regime from period ending December 31, 2025. It should be noted, however, that the types of qualifying expenditure in respect of which we may make claims under the RDEC regime are more restricted than under the SME regime (for example, it may be the case that certain subcontracted costs in respect of which claims may be made under the SME regime do not qualify for relief under the RDEC regime).

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel and share-based compensation expense for personnel in executive, finance, legal and other administrative functions. General and administrative expenses also include allocated facility-related costs, patent filing and prosecution costs and professional fees for marketing, insurance, legal, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the planned development of our product candidates. Additionally, if we believe a regulatory approval of one of our product candidates appears likely, we would anticipate an increase in salaries and related benefits as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

We have experienced, and expect to continue to experience, increased expense with being a public company, including increased accounting, audit, legal, regulatory and compliance costs associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer insurance premiums, as well as higher investor and public relations costs. Additionally, should we fail to maintain our status as a foreign private issuer, we would expect to incur increased expenses to remain compliant with applicable SEC and Nasdaq requirements.

Loss on disposal of property and equipment

Loss on disposal of property and equipment primarily consists of losses arising from the disposal of all categories of property and equipment.

Impairment of operating lease right-of-use assets and related property and equipment

Impairment of operating lease right-of-use assets and related property and equipment consists primarily of impairment losses arising from the impairment of leased properties and leasehold improvements that are currently not be utilized by us.

Other Income (Expense), net

Other income (expense), net consists primarily of foreign currency transaction gains and losses, sublease income and gains or losses arising from the termination of leases.

Interest Income

Interest income consists primarily of interest received from banks and money market funds on our cash and cash equivalents balances. We invest funds in a variety of short-term interest-bearing instruments.

Interest Expense

Interest expense consists primarily of accrued interest expense arising from amortization of the liability related to future royalties and sales milestones, pursuant to our Collaboration Agreement with Blackstone, using the effective interest rate method. On a quarterly basis, we assess the expected present value of the future Blackstone Development Payments under the Blackstone Collaboration Agreement which may be received by us and future royalties and sales milestone payments to Blackstone which may be paid by us. To the extent the amount or timing of such receipts or payments is materially different than our previous estimates we record a cumulative catch-up adjustment to the liability related to future royalties and sales milestones. The adjustment to the carrying amount is recognized as an adjustment to interest expense in the period in which the change in estimate occurred.

Income Tax Benefit (Expense)

We are subject to corporate taxation in the United Kingdom, United States, Germany and Switzerland. Due to the nature of our business, we have generated losses since inception. Our income tax benefit (expense) recognized represents the sum of income tax payable or receivable in the United Kingdom and in the United States.

Un-surrendered UK losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of United Kingdom taxable profits. After accounting for tax credits receivable, we had accumulated tax losses for carry forward in the UK of $418.1 million at December 31, 2023 and $320.8 million at December 31, 2022. No deferred tax assets are recognized on our UK 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. We carry a $3.1 million deferred tax asset balance related to the U.S. entity at December 31, 2023. We have recorded a valuation allowance against the net deferred tax asset where the recoverability due to future taxable profits is unknown. On April 1, 2023 the main rate of the UK corporation tax was increased to 25% for companies with profits in excess of £250,000, or the small profits rate of 19% for companies with profits of £50,000 or less (with marginal relief from the main rate available to companies with profits between £50,000 and £250,000).

In the event we generate profits in the future, we may benefit from the UK “patent box” regime that allows profits attributable to revenues from patents or patented products to be taxed at an effective rate of 10%.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,			
	2023	2022 (As Restated)	Change (in thousands)	Change (in percentage)
Grant income	$ —	$ 166	$ (166)	(100)%
License revenue	1,698	6,194	(4,496)	(73)%
Operating expenses:				
Research and development	(130,481)	(117,354)	(13,127)	11 %
General and administrative	(46,745)	(31,899)	(14,846)	47 %
Loss on disposal of leasehold improvements	(3,791)	(515)	(3,276)	636 %
Impairment of operating lease right-of-use assets and related property and equipment	(382)	—	(382)	100 %
Total operating expenses, net	**(179,701)**	**(143,408)**	**(36,293)**	**25 %**
Other income (expense), net	2,861	2,038	823	40 %
Interest income	13,505	1,708	11,797	691 %
Interest expense	(45,067)	(8,905)	(36,162)	406 %
Total other expense, net	**(28,701)**	**(5,159)**	**(23,542)**	**456 %**
Net loss before income tax	**(208,402)**	**(148,567)**	**(59,835)**	**40 %**
Income tax benefit	19	(272)	291	(107)%
Net loss attributable to ordinary shareholders	**$ (208,383)**	**$ (148,839)**	**$ (59,544)**	**40 %**

Grant Income

There was no grant income recognized for the year ended December 31, 2023 as compared to the $0.2 million recognized for the year ended December 31, 2022. The decrease in grant income of $0.2 million was due to a corresponding decrease in reimbursable expenditures.

License Revenue

License revenue decreased by $4.5 million for the year ended December 31, 2023. During the year ended December 31, 2023, we recognized license revenue of $1.7 million primarily relating to the execution of the Option and License Agreement with Cabaletta Bio Inc., and a non-refundable license fee and license revenue from an investee of Syncona Portfolio Limited, which is a holder of more than 10% of our share capital. During the year ended December 31, 2022, license revenue of $6.2 million primarily related to ModernaTX Inc. (“Moderna”) exercising its option to license certain of our intellectual property, and our entry into a license agreement with Bristol Myers Squibb which included recognition of a nonrefundable upfront payment.

Research and Development Expenses

The following tables provide additional detail on our research and development expenses (in thousands):

	Year Ended December 31,			
	2023	2022 (As Restated)	Change (in thousands)	Change (in percentage)
Direct research and development expenses				
B cell malignancies (Obe-cel, AUTO1/22 & AUTO3)	$ 22,855	$ 42,597	$ (19,742)	(46)%
Other projects (AUTO4, AUTO5, AUTO6, AUTO7 & AUTO8)	3,098	2,920	178	6 %
Total direct research and development expense	**25,953**	**45,517**	**(19,564)**	**(43)%**
Research and development expense and unallocated costs:				
Personnel related (including share-based compensation)	63,542	53,762	9,780	18 %
Indirect research and development expense*	40,986	18,075	22,911	127 %
Total research and development expenses	**$ 130,481**	**$ 117,354**	**$ 13,127**	**11 %**

** Indirect research and development expense includes UK research and development tax credits*

Research and development expenses increased by $13.1 million to $130.5 million for the year ended December 31, 2023 from $117.4 million for the year ended December 31, 2022 primarily due to:

- an increase of $10.8 million in salaries and other employment related costs including share-based compensation expense, which was mainly driven by an increase in the number of employees engaged in research and development activities;
- an increase of $8.2 million in facilities costs related to our new manufacturing facility, The Nucleus, as well as increases in costs related to maintaining our current leased properties;
- an increase of $5.5 million related to the development of our information technology infrastructure and support for information systems related to our new manufacturing facility; and
- a decrease of $5.1 million in UK R&D tax credits (increase in R&D expense) due to a decrease in qualifying research and development expenditures and the reduction in effective tax rate related to the UK research and development tax credit regime under the scheme for SMEs; offset by:
- a decrease of $10.2 million in clinical costs and manufacturing costs primarily relating to obe-cel;
- a decrease of $4.6 million in legal fees and professional consulting fees in relation to our research and development activities;
- a decrease of $1.2 million in depreciation and amortization related to property and equipment; and
- a decrease of $0.5 million related to a decrease in material transportation costs.

General and Administrative Expenses

General and administrative expenses increased by $14.8 million to $46.7 million for the year ended December 31, 2023 from $31.9 million for the year ended December 31, 2022 primarily due to:

- an increase of $8.3 million in salaries and other employment related costs including share-based compensation expenses, which was mainly driven by an increase in the number of employees engaged in general and administrative activities;
- an increase of $3.6 million in commercial readiness costs due to increased commercial readiness activities being undertaken;
- an increase of $1.0 million in legal fees and professional consulting fees in relation to our general and administrative activities;
- an increase of $1.0 million related to information technology infrastructure and support for information systems related to the conduct of corporate and commercial operations;
- an increase of $0.6 million in facility costs due to the increase in space utilized for general and administrative activities and related to general office expenses; and
- an increase of $0.3 million in depreciation and amortization related to property and equipment and intangible assets.

Loss on Disposal of Property and Equipment

For the year ended December 31, 2023, we recognized a loss on disposal of property and equipment of $3.8 million related to fixed assets no longer being utilized in a manufacturing facility that we exited. We incurred a loss on disposal of leasehold improvements of $0.5 million related to those leasehold improvements which were no longer being utilized at one of our Cell Therapy Catapult Limited leased facilities in Stevenage for the year ended December 31, 2022.

Impairment of Operating Lease Right-of-use Assets and Related Property and Equipment

For the year ended December 31, 2023, we recognized an impairment loss on operating lease right-of-use assets and related property and equipment of $0.4 million related to a leased property in Stevenage. There was no similar impairment recognized for the year ended December 31, 2022.

Other Income (Expense), Net

Other income, net, increased to $2.9 million for the year ended December 31, 2023 from $2.0 million for the year ended December 31, 2022. During the year ended December 31, 2023, we recognized a net foreign exchange gain of $2.6 million and sublease income of $0.3 million. This compares to the income of $2.0 million for the year ended December 31, 2022, which included a net foreign exchange gain of $1.7 million, sublease income of $0.2 million and other income of $0.1 million.

Interest Income

Interest income increased to $13.5 million for the year ended December 31, 2023, as compared to $1.7 million for the year ended December 31, 2022. The increase in interest income of $11.8 million primarily relates to an increase in yield and higher account balances associated with our cash and cash equivalents during the year ended December 31, 2023 as compared to the year ended December 31, 2022.

Interest Expense

Interest expense increased to $45.1 million for the year ended December 31, 2023 as compared to $8.9 million for the year ended December 31, 2022. Interest expense increased by $36.2 million primarily due to an increase in the balance of the liability for future royalties and sales milestones, net at December 31, 2022 and a cumulative catch-up adjustment associated with our Collaboration Agreement with Blackstone.

Comparison of Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,			
	2022 (As Restated)	2021 (As Restated)	Change (in thousands)	Change (in percentage)
Grant income	$ 166	$ 823	$ (657)	(80) %
License revenue	6,194	1,507	4,687	311 %
Operating expenses:				
Research and development	(117,354)	(110,839)	(6,515)	6 %
General and administrative	(31,899)	(31,865)	(34)	— %
Loss on disposal of leasehold improvements	(515)	(676)	161	(24) %
Total operating expenses, net	**(143,408)**	**(141,050)**	**(2,358)**	**2 %**
Other income (expense):				
Other income (expense), net	2,038	(145)	2,183	1506 %
Interest income	1,708	262	1,446	552 %
Interest expense	(8,905)	(1,105)	(7,800)	706 %
Total other expense, net	**(5,159)**	**(988)**	**(4,171)**	**422 %**
Net loss before income tax	**(148,567)**	**(142,038)**	**(6,529)**	**5 %**
Income tax benefit	(272)	(58)	(214)	369 %
Net loss attributable to ordinary shareholders	**$ (148,839)**	**$ (142,096)**	**$ (6,743)**	**5 %**

Grant Income

Grant income decreased to $0.2 million for the year ended December 31, 2022 from $0.8 million for the year ended December 31, 2021. The decrease in grant income of $0.6 million was due to a corresponding decrease in reimbursable expenditures.

License Revenue

License revenue increased to $6.2 million for the year ended December 31, 2022, primarily due to a third party, Moderna Therapeutics, exercising its option to license certain of our intellectual property, which triggered an option exercise fee, and our entry into a license agreement with Bristol Myers Squibb which included recognition of a nonrefundable upfront payment. During the year ended December 31, 2021, we recognized $1.5 million of license revenue relating to the grant of the license to Moderna.

Research and Development Expenses

The following table summarizes our research and development expenses incurred by program (in thousands):

	Year Ended December 31,			
	2022 (As Restated)	2021 (As Restated)	Change (in thousands)	Change (in percentage)
Direct research and development expenses				
B cell malignancies (Obe-cel, AUTO1/22 & AUTO3)	$ 42,597	$ 27,135	$ 15,462	57 %
Other projects (AUTO4, AUTO5, AUTO6, AUTO7 & AUTO8)	2,920	4,244	(1,324)	(31)%
Total direct research and development expense	**$ 45,517**	**$ 31,379**	**$ 14,138**	**45 %**
Research and development expense and unallocated costs:				
Personnel related (including share-based compensation)	53,762	54,228	(466)	(1)%
Indirect research and development expense	18,075	25,232	(7,157)	(28)%
Total research and development expenses	**$ 117,354**	**$ 110,839**	**$ 6,515**	**6 %**

** Indirect research and development expense includes UK research and development tax credits*

Research and development expenses increased by $6.5 million to $117.3 million for the year ended December 31, 2022 from $110.8 million for the year ended December 31, 2021 primarily due to:

- an increase of $11.6 million in clinical costs and manufacturing costs primarily relating to obe-cel;
- an increase of $0.4 million in legal fees and professional consulting fees in relation to our research and development activities;
- an increase of $0.2 million related to the development of our information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations; and
- an increase of $0.2 million in cell logistics costs; offset by:
- a decrease of $3.7 million in facilities costs related to the termination and closure of our US manufacturing facility in 2021 and a shift in our overall manufacturing strategy;
- a decrease of $0.9 million in depreciation and amortization related to property and equipment and intangible assets;
- in increase of $0.7 million in UK R&D tax credits (decrease in R&D expense) due to an increase in qualifying research and development expenditures relating to increase in clinical activities; and
- a decrease of $0.6 million in salaries and other employment costs including share-based compensation expenses, which is mainly due to lower exchange rates used upon consolidation for the year ended December 31, 2022 compared to the year ended December 31, 2021, offset by an increase in employee headcount engaged in research and development activities.

General and Administrative Expenses

General and administrative expenses remained consistent at $31.9 million for the year ended December 31, 2022 and 2021, respectively primarily due to:

- an increase of $1.4 million, in salaries and other employment costs including share-based compensation expenses, is mainly driven by an increase in the average number of employees engaged in general and administrative activities;
- an increase of $0.3 million primarily related to information technology costs; and
- a net increase of $0.1 million in legal fees and professional consulting fees in relation to our general and administrative activities, which is offset against lower cost for director and officer insurance; offset by;
- a decrease of $1.0 million of commercial preparation costs due to the timing of related activities;
- a decrease of $0.4 million in facilities costs related to the termination of certain lease agreements in the prior year; and
- a decrease of $0.4 million in depreciation and amortization related to property and equipment and intangible assets.

Loss on Disposal of Property and Equipment

We incurred a loss on disposal of leasehold improvements of $0.5 million related to those leasehold improvements which are no longer being utilized at one of our Cell Therapy Catapult Limited leased facilities in Stevenage for the year ended December 31, 2022. For the year ended December 31, 2021, we incurred a loss on disposal of leasehold improvements of $0.7 million related to the leasehold improvements no longer being utilized in the facility in White City, London.

Other Income (Expense), Net

Other income (expense), net, increased to an income of $2.0 million for the year ended December 31, 2022 from an expense of $0.1 million for the year ended December 31, 2021. During the year ended December 31, 2022, we recognized a net foreign exchange gain of $1.7 million, sublease income of $0.2 million and other income of $0.1 million. This compares to an expense of $0.1 million for the year ended December 31, 2021 which included a foreign exchange loss of $2.2 million offset by a gain on lease terminations of $2.0 million and other income of $0.1 million.

Interest Income

Interest income increased to $1.7 million for the year ended December 31, 2022, as compared to $0.3 million for the year ended December 31, 2021. The increase in interest income of $1.4 million primarily relates to the increase in interest rates on our interest-bearing bank accounts and short-term investments during the year ended December 31, 2022 as compared to the prior year.

Interest Expense

Interest expense increased to $8.9 million for the year ended December 31, 2022 as compared to $1.1 million for the year ended December 31, 2021. Interest expense is primarily related to the liability for future royalties and sales milestones, net which arose upon the execution of our strategic collaboration and financing agreement with Blackstone in November 2021. The increase in interest expense for the year ended December 31, 2022 is primarily driven by the full year of the liability related to the Blackstone collaboration in 2022 compared to a partial year liability accrued in 2021.

Liquidity and Capital Resources

Since our inception, we have not generated any commercial product revenue and have incurred operating losses and negative cash flows from our operations. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through preclinical and clinical development, seek regulatory approval and pursue commercialization of any approved product candidates. We expect that our research and development and general and administrative expenses may increase in connection with our planned research, clinical development and potential commercialization activities. As a result, we will need significant additional capital to fund our operations until such time as we can generate significant revenue from product sales.

We do not currently have any approved products and have never generated any commercial revenue from product sales. We have funded our operations to date primarily with proceeds from government grants, sales of our equity securities through public offerings and pursuant to our at-the market equity facility, through UK research and development tax credits and receipts from the UK SME and RDEC schemes, out-licensing arrangements and strategic collaboration and financing agreements. From our inception in 2014 through December 31, 2023, we have raised $1.1 billion from these capital sources.

As of December 31, 2023, we had cash and cash equivalents on hand of $239.6 million. In February 2024, we received aggregate gross proceeds of $250 million from BioNTech, consisting of $50 million in upfront payments under the License and Option Agreement and $200 million from the sale of ADSs to BioNTech in a private placement. In addition, in February 2024, we received gross proceeds of $350 million from an underwritten offering of our ADSs.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Year Ended December 31,		
	2023	**2022**	**2021**
Net cash used in operating activities	$ (145,587)	$ (112,308)	$ (117,861)
Net cash used in investing activities	(10,986)	(10,841)	(8,857)
Net cash (used in) provided by financing activities	(883)	223,610	284,063
Effect of exchange rate changes on cash, cash equivalents and restricted cash	15,030	(28,376)	(754)
Net (decrease) increase in cash, cash equivalents and restricted cash	**$ (142,426)**	**$ 72,085**	**$ 156,591**

Net Cash Used in Operating Activities

During the year ended December 31, 2023, operating activities used $145.6 million of cash, resulting from our net loss of $208.4 million, and net cash used resulting from changes in our operating assets and liabilities of $0.3 million, partially offset by non-cash charges of $62.5 million. The non-cash charges related to interest expense accrued and cumulative catch-up adjustment of $45.0 million, share-based compensation of $11.2 million, depreciation and amortization of $6.6 million, non-cash operating lease expense of $4.1 million, loss on disposal of leasehold improvements of $3.8 million, impairment of operating lease right-of-use assets and related property and equipment of $0.4 million and loss on termination of operating lease of $0.1 million which is offset by foreign exchange differences of $7.6 million and a deferred income tax movement of $1.0 million. Net cash used in operating activities resulting from changes in our operating assets and liabilities for the year ended December 31, 2023 consisted primarily of a decrease in a $13.6 million in operating lease liabilities, a decrease in accrued expenses and other liabilities of $1.0 million, and a decrease in accounts payable of $0.5 million, offset by a $12.4 million increase in prepaid expenses and other current and non-current assets and a decrease in long-term deposits of $0.9 million.

During the year ended December 31, 2022, operating activities used $112.3 million of cash, resulting from our net loss of $148.8 million, and net cash used resulting from changes in our operating assets and liabilities of $0.5 million, and by non-cash charges of $36.0 million. The non-cash charges related to share-based compensation charges of $12.0 million, interest expense accrued and cumulative catch-up adjustment of $8.9 million, depreciation and amortization of $7.4 million, foreign exchange differences of $4.0 million, non-cash operating lease expense of $3.5 million and loss on disposal of leasehold improvements of $0.5 million which is offset by a deferred tax movement of $0.3 million. Net cash used in operating activities resulting from changes in our operating assets and liabilities for the year ended December 31, 2022 consisted primarily of an increase in accrued expenses and other liabilities of $16.0 million, offset by a $10.8 million increase in prepaid expenses and other current and non-current assets and a decrease of $4.7 million in operating lease liabilities.

During the year ended December 31, 2021, operating activities used $117.9 million of cash, resulting from our net loss of $142.1 million, offset by net cash used resulting from changes in our operating assets and liabilities of $0.4 million and by non-cash charges of $23.8 million. The non-cash charges primarily related to share-based compensation charges of $9.9 million, depreciation and amortization of $8.5 million, non-cash operating lease expense of $3.7 million, interest expense accrued and cumulative catch-up of $1.1 million and loss on disposal of leasehold improvements of $0.7 million which is offset by a deferred tax movement of $0.1 million. Net cash used resulting from changes in our operating assets and liabilities for the year ended December 31, 2021, consisted primarily of a $6.1 million decrease in prepaid expenses and other assets and current and non-current and $0.6 million decrease in long term deposits, offset by a decrease of $3.9 million in accounts payable and accrued expenses and other liabilities and a decrease in operating lease liabilities of $2.4 million.

Net Cash Used in Investing Activities

During the years ended December 31, 2023, 2022, and 2021, we used $11.0 million, $10.8 million and $8.9 million, respectively, of cash in investing activities which consisted primarily of purchases of property and equipment.

Net Cash (Used in) Provided by Financing Activities

During the year ended December 31, 2023, net cash used in financing activities was $0.9 million which pertains to primarily to payments of equity issuance costs.

During the year ended December 31, 2022, net cash provided by financing activities was $223.6 million, consisting of net cash proceeds from our December underwritten public offering of $153.5 million, and $70.0 million from two development milestone payments in accordance with our collaboration and strategic financing with Blackstone. We also received cash proceeds of $0.1 million from the exercise of share options.

During the year ended December 31, 2021, net cash provided by financing activities was $284.1 million, consisting primarily of net cash proceeds of $147.6 million from our November 2021 private placement and strategic financing with Blackstone and $106.9 million from our February 2021 follow-on equity capital raise. We also raised net cash proceeds of $29.6 million through sales pursuant to our Open Market Sales Agreement with Jefferies LLC.

Cash Denomination

The following table reflects unrestricted cash denominations in U.S. dollars, U.K. pounds sterling and Euros as of (in thousands):

	December 31,	
	2023	**2022**
Total cash and cash equivalents	$ 239,566	$ 382,436
U.S. dollars	$ 105,771	$ 199,809
Pound sterling	£ 104,803	£ 151,174
Euro*	€ 343	€ 175

* Euro amounts disclosed include immaterial account balances of Swiss francs.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. Our expenses will increase as we:

- seek regulatory approvals for any product candidates that successfully complete preclinical and clinical trials;
- establish a sales, marketing and distribution infrastructure in anticipation of commercializing of any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, medical, and development personnel;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- maintain, expand and protect our intellectual property portfolio.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support development and commercialization of our product candidates.

Based on our current clinical development and commercialization plans, we believe our existing cash and cash equivalents of $239.6 million at December 31, 2023, together with the aggregate gross proceeds received in February 2024 of $600 million from the BioNTech collaboration and private placement and our underwritten offering, will enable us to fund our current and planned operating expenses and capital expenditure requirements for at least twelve months from the issuance of our annual report. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we receive regulatory approval for our other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the costs, timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the extent to which we in-license or acquire additional product candidates or technologies.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private equity offerings, reimbursable UK research and development tax credits and receipts from the UK SME and RDEC schemes, out-licensing arrangements, or strategic collaboration agreements. To the extent that we raise additional capital through the sale of equity, the ownership interest of existing shareholders may be diluted. If we raise additional funds through other third-party funding, collaborations agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

Operating Lease, Purchase, and Other Obligations

Operating Leases

As of December 31, 2023, we had operating lease obligations of $53.0 million under non-cancellable leases for laboratory and office property in the United Kingdom and United States. Further details of our operating leases are provided in Note 18 to our consolidated financial statements included in this Annual Report as well as Part I, Item 2 of this Annual Report.

Purchase Obligations

We enter into contracts in the normal course of business with CROs and other third parties for clinical trials and preclinical research studies and testing. These contracts are generally cancellable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancellable obligations of our service providers, up to the date of cancellation.

As of December 31, 2023, our unconditional purchase obligations for capital expenditures totaled $4.3 million and included signed orders for capital equipment and capital expenditure for construction and related expenditure relating to our properties in the UK and the United States, of which we expect to incur $0.4 million within one year, and $3.9 million within one to four years.

As of December 31, 2023, our unconditional purchase obligations for reagents and disposables totaled $0.6 million, which we expect to incur within one year.

We have contingent payment obligations that we may incur upon achievement of clinical, regulatory and commercial milestones, as applicable, or royalty payments that we may be required to make under our license agreements with UCLB, Noile-Immune Biotech, our advisory arrangements with Evercore and goetzpartners; however, the timing and likelihood of such payments is not currently known. Further details to our commitments are provided in Note 19 to our consolidated financial statements included in this Annual Report.

Financing obligations

Blackstone Collaboration Agreement

Pursuant to the Blackstone Collaboration Agreement, entered into on November 6, 2021, Blackstone agreed to pay us up to $150 million to support the continued development of our CD19 CAR T cell investigational therapy product candidate, obecabtagene autoleucel (obe-cel), as well as next generation product therapies of obe-cel in B-cell malignancies. These payments include (i) an upfront payment of $50 million and (ii) up to $100 million payable based on the achievement of certain specified clinical, manufacturing and regulatory milestones (each such payment, a "Blackstone Development Payment" and collectively, the "Blackstone Development Payments"). In exchange for the Blackstone Development Payments, we agreed to make payments to Blackstone (the "Revenue Share Payments") equal to a mid-single digit royalty, subject to the Aggregate Cap (as defined in the Blackstone Collaboration Agreement) on payments under the Blackstone Collaboration Agreement, based on net sales anywhere in the world of (i) Collaboration Products in B-cell malignancies, (ii) subject to certain conditions set forth in the Blackstone Collaboration Agreement, its CD19 and CD22 CAR T cell investigational therapy product candidate known as AUTO3 in B-cell malignancies, and (iii) certain Collaboration Products to the extent developed or commercialized in indications other than a B-cell malignancy ("Obe-cel Franchise Products"). We are also obligated to make payments (the "Sales Milestone Payments"), subject to the Aggregate Cap, if certain cumulative net sales levels are achieved.

In November 2021, the upfront payment of $50 million was paid by Blackstone upon execution of the Blackstone Collaboration Agreement. In December 2022, two Blackstone Development Payments were paid by Blackstone of $35 million each as a result of (i) the joint steering committee's review of Autolus' interim analysis of pivotal FELIX Phase 2 clinical trial of obe-cel in relapsed/refractory (r/r) adult Acute Lymphoblastic Leukemia (ALL) and (ii) achievement of a pre-agreed manufacturing milestone as a result of completion of planned activities demonstrating the performance and qualification of the obe-cel manufacturing process. The remaining $30 million will be payable to us on the achievement on certain specified regulatory milestones. We consider the achievement of the specified regulatory milestone as probable when actually achieved. Further details of the Blackstone Collaboration Agreement are provided in Note 11 to our consolidated financial statements included in this Annual Report.

BioNTech Collaboration Agreement

Obe-cel Revenue Interest

Under the BioNTech License Agreement, BioNTech has also agreed to financially support the expansion of the clinical development program for, and planned commercialization of obe-cel. In exchange for our grant of rights to future revenues from the sales of obe-cel, BioNTech made an upfront payment to us of $40 million. In addition, BioNTech made an upfront payment of $10 million in consideration for licenses and options granted under the agreement. We will pay BioNTech a low single-digit percentage of annual net sales of obe-cel, which may be increased up to a mid-single digit percentage in exchange for milestone payments of up to $100 million in the aggregate on achievement of certain regulatory events for specific new indications upon BioNTech's election.

JOBS Act

The Jumpstart Our Business Startups Act, or the JOBS Act, provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As of December 31, 2023, we ceased to be an emerging growth company and, as a result, are no longer able to take advantage of reduced disclosure and other obligations that are available to emerging growth companies.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ 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 included in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Lease Term—Impact on Right-of-Use Assets and Lease Liabilities

In September 2021, we entered into an arrangement for lease with the landlord, Forge Life Sciences Nominee, an affiliate of the Reef Group, for the design, construction and lease of our new 70,000 square foot commercial manufacturing facility referred to as The Nucleus, in Stevenage, United Kingdom. Under this arrangement, the landlord leased the facility to us on agreed terms, upon satisfaction of certain conditions and completion of construction. Beginning in November 2022, the landlord handed over various portions of the facility to us; on July 31, 2023, the landlord confirmed practical completion of The Nucleus. We were required to pay a pro-rated license fee for each portion of the facility which we were granted access until execution of the lease agreement. As the landlord provided us with access to portions of the facility, the definition of a lease in accordance with ASC 842 was met. The lease term can materially impact the value of the right of use assets and lease liabilities recorded on our balance sheet as required under ASC 842.

On September 19, 2023, we entered into a 20-year lease agreement with Forge Life Sciences Nominee for The Nucleus. We calculated the lease term for The Nucleus by taking into account the noncancellable period specified in the agreement together with the periods a license fee was payable by us to the landlord for portions of The Nucleus handed over to us.

Accrued interest expense and liability related to future royalties and sales milestones, net and cumulative catch-up adjustments

We accounted for the Blackstone Collaboration Agreement as a liability. The liability related to future royalties and sales milestones, net and the related accrued interest expense are measured based on our current estimates of the timing and amount of expected future royalty and milestone payments expected to be paid and the Blackstone Development Payments expected to be received over the estimated term of the agreement.

The liability is amortized using the effective interest rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreement. Each reporting period we assess the estimated probability, timing and amount of the future expected royalty, sales milestone payments and the Blackstone Development Payment over the estimated term. If there are changes to the estimates, we recognize the impact to the liability's amortization schedule and the related accrued interest expense using the catch-up method.

Our estimate of the probability, timing and amount of expected future royalties and sales milestones to be paid by us and the expected Blackstone development payment to be paid to us, considers significant unobservable inputs. These inputs include regulatory approval, the estimated patient population, estimated selling price, estimated sales, estimated peak sales and sales ramp, timing of the expected launch and its impact on the royalties as well as the overall probability of a success. Additionally, the transaction costs associated with the liability will be amortized to accrued interest expense over the estimated term of the agreements.

The carrying amount of the Blackstone Collaboration Agreement liability is based on our estimate of the future royalties and sales milestones to be paid to Blackstone by us and the expected Blackstone Development payment to be received over the life of the arrangement as discounted using the initial effective interest rate. The excess estimated present value of future royalty and sales milestone payments and the future Blackstone Development Payment received over the carrying amount is recognized as a cumulative catch-up adjustment within interest expense using the effective interest rate method.

Income Taxes and Deferred Tax

We account for income taxes under the asset and liability method which includes the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in our financial statements. Under this approach, deferred taxes are recorded for the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the current year plus deferred taxes.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. The amount of deferred tax is based on the expected manner of realization or settlement of the carrying amount of assets and liabilities, using tax rates enacted or substantively enacted at the balance sheet date. A deferred tax asset is recognized only to the extent that it is probable that future taxable profits will be available against which the asset can be utilized. No deferred tax assets are recognized on our losses carried forward and other attributes because there is currently no indication that we will make sufficient profits to utilize these attributes.

We are subject to corporate income taxes in the United Kingdom, the United States, Germany and Switzerland. The calculation of our tax provision involves the application of tax law in multiple jurisdictions and requires judgement and estimates.

We evaluate the realizability of our deferred tax assets at each reporting date, and we establish a valuation allowance when it is more likely than not that all or a portion of our deferred tax assets will not be realized.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income of the same character and in the same jurisdiction. We consider all available positive and negative evidence in making this assessment, including, but not limited to, the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. In circumstances where there is sufficient negative evidence indicating that our deferred tax assets are not more likely than not realizable, we establish a valuation allowance.

We use a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate tax positions taken or expected to be taken in a tax return by assessing whether they are more likely than not sustainable, based solely on their technical merits, upon examination, and including resolution of any related appeals or litigation process. The second step is to measure the associated tax benefit of each position as the largest amount that we believe is more likely than not realizable. Differences between the amount of tax benefits taken or expected to be taken in our income tax returns and the amount of tax benefits recognized in our financial statements represent our unrecognized income tax benefits, which we either record as a liability or as a reduction of deferred tax assets.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate accruals for research and development expenses. This process involves reviewing and identifying services which have been performed by third parties on our behalf and determining the value of these services. In addition, we make estimates of costs incurred to date but not yet invoiced, in relation to external clinical research organizations and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs, when evaluating the adequacy of the accrued liabilities for research and development. We make judgments and estimates in determining the accrued balance in any accounting period.

Recent Accounting Pronouncements Not Yet Adopted

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, “Summary of Significant Accounting Policies,” to our consolidated financial statements included in in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business, which are principally limited to interest rate fluctuations and foreign currency exchange rate fluctuations, particularly between pound sterling and U.S. dollar, and credit risks. We maintain significant amounts of cash and cash equivalents that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements.

Interest Rate Risk

Our exposure to interest rate sensitivity is primarily impacted by changes in the underlying U.S. and UK bank interest rates. As of December 31, 2023 and 2022, we had cash and cash equivalents of $239.6 million and $382.4 million, respectively. Our surplus cash has been invested in interest-bearing savings and money market funds. We have not entered into investments for trading or speculative purposes. An immediate hypothetical one percentage point change in interest rates would have resulted in a $1.3 million increase in interest income on our Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2023.

As of December 31, 2023 and 2022, we had no debt outstanding that is subject to interest rate variability. Therefore, we are not subject to interest rate risk related to debt. The Blackstone Collaboration Liability has a fixed effective interest rate and is not subject to any fluctuations due to interest rate risk.

Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. Our exposure to the risk of changes in foreign exchange rates relates primarily to fluctuations in value of foreign currency cash and cash equivalent balances held by our main operating subsidiary in the United Kingdom, our operating activities in the United States, and outsourced supplier agreements denominated in currencies other than pound sterling. We minimize foreign currency risk by maintaining cash and cash equivalents of each currency at levels sufficient to meet foreseeable expenditure to the extent practical.

As of December 31, 2023, 92% of our cash and cash equivalents were held by our UK subsidiary, of which 61% were denominated in pound sterling, 39% were denominated in U.S. dollars and immaterial amounts were denominated in euros and Swiss francs. The significant remainder of our cash and cash equivalents are held by our U.S. subsidiary and denominated in U.S. dollars.

Changes in exchange rates had a material impact on U.S. dollar balances held by our main operating subsidiary in the UK, which resulted in material foreign exchange gains and losses in the Consolidated Statements of Operations and Comprehensive Loss due to the appreciation and depreciation of the subsidiary's U.S. dollars in pounds sterling terms. Further movements in exchange rates or returns to previous exchange rate levels have caused, and may continue to cause, material fluctuations or equivalent losses in the Consolidated Statements of Operations and Comprehensive Loss.

We maintain our accounting records in pounds sterling, our functional currency, and present our consolidated financial statements in U.S. dollars for financial reporting purposes. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net income (loss) for the respective periods. We recorded foreign exchange gains of $2.6 million and $1.8 million for the years ended December 31, 2023, and 2022, respectively and a foreign exchange loss of $2.3 million for the year ended December 31, 2021, which are included in other income (expense), net in the Consolidated Statements of Operations and Comprehensive Loss.

Assets and liabilities are translated at the exchange rates at the balance sheet dates and revenue and expenses are translated at the average exchange rates and shareholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net income (loss) but are included in foreign exchange adjustment to accumulated other comprehensive income (loss), a component of shareholders' equity.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

Credit Risk

We are exposed to credit risk from our operating activities, primarily cash and cash equivalents held with banks and financial institutions. We maintain significant amounts of cash and cash equivalents that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements. Our cash and cash equivalents are held with multiple banks and financial institutions. We monitor the credit rating of those banks and financial institutions on a regularly basis. Our investment policy limits investments to certain types of instruments, such as money market funds, bank term deposits and bank notice accounts and 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.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 begin on page F-1 of this report.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed 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 Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2023. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2023, our disclosure controls and procedures were not effective due to the material weakness in internal control over financial reporting described below.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Exchange Act Rules 13a-15(f) and 15d-15(f) define this as a process designed by, or under the supervision of, our Chief Executive Officer and our Chief Financial Officer and effected by the Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Furthermore, projections of any evaluation of the effectiveness of internal controls to future periods may prove invalid due to changes in our circumstances and the risk that compliance with policies, procedures and controls is not sustained.

Management has assessed the effectiveness of internal control over financial reporting as of December 31, 2023, based on the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2023 was not effective due to the material weakness in internal control over financial reporting described below.

Material Weakness and Remediation Plan

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements for the year ended December 31, 2023, our management identified a material weakness that resulted from our misinterpretation and application of ASC Topic 740, Income Taxes, in relation to our UK small medium enterprise tax credits, which we historically presented in income tax benefit (expense) rather than as a reduction to research and development expense. The material weakness in our internal control resulted in the restatement of our consolidated financial statements as of December 31, 2023 and 2022 and for the years ended December 31, 2023, 2022 and 2021 included in this report.

Management is in the process of designing and implementing a remediation plan intended to address the control deficiency that resulted in the material weakness described above. These remediation efforts are underway and include enhancing the training provided to the individuals operating the income taxation controls. Management will report regularly to the Audit Committee regarding the status of the implementation activities.

Changes in Internal Control Over Financial Reporting

Except as described above, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of our fiscal year ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption for "non-accelerated filers."

Item 9B. Other Information

Insider Trading Arrangements

During the three months ended December 31, 2023, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth information regarding members of our senior management and our directors, including their ages as of March 21, 2024. There are no family relationships among any of our senior management or our directors.

NAME	AGE	POSITION(S)
Senior Management:		
Christian Itin, Ph.D.	59	Chief Executive Officer and Director
Robert Dolski	54	Senior Vice President, Chief Financial Officer
Edgar Braendle, M.D.*	64	Senior Vice President, Chief Development Officer
David Brochu	68	Senior Vice President, Chief Technical Officer
Martin Pulé, MBBS	51	Senior Vice President, Founder, Chief Scientific Officer
Brent Rice	57	Senior Vice President, Chief Commercial Officer
Alexander Swan	59	Senior Vice President, Chief Human Resources Officer
Christopher Vann	59	Senior Vice President, Chief Operating Officer
Christopher Williams, Ph.D.	44	Senior Vice President, Chief Business Development Officer
Non-Executive Directors:		
John Johnson	66	Chairman of the Board of Directors
Joseph Anderson, Ph.D.	64	Director
Robert Azelby	56	Director
Linda Bain	53	Director
John Berriman	75	Director
Cynthia Butitta	69	Director
Robert Iannone, M.D., M.S.C.E.	57	Director
Elisabeth Leiderman, M.D.	47	Director
Martin Murphy, Ph.D.	55	Director
William Young, Ph.D.	79	Director

*On March 14, 2024, we announced Dr. Edgar Braendle had tendered his resignation.

Senior Management

Christian Itin, Ph.D. has served as our Chief Executive Officer since 2016 and as a director since 2014. He served as Chairman of our board of directors from 2014 to September 2021. Prior to joining us, Dr. Itin served as chief executive officer and chairman of the board of directors at Cytos Biotechnology Ltd, a biotechnology company, from 2012 until it merged with Kuros Biosurgery Holding Ltd in 2016. From 2016 until 2018, he served as chairman, and from 2018 to 2019 as non-executive director, of Kuros Biosciences Ltd. Dr. Itin served as president, chief executive officer and director of Micromet, Inc., a biopharmaceutical company, from 2006 until it was acquired by Amgen Inc. in 2012. From 1999 until 2006, he served in a number of capacities with Micromet, Inc.'s subsidiary, Micromet AG, including head of IP and licensing, vice president of business and corporate development, chief business officer and ultimately as its chief executive officer. Before joining Micromet, Dr. Itin was a co-founder of Zyomyx, a protein chip company. Dr. Itin also served as a non-executive director of Kymab Ltd., a privately held biopharmaceutical company, from 2012 until its sale to Sanofi in 2021. Dr. Itin received a Diploma in Biology and a Ph.D. in Cell Biology summa cum laude from the University of Basel, Switzerland. In addition, he performed post-doctoral research at the Biocenter of University of Basel and at the Stanford University School of Medicine. We believe that Dr. Itin is qualified to serve on our board of directors because of his deep knowledge of our company and his extensive experience serving in executive and non-executive leadership positions at other public and private biotechnology companies.

Robert Dolski has served as our Chief Financial Officer since August 2023. He previously served as Chief Financial Officer at Checkmate Pharmaceuticals from January 2021, until its acquisition by Regeneron Pharmaceuticals in May 2022, where he was responsible for investor relations, financial strategy and management. He served as Vice President, Finance at Akcea Therapeutics from May 2019, until its acquisition by Ionis Pharmaceuticals in October 2020, where he held similar finance responsibilities and supported the development and commercialization of several rare disease programs. Mr. Dolski served as Vice President, Head of Financial Planning and Analysis at Moderna Therapeutics from 2016 to May 2019, as Senior Director, Finance at Forum Pharmaceuticals, Inc., and as Vice President, Finance and Treasury at Human Genome Sciences, Inc., prior to its acquisition by GlaxoSmithKline. Mr. Dolski started his career as Director of Finance at Amgen Inc. He holds an MBA from The Wharton School of the University of Pennsylvania and a B.S..degree in civil engineering and strategic management from the University of Pennsylvania.

Edgar Braendle, M.D., has served as our Chief Development Officer since July 2021. Prior to joining us, he served as Chief Medical Officer and Global Head of Development at Sumitomo Dainippon Pharma Oncology ("SDPO") from July 2020 to July 2021, where he was responsible for leading the global oncology development programs. Prior to then, from October 2017 until July 2020, Dr. Braendle served as Executive Vice President, Head of Research and Development and Chief Medical Officer at Boston Biomedical Inc., where he led their discovery research and clinical strategies. He started his industry career at Schering AG. Dr. Braendle has a M.D and training in hematologic malignancies and solid tumor oncology, pharmacology and urology at the University of Aachen, University of Bonn, and the University of Ulm in Germany.

David Brochu has served as our Senior Vice President, Chief Technical Officer since January 2021, having previously served as our Senior Vice President, Head of Product Delivery from October 2019 to January 2021 and as our Vice President of Technical Operations from March 2019 to October 2019. Mr. Brochu previously served as vice president of technical operations and program head at Kedrion USA, leading its next generation IVIG development and industrialization effort. Prior to this, he was the vice president of plasma collection operations for Talecris Biotherapeutics (formerly Bayer HealthCare LLC), where he led the operations buildout in the Western United States. He previously held engineering and technical operations leadership roles at Bayer and Warner Lambert in the United States, EU and South America. Mr. Brochu has over 30 years of operational and development experience. He holds a B.S. degree in chemical engineering from Northeastern University.

Martin Pulé, MBBS founded our predecessor company and has served as our Senior Vice President and Chief Scientific Officer since 2014. He also served as a member of our predecessor company's board of directors from 2014 to 2018. Dr. Pulé has served as a clinical senior lecturer in the Department of Hematology at UCL Cancer Institute since 2010 and as an Honorary Consultant in Hematology at UCL Hospital since 2010. He entered the T cell engineering field in 2001 as a travelling Fulbright Scholar at the Center for Cell and Gene Therapy at Baylor College of Medicine, Houston, Texas. Dr. Pulé holds an M.B.B.S. degree from University College Dublin and is a Fellow of the Royal College of Pathologists.

Brent Rice has served as our Senior Vice President, Chief Commercial Officer since December 2021, having previously served as our Vice President, Chief Commercial Officer (US) from June 2020 to December 2021 and as our Vice President, Global Market Access from October 2018 to June 2020. Previously, Mr. Rice served as the Head of Managed Markets for Juno Therapeutics from 2017 to 2018, where he was responsible for building its payer, access and reimbursement strategy and capability. Prior to joining Juno Therapeutics, Mr. Rice served with Amgen Inc. from 1999 to 2017 in positions of escalating responsibility, where he supported Amgen's portfolio of products through partnerships and life cycle management. Mr. Rice holds a B.A. degree in Russian Studies from the University of California at Los Angeles and an M.B.A. from the University of Denver.

Alexander Swan has served as our Chief Human Resources Officer since January 2023, having previously served as our Senior Vice President, Human Resources from October 2021 to January 2023 and as our Vice President, Human Resources from May 2018 to October 2021. Prior to joining our company, he was EMEA Head of Human Resources for Kite Pharma, where he was responsible for all aspects of human resources, including talent management, organization development, policy and procedure development and compensation and benefits. Previously, Mr. Swan was involved in a number of start-up companies, including Amryt Pharmaceuticals, Taiho Oncology and Aegerion Pharmaceuticals. From 2004 to 2012, Mr. Swan was responsible for developing and leading all HR-associated activities for Celgene in EMEA. He has also held a number of positions within local government and the UK National Health Service, helping strategically with talent acquisition and organization development. Mr. Swan holds a Master's degree in Law from the University of Leicester and is also a Fellow of the Chartered Institute of Personnel and Development.

Christopher Vann has served as our Senior Vice President, Chief Operating Officer since 2016. Prior to joining us, he worked at Hoffmann-La Roche's Swiss headquarters from 1994 to 2016, most recently serving as its commercial director from 2011 to 2016, where he was primarily responsible for leading the lung cancer commercial team and general management of the Tarceva brand. Mr. Vann has significant experience in global lifecycle management of oncology products as well as implementing marketing strategy at a regional and national level. This includes launching several oncology, immunology and transplant products in the United States, United Kingdom, Romania, Russia, South Africa and countries in Asia, including Japan. Mr. Vann holds a B.S. degree in Toxicology and Pharmacology from the School of Pharmacy, University of London.

Christopher Williams, Ph.D. has served as our Chief Business Officer since January 2024. Prior to this role, he served as Senior Vice President, Corporate Development from October 2021 to February 2024, and as Vice President, Global Head of Business Development from December 2018 to October 2021. Dr. Williams was part of the team that founded our predecessor company in 2014 and he initially served as a non-executive director of Autolus Limited. In 2016, he transitioned to establish our business development function as Director, Business Development. He previously worked at UCL Business, where he led the establishment of strategic collaborations, licensing deals, new companies, and financing transactions across a portfolio of cell and gene therapies in oncology and rare diseases. He served as non-executive director of Orchard Therapeutics, a company he founded during his tenure at UCL Business, and has worked in business development roles at Thiologics, Canbex and Eli Lilly. He has also worked in research roles at GSK, Inpharmatica and Imperial College London. Dr. Williams holds a Ph.D. in Biochemistry from Imperial College London and a B.Sc. degree in Genetics from Cardiff University.

Non-Executive Directors

John H. Johnson was appointed as Chairman of our board of directors in September 2021. Since May 2022, he has served as the Chief Executive Officer and a non-executive director of Reaction Biology, a provider of drug discovery services. Previously, he served as Chief Executive Officer of Strongbridge Biopharma plc, between July 2020 and October 2021, until its acquisition by Xeris Biopharma Holdings. Since October 2021, he has served as a non-executive director for Xeris. He previously served as chairman of Strongbridge's board of directors from 2015 until November 2019 and Executive Chairman from November 2019 until July 2020. Additionally, he has served as a member of the board of directors of Verastem, Inc. since April 2020, and Axogen, Inc. since July 2021. Mr. Johnson served as a board member of Melinta Pharmaceuticals, Inc. through September 2019, having served as Chief Executive Officer from February 2019 through August 2019 and as interim Chief Executive Officer from October 2018 through February 2019. Mr. Johnson is the former lead independent director of Sucampo Pharmaceuticals, Inc., from 2016 until 2018, and a former director of Histogenics Corporation, from 2013 until 2019, AVEO Pharmaceuticals, Inc., from 2018 until 2019, and Portola Pharmaceuticals, Inc., from 2014 until 2020. From July 2018 to November 2018, Mr. Johnson served as an interim executive officer of Portola. He is a recognized leader in the biopharmaceutical industry with more than 30 years of experience at leading global organizations, including Johnson & Johnson, Eli Lilly & Company, ImClone, and Pfizer, Inc. Mr. Johnson previously served on the board of directors of Pharmaceutical Research and Manufacturers of America (PhRMA), the Health Section Governing Board of Biotechnology Industry Organizations (BIO), and BioNJ, and holds a B.S. degree from East Stroudsburg University of Pennsylvania. We believe that Mr. Johnson is qualified to serve on our board of directors because of his extensive experience with life science companies.

Joseph Anderson, Ph.D. has served on our board of directors since 2016. He is a Partner at Sofinnova Partners, an investment firm that he joined in October 2020. He served as the chief executive officer and a member of the board of directors of Arix Bioscience plc, a global life sciences company, from 2016 to 2020. He has founded and managed public equity funds and served as a member of the following boards of directors: Algeta ASA (acquired by Bayer AG) from 2009 to 2013, Amarin plc from October 2009 to 2013, Cytos Biotechnology Ltd, a biotechnology company, from 2012 until it merged with Kuros Biosurgery Holding Ltd in 2016, and Epigenomics AG from 2012 to 2014. He was a partner at Abingworth LLP, an international investment group dedicated to the life sciences and healthcare sectors, from 2004 to 2015. From 1999 to 2003, Dr. Anderson served at First State Investments in London, part of the Commonwealth Bank of Australia, where he was head of global healthcare equities and portfolio manager. He was a pharmaceuticals analyst at the investment bank Dresdner Kleinwort Benson from 1998 to 1999. From 1990 to 1998, Dr. Anderson established and was head of the strategy unit at The Wellcome Trust, one of the world's largest medical foundations. He currently serves as a non-executive director of RedX Pharma plc and F2G Limited. Dr. Anderson holds a Ph.D. in Biochemistry from the University of Aston and a B.S. degree in Biological Science from Queen Mary College, University of London. We believe that Dr. Anderson is qualified to serve on our board of directors because of his extensive experience with life science companies.

Robert Azelby has served on our board of directors since January 2024. He most recently served as President and Chief Executive Officer of Eliem Therapeutics Inc., between October 2020 and February 2023. Prior to Eliem, he served as the Chief Executive Officer of Alder BioPharmaceuticals, Inc. from 2018 until its acquisition by H. Lundbeck A/S in October 2019. Mr. Azelby served as Executive Vice President, Chief Commercial Officer of Juno Therapeutics, Inc. from 2015 through its acquisition by Celgene in 2018. Earlier, during a 15-year tenure at Amgen, Mr. Azelby served in commercial roles including Vice President and General Manager of Amgen Oncology, Vice President of Oncology Sales, Vice President of the Commercial Effectiveness Unit and General Manager of Amgen Netherlands. He currently serves on the Board of Directors at ADC Therapeutics SA, since June 2023, and also served on the Board of Directors of Chinook Therapeutics Inc. between April and August 2023, Clovis Oncology Inc. from 2018 until July 2023, Eliem Therapeutics Inc. from 2020 until February 2023, Alder BioPharmaceuticals Inc. from 2018 until November 2019, and Immunomedics, Inc. from February 2020 to October 2020. He holds a B.A. degree in Economics and Religious Studies from the University of Virginia and an MBA from Harvard Business School. We believe that Mr. Azelby is qualified to serve on our board of directors because of his broad experience in our industry, his commercial and management background and his track record of effective leadership.

Linda Bain has served on our board of directors since 2018. She currently serves as the Chief Operating Officer and Chief Financial Officer of Mariana Oncology, Inc., positions she has held since May 2023. She has also served as a non-executive director of Arvinas, Inc. since June 2020 and Hemab Therapeutics since January 2022. Between July 2021 and September 2022, Ms. Bain served as a non-executive director for VBI Vaccines, Inc. Prior to joining Mariana Oncology, Ms. Bain served as the Chief Financial Officer of Codiak Biosciences, Inc. from 2015 to April 2023 and Chief Financial Officer and treasurer of Avalanche Biotechnologies, Inc. from 2014 to 2015. Ms. Bain served at Bluebird bio, Inc., a gene therapy biotechnology company, as vice president of finance and business operations from 2011 to 2014, and Chief Accounting Officer and treasurer from 2013 to 2014. From 2008 to 2011, Ms. Bain served as Vice President of Finance at Genzyme Corporation. From 2007 to 2008, she served as vice president at Fidelity Investments, and from 2000 to 2007, she held a number of positions at AstraZeneca plc. She received her B.S. degree in Accounting and Business Administration and an Honors Degree in Accounting and Business Administration from the University of the Free State in South Africa. Ms. Bain is a certified public accountant. We believe that Ms. Bain is qualified to serve on our board of directors because of her extensive experience in our industry, her background in accounting and finance and her leadership skills.

John Berriman has served on our board of directors since 2014. He has served as chairman of the board of directors of Depixus SAS since 2015, and Autifony Therapeutics Ltd. since 2011. He previously served as chairman of the board of directors of Confo Therapeutics NV, between 2016 and August 2023, ReNeuron Group plc between 2015 and September 2020, Heptares Therapeutics Ltd from 2007 until its acquisition by Sosei Group in 2015, Algeta ASA from 2004 through its listing on the Oslo Stock Exchange in 2007 (and subsequently served as deputy chairman from 2008 until it was sold to Bayer AG in 2014), and as a director of Micromet, Inc. from 2006 until it was sold to Amgen Inc. in 2012. From 1997 to 2004, he was a director of Abingworth Management, an international healthcare venture capital firm, where he was involved in founding, financing and serving as a director of several biotechnology companies in Europe and the United States, many of which obtained listings on public stock exchanges. Prior to that, Mr. Berriman spent 14 years with Celltech Group plc and was a member of its board when it listed on the London Stock Exchange in 1994. He holds a M.S. in Chemical Engineering from the University of Cambridge and an M.B.A. from the London Business School. We believe that Mr. Berriman is qualified to serve on our board of directors because of his extensive experience in our industry, including his strategic management and operational experience, his experience serving on public company boards and his experience with public offerings, private investments and mergers.

Cynthia Butitta has served on our board of directors since 2018. Ms. Butitta served as the executive vice president and chief financial officer of Kite Pharma Inc., a biopharmaceutical company, from 2014 to 2016 and as its chief operating officer from 2014 to 2017. From 2011 to 2012, she served as senior vice president and chief financial officer at NextWave Pharmaceuticals, Inc., a specialty pharmaceutical company. Ms. Butitta served as chief operating officer of Telik, Inc., a biopharmaceutical company, from 2001 to 2010 and as its chief financial officer from 1998 to 2010. She has served as a member of the board of directors of UroGen Pharma Ltd. since 2017, Olema Pharmaceuticals Inc. since 2020 and Century Therapeutics since 2021. Ms. Butitta holds a B.S. degree with honors in Business and Accounting from Edgewood College in Madison, Wisconsin and an M.B.A. in Finance from the University of Wisconsin, Madison. We believe that Ms. Butitta is qualified to serve on our board of directors because of her extensive financial and operational experience within the biotechnology and high-technology industries, as well as her leadership skills.

Robert Iannone, M.D., M.S.C.E. has served on our board of directors since June 2023. Since May 2019, he has served as Executive Vice President, Global Head of Research & Development of Jazz Pharmaceuticals plc., and also served as its Chief Medical Officer from December 2019 until October 2021. From April 2018 until May 2019, Dr. Iannone served as Head of Research and Development and Chief Medical Officer of Immunomedics, Inc., a biopharmaceutical company. From 2014 to 2018, he served as Senior Vice President and Head of Immuno-oncology, Global Medicines Development, and the Global Products Vice President at AstraZeneca plc. From 2004 to 2014, Dr. Iannone held several management roles at Merck & Co., Inc., culminating in his role as Executive Director and Section Head of Oncology Clinical Development. Before joining industry, Dr. Iannone was Assistant Professor of Pediatrics at the University of Pennsylvania School of Medicine. He has served on the board of directors of iTeos Therapeutics, Inc., a clinical-stage biopharmaceutical company, since May 2021, and previously served on the Board of Jounce Therapeutics between January 2020 and its acquisition by Concentra Biosciences in May 2023. He has served on the Cancer Steering Committee of the Foundation for the National Institutes of Health since 2011. Dr. Iannone received an B.S. degree from The Catholic University of America, an M.D. from Yale University and an M.S.C.E. from the University of Pennsylvania. He completed his Residency and Chief Residency in Pediatrics and a Fellowship in Pediatric Hematology-Oncology at Johns Hopkins University. We believe that Dr. Iannone is qualified to serve on our board of directors because of his extensive experience as a pharmaceutical company executive and in the clinical development and regulation of pharmaceuticals.

Elisabeth Leiderman, M.D, has served on our board of directors since December 2023. She most recently served as the Chief Financial Officer and Chief Business Officer of Atsena Therapeutics, a clinical-stage gene therapy company focused on reversing and preventing blindness, from November 2022 until November 2023. From September 2020 until October 2022, she served as Chief Financial Officer and Head of Corporate Development for Decibel Therapeutics, a clinical-stage biotechnology company developing novel gene therapeutics for restoration of hearing loss and balance disorders. Before joining Decibel, from January 2020 to August 2020, Dr. Leiderman served as Chief Business Officer for Complexa, Inc., a clinical stage biopharmaceutical company focused on life-threatening fibrosis and inflammatory diseases. Prior to Complexa, she served as Senior Vice President, Head of Corporate Development at Fortress Biotech from 2016 to 2019. Dr. Leiderman is currently a member of the board of directors and chair of the audit committee of bluebird bio, Inc., a position she has held since October 2021. Earlier in her career, from 2007 to 2016, Dr. Leiderman developed transaction and capital markets expertise in the healthcare investment banking groups at Nomura, Credit Suisse, Jefferies and UBS. Dr. Leiderman began her career in medical affairs at AstraZeneca, where she analyzed product and industry trends related to the central nervous system. Dr. Leiderman holds an M.D. from the Sackler School of Medicine at Tel Aviv University, an M.B.A. from The Wharton School at the University of Pennsylvania and a B.A. degree from the University of Pennsylvania. We believe that Dr. Leiderman is qualified to serve on our board of directors because of her extensive experience as a pharmaceutical company executive, her financial and operational expertise, and her leadership skills.

Martin Murphy, Ph.D. has served on our board of directors since 2014. He served as Chair of Syncona Investment Management Limited, part of the global life science company Syncona Ltd., from January 2023 until November 2023 and as the chief executive officer of Syncona Investment Management Limited from 2016 until December 2022, and he founded Syncona Partners LLP and served as its chief executive officer from 2012 to 2016. He was a partner at MVM Life Science Partners LLP, a venture capital company focused on life science and healthcare investments, from 2003 to 2012. During his time at MVM, Dr. Murphy was a member of the management and investment committees and led MVM's European operations. Before MVM, Dr. Murphy worked at 3i Group plc and McKinsey & Company. He has a Ph.D. in Biochemistry from the University of Cambridge. We believe that Dr. Murphy is qualified to serve on our board of directors because of his extensive experience as an investor, particularly in the life sciences industry.

William D. Young, Ph.D. has served on our board of directors since November 2021 and was appointed to our board of directors as Blackstone's designee pursuant to the terms of the collaboration and financing agreement we entered into with Blackstone in November 2021. He has served as a Senior Advisor to the Blackstone Life Sciences group since 2018, following Blackstone's acquisition of Clarus Ventures. Mr. Young became a Venture Partner with Clarus in 2010 after serving as Chief Executive Officer of Monogram Biosciences, from 1999 until the sale of the company to LabCorp in 2009. Prior to then, he was at Genentech for 19 years, serving in various positions of increasing responsibility, most recently serving as Chief Operating Officer, and was responsible for all of the biotechnology company's development, operations and commercial functions. Prior to Genentech, Mr. Young was at Eli Lilly and Company for 14 years. Mr. Young has served as chairman of the board of directors of Nanostring Technologies since 2010 and as a non-executive director of Praxis Precision Medicine since 2016. Previously he served on the board of directors of Theravance Biopharma between 2013 and 2014 and as its lead independent director between 2014 and May 2023, and as a director of Vertex Pharmaceuticals from 2014 until 2020. Mr. Young received his B.S degree in chemical engineering from Purdue University, his MBA from Indiana University and an honorary doctorate in engineering from Purdue University. In 1993, he was elected to the National Academy of Engineering for his leadership in research, development and manufacturing of recombinant proteins using recombinant DNA technology. We believe that Dr. Young is qualified to serve on our board of directors because of his extensive experience in the life sciences industry.

Board Diversity

The table below provides certain information regarding the diversity of our board of directors as of March 21, 2024. Our 2023 Board Diversity Matrix is included in our Annual Report on Form 20-F, filed with the SEC on March 7, 2023.

Board Diversity Matrix				
Country of Principal Executive Offices:	United Kingdom			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
Total Number of Directors	11			
	Male	**Female**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	8	3	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	0	0	0	0
LGBTQ+	0			
Did Not Disclose Demographic Background	0			

Code of Ethics

We have adopted a Code of Business Conduct and Ethics, or the Code of Ethics, that is applicable to all of our employees, officers and directors and is available on our website at https://www.autolus.com/investor-relations/corporate-governance/documents-charters. Information contained on, or that can be accessed through, our website does not constitute a part of this report and is not incorporated by reference herein. If we make any amendment to the Code of Ethics or grant any waivers, including any implicit waiver, from a provision of the Code of Ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. If a waiver or amendment of the Code of Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B of Form 20-F, we are required to disclose such waiver or amendment on our website.

Composition of Our Board of Directors

Our board of directors presently has eleven members. As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that Drs. Anderson, Iannone, Leiderman and Murphy, Mses. Butitta and Bain and Messrs. Azelby, Berriman, Johnson and Young representing ten of our eleven directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of director and that each of these directors is "independent" as that term is defined under Nasdaq rules.

Pursuant to the BioNTech Letter Agreement, BioNTech received the right to nominate a director to the Company's board of directors. If BioNTech acquires beneficial ownership of at least 30% of the issued and outstanding Ordinary Shares of the Company within five years of the Execution Date, BioNTech will have the right to designate an additional director who shall be independent. BioNTech's director nomination rights under the BioNTech Letter Agreement shall automatically terminate upon BioNTech's ownership of Ordinary Shares dropping below certain specified percentages.

In accordance with our Articles of Association, our board of directors are divided into three classes with staggered three-year terms. At each annual general meeting of shareholders, the directors whose terms expire will retire and are eligible for re-appointment by ordinary resolution at such annual general meeting. At each annual general meeting, the successors to directors whose terms then expire or the directors who have been re-appointed will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- Class I, which consists of Joseph Anderson, Martin Murphy and Robert Iannone vacancy, whose terms will expire at our 2025 annual general meeting;
- Class II, which consists of John Johnson, Robert Azelby, John Berriman and Elisabeth Leiderman, whose terms will expire at our 2026 annual general meeting;
- Class III, which consists of Christian Itin, Cynthia Butitta, Linda Bain and William Young, whose terms will expire at our 2024 annual general meeting.

Each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal.

Committees of Our Board of Directors

Our board of directors has four standing committees: an audit committee, a compensation committee, a nominating and corporate governance committee, and a research and development committee. The board has adopted a written charter for each of the committees below that is available to shareholders on our website at http://www.autolus.com/investor-relations/corporate-governance.

Audit Committee

The audit committee is composed of Ms. Bain (chair), Dr. Anderson, Ms. Butitta and Dr. Leiderman, and assists the board of directors in overseeing our accounting and financial reporting processes. The audit committee consists exclusively of members of our board who are financially literate, and our board of directors has determined that Ms. Bain is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board of directors has determined that each member of the audit committee is an independent director under Nasdaq listing rules and under Rule 10A-3 under the Exchange Act. Our audit committee meets at least four times per year and oversees and reviews our internal controls, accounting policies and financial reporting, and provides a forum through which our independent registered public accounting firm reports. Our audit committee meets regularly with our independent registered public accounting firm without management present.

The primary functions of the audit committee include:

- recommending the appointment of the independent auditor to shareholders for approval at the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board of directors on at least an annual basis;
- reviewing and discussing with management and our independent registered public accounting firm our financial statements and our financial reporting process; and
- reviewing, approving or ratifying any related party transactions.

Compensation Committee

The compensation committee is composed of Mr. Berriman (chair), Ms. Butitta and Dr. Murphy. Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard board member fees. Although foreign private issuers are not required to meet this heightened standard, all of our compensation committee members meet this heightened standard.

The primary functions of the compensation committee include:

- identifying, reviewing, overseeing and proposing policies relevant to the compensation and benefits of our directors and senior management;
- evaluating the performance of senior management in light of such policies and reporting to the board; and
- overseeing and administering our share option plan, equity incentive plan and other benefit plans in operation from time to time.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is composed of Mr. Young (chair), Dr. Anderson, Mr. Azelby and Ms. Bain.

The primary functions of the nominating and corporate governance committee include:

- drawing up selection criteria and appointment procedures for directors;
- recommending nominees for appointment to our board of directors and its corresponding committees; and
- assessing the functioning of individual members of our board of directors and management and reporting the results of such assessment to the full board of directors.

Research and Development Committee

The research and development committee is composed of Drs. Iannone, Itin and Murphy and Mr. Young.

The primary functions of the research and development committee include:

- overseeing our scientific, technical, research and development strategy, and the implementation thereof;
- advising our board of directors and management regarding program prioritization, clinical development strategy, regulatory strategy and interactions, intellectual property, product manufacture and supply, and related matters; and
- reviewing and assessing business development opportunities related to research collaborations, licensing or strategic transactions.

Corporate Governance.

We qualify as a "Foreign Private Issuer," as defined in Rule 3b-4 under the Exchange Act. As a result, in accordance with Nasdaq listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards.

Although we have voluntarily chosen to file registration statements, periodic reports and current reports on U.S. domestic issuer forms, we will maintain our status as a foreign private issuer. While we voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of limited exemptions from the following:

- U.S. federal proxy rules pursuant to Section 14 of the Exchange Act and Regulations 14A and 14C thereunder;
- Regulation FD;
- Section 16 rules requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades in a short period of time, which will provide less data in this regard than shareholders of U.S. companies that are subject to the Exchange Act;
- the requirement that our board have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- the requirement to have independent director oversight of director nominations.

We intend to follow U.K. corporate governance practices in lieu of Nasdaq corporate governance requirements as follows:

- We do not intend to follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under English law. In accordance with generally accepted business practice, our Articles of Association provide alternative quorum requirements that are generally applicable to meetings of shareholders.
- We do not intend to follow Nasdaq Rule 5605(b)(2), which requires that independent directors regularly meet in executive sessions where only independent directors are present. Our independent directors may choose to meet in executive sessions at their discretion.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq's Notification of Noncompliance requirement (Nasdaq Rule 5625) and the Voting Rights requirement (Nasdaq Rule 5640). Further, we must have an audit committee that satisfies Nasdaq Rule 5605(c)(3), which addresses audit committee responsibilities and authority and requires that the audit committee consist of members who meet the independence requirements of Nasdaq Rule 5605(c)(2)(A)(ii).

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and Nasdaq listing rules. Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

Item 11. Executive Compensation

As a foreign private issuer, we are permitted by Item 402(a)(i) of Regulation S-K to respond to this Item 11 by providing the information required by Items 6.B. and 6.E.2 of Form 20-F. Accordingly, we are not required to disclose executive compensation according to the requirements of Regulation S-K that are applicable to U.S. domestic issuers.

The following discussion provides the amount of compensation paid, and benefits in-kind granted, by us and our subsidiaries to our directors, members of our senior management and non-employee directors for services in all capacities to us and our subsidiaries for the year ended December 31, 2023, as well as the amount contributed by us or our subsidiaries into money purchase plans for the year ended December 31, 2023 to provide pension, retirement or similar benefits to, our directors, members of our senior management and non-employee directors.

Director Compensation

For the year ended December 31, 2023, the table below sets forth the compensation paid to our directors. In the case of Dr. Itin, our Chief Executive Officer, the table below sets forth the compensation paid to him for services as a member of our senior management. He does not receive any compensation for serving as an executive director. All such amounts are established and paid in pounds sterling.

Name	Salary/Fees	Annual Bonus	Pension Benefit	All Other Compensation	Total
Christian Itin, Ph.D. Executive Director	£ 432,000	£ 362,880	£ —	£ 1,126,261	£ 1,921,141
John Johnson Chairman of the Board	£ 51,876	£ —	£ —	£ 154,774	£ 206,650
Joseph Anderson, Ph.D. Non-Executive Director	£ 40,872	£ —	£ —	£ 122,273	£ 163,145
Jay Backstrom, M.D, M.P.H* Non-Executive Director	£ 7,000	£ —	£ —	£ —	£ 7,000
Linda Bain Non-Executive Director	£ 47,250	£ —	£ —	£ 122,273	£ 169,523
John Berriman Non-Executive Director	£ 40,872	£ —	£ —	£ 122,273	£ 163,145
Cynthia Butitta Non-Executive Director	£ 42,372	£ —	£ —	£ 122,273	£ 164,645
Kapil Dhingra, M.D.**** Non-Executive Director	£ 48,581	£ —	£ —	£ 75,814	£ 124,395
Robert Iannone, M.D., M.S.C.E** Non-Executive Director	£ 20,481	£ —	£ —	£ 114,382	£ 134,863
Elisabeth Leiderman, M.D.*** Non-Executive Director	£ 1,169	£ —	£ —	£ 11,556	£ 12,725
Martin Murphy, Ph.D. Non-Executive Director	£ 36,003	£ —	£ —	£ 122,273	£ 158,276
William Young, Ph.D. Non-Executive Director	£ 37,708	£ —	£ —	£ 138,116	£ 175,824

* *Dr. Backstrom resigned from the board of directors effective February 28, 2023.*

** *Dr. Iannone joined the board of directors effective June 15, 2023.*

*** *Dr. Leiderman joined the board of directors effective December 20, 2023.*

**** *Dr. Dhingra resigned from the board of directors effective December 31,2023.*

Non-Executive Letters of Appointment

Non-executive directors are engaged on letters of appointment that set out their duties and responsibilities. The non-executive directors do not receive benefits upon termination or resignation from their respective positions as directors.

Non-Executive Director Compensation Policy

In April 2023, following market research and advice from its compensation consultant, our board of directors amended our non-executive director compensation policy to increase the retainer fee and equity awards for, respectively, the chair and other non-executive directors.

Under this policy, we pay each of our non-executive directors a cash retainer for service on our board of directors and committees of our board of directors. Our chair or lead independent director, as applicable, also receives an additional cash retainer. These retainers are payable in arrears in twelve equal monthly installments at the end of each calendar month, provided that the amount of such payment will be prorated for any portion of such month that the director is not serving on our board. Non-executive directors residing outside the UK will be paid the applicable amounts converted from pounds sterling into a currency of their request at the time of payment. We will also reimburse our directors for their reasonable out-of-pocket expenses in connection with attending board and committee meetings.

Non-executive directors are eligible to receive cash compensation as follows:

	Annual Cash Retainer (£)
Annual retainer for board of director chair	52,500
Annual retainer for board of director member	31,500
Additional retainer for audit committee chair	13,000
Additional retainer for audit committee member	6,500
Additional retainer for compensation committee chair	10,000
Additional retainer for compensation committee member	5,000
Additional retainer for nominating and governance committee chair	7,000
Additional retainer for nominating and governance committee member	3,500
Additional retainer for research and development committee chair	12,000
Additional retainer for research and development committee member	6,000

Equity Compensation

In addition to cash compensation, each non-executive director is eligible to receive share options under our equity incentive plans. Any share options granted under this policy shall have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of service. Vesting schedules for equity awards are subject to the non-executive director's continuous service on each applicable vesting date.

Notwithstanding any vesting schedule, for each non-executive director who remains in continuous service with us until immediately prior to the closing of a change in control (as such term is defined in our 2018 Plan), the shares subject to his or her then-outstanding initial or annual equity awards that were granted pursuant to this policy will become fully vested immediately prior to the closing of such change in control.

Upon the termination of the membership of the non-executive director on the board for any reason, his or her options granted under this policy shall remain exercisable for three months following his or her date of termination (or such longer period as the board may determine in its discretion on or after the date of grant of such options).

Initial Award

Each new non-executive director elected to our board of directors is granted an initial, one-time equity award of options to purchase 80,000 of our ADSs on the date of such director's initial election or appointment to the board of directors, which will vest in equal monthly installments through the third anniversary of the grant date. In addition, a non-executive director who is initially appointed to serve as chair of the board receives an option to purchase 40,000 of our ADSs on the date of such appointment to chair, which will vest in equal monthly installments through the third anniversary of the grant date.

Annual Awards

On the date of each of our annual meeting of shareholders, each non-executive director that continues to serve will be granted an option to purchase 80,000 of our ADSs or ordinary shares, which will vest in equal monthly installments through the first anniversary of the grant date. In October 2022, the Compensation Committee of the board approved a one-time increase in the annual equity award grant to non-executive directors, from 80,000 to 105,000 shares, to be awarded at the conclusion of our 2023 Annual General Meeting of Shareholders.

Senior Management Compensation

The compensation for each member of our executive management comprises the following elements: base salary, annual bonus, personal benefits, pension or 401(k) plan and long-term incentives. For the year ended December 31, 2023, the aggregate compensation accrued or paid to the members of our senior management for services, whether or not a director, in all capacities was $11.4 million. The amount set aside or accrued by us to provide pension, retirement or similar benefits to members of senior management amounted to a total of $1,108 in the year ended December 31, 2023.

Management Incentive Compensation Plan

On May 17, 2016, the board of directors adopted the Management Incentive Compensation Plan. The Management Incentive Compensation Plan is designed to offer annual incentive compensation to our members of senior management and managers by rewarding the achievement of corporate goals and specifically measured personal goals that are consistent with and support the achievement of the corporate goals. The key terms of the Management Incentive Compensation Plan are summarized below.

Administration and Eligibility

Our Chief Executive Officer is responsible for the administration of the Management Incentive Compensation Plan; however, the compensation committee of the board of directors is responsible for approving any incentive awards to our Chief Executive Officer and other members of our senior management.

In order to be eligible to receive an incentive award under the Management Incentive Compensation Plan, an individual must have been employed with us for at least three consecutive months during a plan year, which runs from January 1 to December 31, and must achieve a rating of at least 75% of his or her personal goal.

For the year ended December 31, 2023 the Compensation Committee of our board of directors determined that our corporate goals were achieved at a level of 120%. Pursuant to the terms of the Management Incentive Compensation Plan, our Chief Executive Officer and executive director received an incentive award of £362,880, based on his target bonus percentage of 60%, an overall goal achievement level of 140%, and his base salary of £432,000.

Form and Determination of Incentive Awards

Incentive award payments may be made in cash, or, at the discretion of the compensation committee and subject to the approval of our board of directors, through the issuance of equity.

An individual's potential incentive award is calculated by multiplying his or her base salary as of the end of the plan year by the participant's "target award multiplier," which is a percentage ranging from 10% to 60%. The resulting amount is then divided between a corporate component and an individual component based on the weighting assigned for the individual's management level. After the end of the plan year, the actual achievement of the corporate and individual goals is determined, each expressed as a percentage of complete achievement, resulting in the calculation of the individual's total incentive award.

Annual performance reviews for participants in the Management Incentive Compensation Plan are completed following the end of the applicable plan year, with payment of incentive awards made as soon as practicable thereafter.

Termination of Employment

If a participant in the Management Incentive Compensation Plan gives or receives notice of termination or his or her employment is terminated prior to the payment of an incentive award under the Management Incentive Compensation Plan, our board of directors has discretion as to whether or not to pay an incentive award and whether to pay the full amount of the incentive award or a portion thereof.

Amendment

Our board of directors may abolish or alter the Management Incentive Compensation Plan at any time before, during or after a plan year is completed.

Senior Management Employment Arrangements

We have entered into arrangements with members of our senior management to grant restricted shares that are subject to vesting and a repurchase right in favor of us in the event the individual terminates his or her employment prior to the vesting date.

In order to align the interests of our executive management with our shareholders, members of our executive management are eligible to receive share-based awards pursuant to our equity incentive plans. The amount of the awards will generally be subject to the discretion of our board of directors and our compensation committee.

Outstanding Equity Awards, Grants and Option Exercise

The following table summarizes the equity awards that we granted to members of our board of directors and senior management pursuant to the terms of the 2017 Plan or 2018 Plan during the year ended December 31, 2023.

Name	Ordinary Share Underlying Option	Exercise Price	Grant Date	Expiration Date
Senior Management				
Christian Itin, Ph.D.	500,000	$ 1.91	3/6/2023	3/6/2033
	500,000	$ 2.31	10/12/2023	10/12/2033
Robert Dolski	500,000	$ 2.50	7/17/2023	7/17/2033
	250,000	$ 2.31	10/12/2023	10/12/2033
Edgar Braendle, M.D.	200,000	$ 1.91	3/6/2023	3/6/2033
	200,000	$ 2.31	10/12/2023	10/12/2033
David Brochu	250,000	$ 1.91	3/6/2023	3/6/2033
	250,000	$ 2.31	10/12/2023	10/12/2033
Martin Pule, MBBS	150,000	$ 1.91	3/6/2023	3/6/2033
	150,000	$ 2.31	10/12/2023	10/12/2033
Brent Rice	150,000	$ 1.91	3/6/2023	3/6/2033
	150,000	$ 2.31	10/12/2023	10/12/2033
Alexander Swan	250,000	$ 1.91	3/6/2023	3/6/2033
	250,000	$ 2.31	10/12/2023	10/12/2033
Christopher Vann	200,000	$ 1.91	3/6/2023	3/6/2033
	200,000	$ 2.31	10/12/2023	10/12/2033
Non-Executive Directors				
John Johnson	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
Joseph Anderson, Ph.D.	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
Linda Bain	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
John Berriman	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
Cynthia Butitta	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033

Name	Ordinary Share Underlying Option	Exercise Price	Grant Date	Expiration Date
Non-Executive Directors				
Kapil Dhingra, M.D.*	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
Robert Iannone, M.D., M.S.C.E.	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
Elisabeth Leiderman, M.D.	80,000	$ 5.50	12/20/2023	12/20/2033
Martin Murphy, Ph.D.	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
William Young, Ph.D.	80,000	$ 2.38	6/30/2023	6/30/2033
	25,000	$ 2.38	6/30/2023	6/30/2033
**Dr. Dhingra resigned from the board of directors effective December 31,2023.*				

As of December 31, 2023, members of our board of directors and senior management held vested share options to purchase an aggregate of 4,116,298 ordinary shares. No share options were exercised by any members of our board of directors and senior management during the year ended December 31, 2023.

Equity Incentive Plans

We have granted equity securities under a share option plan and an equity incentive plan, which are summarized below.

2017 Share Option Plan

In 2017, our board of directors and shareholders approved the 2017 Plan to provide equity incentives to certain eligible employees and directors, consultants and advisors. The 2017 Plan provided for the grant of potentially tax-favored Enterprise Management Incentives ("EMI"), options to our UK employees and for the grant of options to our U.S. employees. The 2017 Plan terminated in connection with our IPO; accordingly, as of September 30, 2018, there were no shares available for future grants under the 2017 Plan. Options previously granted pursuant to the 2017 Plan and that are currently outstanding remain subject to the terms of the 2017 Plan.

2018 Equity Incentive Plan

The 2018 Plan was approved by our board of directors and shareholders in June 2018 and became effective as of our IPO. The 2018 Plan allows for the grant of equity-based incentive awards to our employees and directors, including directors who are also our employees. Except where the context indicates otherwise, references hereunder to our ordinary shares shall be deemed to include a number of ADSs equal to the number of ordinary shares. The material terms of the 2018 Plan are summarized below:

Eligibility and Administration

Our employees and directors, and employees and consultants of our subsidiaries, referred to as service providers are eligible to receive awards under the 2018 Plan. The 2018 Plan is administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our directors and/or officers (referred to as the plan administrator below), subject to certain limitations imposed under the 2018 Plan, and other applicable laws and stock exchange rules. Our board of directors has delegated concurrent authority to administer the 2018 Plan to the compensation committee. The plan administrator has the authority to take all actions and make all determinations under the 2018 Plan, to interpret the 2018 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2018 Plan as it deems advisable. The plan administrator also has the authority to determine which eligible service providers receive awards, grant awards, set the terms and conditions of all awards under the 2018 Plan, including any vesting and vesting acceleration provisions, and designate whether such awards will cover our ordinary shares or ADSs, subject to the conditions and limitations in the 2018 Plan.

Shares Available for Awards

The maximum number of ordinary shares that may be issued under our 2018 Plan was initially 3,281,622 shares, which consisted of 3,025,548 ordinary shares under the 2018 Plan at the time of its adoption and 256,074 ordinary shares that remained available for future grants under the 2017 Plan at the time of its termination. Additionally, the number of ordinary shares reserved for issuance under the 2018 Plan will automatically increase on October 1st of each year, for a period of not more than ten years, commencing on October 1, 2018 and ending on (and including) October 1, 2027, by an amount equal to the lesser of (i) 4% of the total number of ordinary shares outstanding on September 30 of the same calendar year or (ii) such fewer number of ordinary shares as the board of directors may designate prior to the applicable October 1st date. As of December 31, 2023, 22,298,243 ordinary shares may be issued under the 2018 Plan, of which 3,833,665 ordinary shares were available for future grant as of that date.

If an award under the 2018 Plan, or any prior equity incentive plan, expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2018 Plan. Awards granted under the 2018 Plan in substitution for any options or other equity or equity-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2018 Plan, but will count against the maximum number of shares that may be issued upon the exercise of incentive options.

Awards

The 2018 Plan provides for the grant of options, share appreciation rights ("SARs"), restricted shares, dividend equivalents, restricted share units ("RSUs"), and other share-based awards. All awards under the 2018 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms, change of control provisions and post-termination exercise limitations. A brief description of each award type follows.

Options and SARs. Options provide for the purchase of our ordinary shares in the future at an exercise price set on the grant date. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR.

Restricted Shares and RSUs. Restricted shares are an award of nontransferable ordinary shares that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver our ordinary shares in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on our ordinary shares prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted shares and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2018 Plan.

Other Share-Based Awards. Other share-based awards are awards of fully vested ordinary shares and other awards valued wholly or partially by referring to, or otherwise based on, our ordinary shares or other property. Other share-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other share-based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

Performance Criteria

The plan administrator may select performance criteria for an award to establish performance goals for a performance period.

Certain Transactions

In connection with certain corporate transactions and events affecting our ordinary shares, including a change of control, another similar corporate transaction or event, another unusual or nonrecurring transaction or event affecting us or our financial statements or a change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2018 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2018 Plan and replacing or terminating awards under the 2018 Plan. In addition, in the event of certain non-reciprocal transactions with our shareholders, the plan administrator will make equitable adjustments to the 2018 Plan and outstanding awards as it deems appropriate to reflect the transaction.

Plan Amendment and Termination

Our board of directors may amend or terminate the 2018 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2018 Plan, may materially and adversely affect an award outstanding under the 2018 Plan without the consent of the affected participant and shareholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator cannot, without the approval of our shareholders, amend any outstanding option or SAR to reduce its price per share or cancel any outstanding option or SAR in exchange for cash or another award under the 2018 Plan with an exercise price per share that is less than the exercise price per share of the original option or SAR. The 2018 Plan will remain in effect until the tenth anniversary of its effective date unless earlier terminated by our board of directors. No awards may be granted under the 2018 Plan after its termination.

Transferability and Participant Payments

Except as the plan administrator may determine or provide in an award agreement, awards under the 2018 Plan are generally non-transferable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2018 Plan, and exercise price obligations arising in connection with the exercise of options under the 2018 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or cheque, our ordinary shares that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

Non-U.S. Participants

The plan administrator may modify awards granted to participants who are non-U.S. nationals or employed outside the United States or establish sub-plans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions.

U.S. Taxpayers

Awards may be granted under the 2018 Plan to U.S. taxpayers.

2018 Non-Employee Sub Plan

The 2018 Non-Employee Sub Plan will govern equity awards granted to our non-executive directors and our service providers. The 2018 Non-Employee Sub Plan was adopted under the 2018 Plan and provides for equity- and cash-based awards to be made on identical terms to awards made under our 2018 Plan. If all or any part of an award granted under the 2018 Non-Employee Sub Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares covered by the award will become or again be available for new grants under the 2018 Non-Employee Sub Plan.

Clawbacks

As a U.S. public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws as a result of misconduct, our Chief Executive Officer and Chief Financial Officer may be legally required to reimburse us for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of Section 304 of the Sarbanes-Oxley Act. Additionally, we have implemented a Dodd-Frank Act-compliant clawback policy, as required by SEC rules.

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

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of February 29, 2024 by:

- each beneficial owner of 5% or more of our outstanding ordinary shares;
- each of our current directors and each member of our senior management; and
- all of our directors and senior management as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include ordinary shares that can be acquired within 60 days of February 29, 2024. These ordinary shares, however, are not included in the computation of the percentage ownership of any other person. Percentage ownership calculations are based on 265,812,217 ordinary shares outstanding (including ordinary shares in the form of ADSs) as of February 29, 2024.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

Except as otherwise indicated, the addresses of the persons listed in the table is c/o Autolus Therapeutics plc, 191 Wood Lane, White City, London W12 7FP, United Kingdom.

NAME OF BENEFICIAL OWNER	Number of Ordinary Shares Beneficially Owned (#)	Percent of Ordinary Shares Beneficially Owned (%)
5% or Greater Shareholders:		
Syncona Portfolio Limited (1)	33,527,162	12.6 %
BioNTech SE (2)	33,333,333	12.5 %
BXLS V - Autobahn L.P (3)	23,750,917	8.9 %
Paradigm BioCapital Advisors LP (4)	16,028,002	6.0 %
Deep Track Capital, LP (5)	15,619,297	5.9 %
Qatar Investment Authority (6)	15,000,000	5.6 %
PPF Capital Partners Fund B.V. (7)	14,612,275	5.5 %
Senior Management and Directors:		
Christian Itin, Ph.D. (8)	2,258,501	0.8 %
Robert Dolski (9)	—	*
Edgar Braendle M.D.(10)	418,162	*
David Brochu (11)	518,541	*
Martin Pulé, MBBS (12)	1,030,648	*
Brent Rice (13)	207,724	*
Alexander Swan (14)	259,165	*
Christopher Vann (15)	676,792	*
Christopher Williams, Ph.D. (16)	228,521	*
John Johnson (17)	130,276	*
Joseph Anderson, Ph.D. (18)	139,999	*
Robert Azelby (19)	2,222	*
Linda Bain (20)	171,396	*
John Berriman (21)	292,028	*
Cynthia Butitta (22)	197,094	*
Robert Iannone, M.D, M.S.C.E (23)	69,999	*
Elisabeth Leiderman M.D. (24)	4,444	*
Martin Murphy, Ph.D. (25)	139,999	*
William Young, Ph.D. (26)	108,749	*
All directors and senior management as a group (19 persons) (27)	**6,854,260**	**2.6 %**

* Represents beneficial ownership of less than one percent.

(1) The information shown is based, in part, upon disclosures filed on a Schedule 13G/A on February 14, 2024 by Syncona Portfolio Limited. The number reported consists of (i) 12,180,333 ordinary shares and (ii) 21,346,829 ADSs. Syncona Portfolio Limited is a wholly owned subsidiary of Syncona Holdings Limited, which, in turn, is a wholly controlled subsidiary of Syncona Limited, a publicly-listed company. Each of Syncona Holdings Limited and Syncona Limited may be deemed to have voting and dispositive power over the securities held by Syncona Portfolio Limited. Investment and voting decisions with respect to these securities are made by Syncona Portfolio Limited acting upon the recommendation of an investment committee of Syncona Investment Management Limited, also a subsidiary of Syncona Holdings Limited. The members of this investment committee consist of Roel Bulthuis and Christopher Hollowood. The address for Syncona Portfolio Limited is PO Box 273, Sir William Place, St Peter Port, Guernsey GY1 3RD, Channel Islands.

(2) The information shown is based, in part, upon disclosures filed on a Schedule 13D on February 21, 2024 by BioNTech. The number reported consists of 33,333,333 ADSs. The members of the Management Board consists of Prof. Ugur Sahin, M.D., Jens Holstein, Sean Marett, Dr. Sierk Poetting, Dr. Özlem Türeci, Ryan Richardson and James Ryan. The members of the Supervisory Board of BioNTech consist of Helmut Jeggle, Michael Motschmann, Baroness Nicola Blackwood, Prof. Anja Morawietz, Dr. Ulrich Wandschneider and Prof. Rudolf Staudigl. The address of the principal business office, Management Board and Supervisory Board of BioNTech is An der Goldgrube 12, D-55131 Mainz, Germany.

(3) The information shown is based, in part, upon disclosures filed on a Schedule 13D/A on December 13, 2022 by Blackstone Inc. The number reported consists of (i) 20,485,611 ADSs and (ii) 3,265,306 warrants. Blackstone Life Sciences Associates V (CYM) L.L.C. ("Autobahn GP") is the general partner of BXLS V – Autobahn L.P. ("BLXS V"). Blackstone Clarus GP L.L.C. is the general partner of Autobahn GP. The sole member of Blackstone Clarus GP L.L.C. is Blackstone Holdings I L.P. The general partner of Blackstone Holdings I L.P. is Blackstone Holdings I/II GP L.L.C. The sole member of Blackstone Holdings I/II GP L.L.C. is Blackstone Inc. The sole holder of the Series II preferred stock of Blackstone Inc. is Blackstone Group Management L.L.C. Blackstone Group Management L.L.C. is wholly-owned by Blackstone's senior managing directors and controlled by its founder, Stephen A. Schwarzman. The address of the principal business office of BLXS V and Autobahn GP is 101 Main Street, Suite 1210, Cambridge, MA 02142. The address of the principal business office of each of the other Blackstone entities and Mr. Schwarzman is c/o Blackstone Inc., 345 Park Avenue, New York, NY 10154.

(4) The information shown is based, in part, upon disclosures filed on a Schedule 13G/A on February 14, 2024 by (1) Paradigm BioCapital Advisors LP (the "Adviser"); (2) Paradigm BioCapital Advisors GP LLC (the "GP"); (3) Senai Asefaw, M.D. ("Senai Asefaw"); and (4) Paradigm BioCapital International Fund Ltd. (the "Fund"). The number reported consists of 12,611,335 ADSs. The Fund is a private investment vehicle. The Fund and a separately managed account managed by the Adviser (the "Account") directly beneficially own 12,611,335 ADSs. In addition Paradigm BioCapital Advisors LP purchased a further 3,416,667 ADSs in February 2024. The Adviser is the investment manager of the Fund and the Account. The GP is the general partner of the Adviser. Senai Asefaw is the managing member of the GP. The Adviser, the GP and Senai Asefaw may be deemed to beneficially own the Ordinary Shares directly beneficially owned by the Fund and the Account. Each Reporting Person disclaims beneficial ownership with respect to any Ordinary Shares other than the Ordinary Shares directly beneficially owned by such Reporting Person. The principal business office of the Reporting Persons is 767 Third Avenue, 17th Floor, New York, NY 10017.

(5) The information shown is based, in part, upon disclosures filed on a Schedule 13G/A on February 14, 2024 by Deep Track Capital, LP. The number reported consists of 11,869,297 ADSs. In addition Deep Track Capital, LP purchased a further 3,750,000 ADSs in February 2024. Deep Track Biotechnology Master Fund, Ltd is a wholly owned subsidiary of Deep Track Capital, LP. The address of the principal business office of Deep Track Capital, LP is 200 Greenwich Ave, 3rd Floor, Greenwich, CT 06830. The address of the principal business office of Deep Track Biotechnology Master Fund, Ltd. is c/o Walkers Corporate Limited, 190 Elgin Ave, George Town, KY1-9001, Cayman Islands. Deep Track Capital, LP. and Deep Track Biotechnology Master Fund, Ltd are controlled by its founder, David Kroin. The address of the principal business office of Mr. Kroin is c/o Deep Track Capital, LP, 200 Greenwich Ave, 3rd Floor, Greenwich, CT 06830.

(6) The information shown is based, in part, upon disclosures filed on a Schedule 13G on December 13, 2022 by Qatar Investment Authority. The number reported consists of 15,000,000 ADSs. The address of the principal business office of Qatar Investment Authority is Ooredoo Tower (Building 14), Al Dafna Street (Street 801), Al Dafna (Zone 61), Doha, P.O. Box 23224, Qatar.

(7) The information shown is based, in part, upon disclosures filed on a Schedule 13D/A on June 23, 2021 by PPF Capital Partners Fund B.V., PPF Group N.V. and Renata Kellnerova. The number reported consists of 14,612,275 ADSs. The principal shareholder of PPF Capital Partners Fund B.V. is PPF Group N.V., which is ultimately beneficially owned by Renata Kellnerova. The address of the principal office of each of PPF Group and PPF Capital is Strawinskylaan 933, 1077XX Amsterdam, The Netherlands. The address of the principal office of Renata Kellnerova is c/o PPF a.s., Evropská 2690/17, P.O. Box 177, 160 41 Prague 6, Czech Republic.

(8) Consists of (i) 1,066,009 ordinary shares issuable upon conversion of restricted ordinary shares, (ii) 50,000 ordinary shares issuable upon restricted stock units and (iii)) 1,142,492 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(9) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(10) Consists of (i) 79,622 ordinary shares issuable upon conversion of restricted stock units and (ii) 338,540 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(11) Consists of (i) 113,125 ordinary shares issuable upon conversion of restricted stock units and (ii) 405,416 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(12) Consists of (i) 538,677 ordinary shares, (ii) 160,064 ordinary shares issuable upon conversion of restricted ordinary shares, and (iii) 331,907 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(13) Consists of (i) 9,400 ADSs and (ii) 37,907 ordinary shares issuable upon conversion of restricted stock units and (iii) 160,417 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(14) Consists of (i) 38,657 ordinary shares issuable upon conversion of restricted stock units, and (ii) 220,508 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(15) Consists of (i) 112,211 ordinary shares issuable upon conversion of restricted ordinary shares, ii) 40,000 ordinary shares issuable upon conversion of restricted stock units and (iii) 524,581 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(16) Consists of (i) 8,198 ordinary shares issuable upon conversion of restricted ordinary shares, (ii) 19,808 ordinary shares issuable upon conversion of restricted stock units and (iii) 200,515 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(17) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(18) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(19) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(20) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(21) Consists of (i) 62,794 ordinary shares and (ii) 73,537 ordinary shares issuable upon conversion of restricted ordinary shares, and (iii) 155,697 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(22) Consists of (i) 10,000 ADSs and (ii) 187,094 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(23) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(24) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(25) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(26) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

(27) Consists of (i) 19,400 ADSs, (ii) 601,471 ordinary shares, (iii) 1,420,019 ordinary shares issuable upon conversion of restricted ordinary shares, (iv) 379,119 ordinary shares issuable upon conversion of restricted stock units and (v) 4,434,251 ordinary shares underlying options that are vested and exercisable within 60 days of February 29, 2024.

Significant Changes in Percentage Ownership

The significant changes in the beneficial ownership percentage held by our major shareholders during the past three years result from our February 2021 and December 2022 follow-on offerings of ADSs, our February 2024 underwritten offering of ADSs, our sale of ADSs to Blackstone in November 2021 in connection with our Blackstone strategic collaboration agreement and our sale of ADSs to BioNTech in February 2024 in the BioNTech Private Placement, and the dilution resulting from these offerings.

Voting Rights

The voting rights of the principal shareholders do not differ from the voting rights of other shareholders.

Shareholders in the United States

As of December 31, 2023, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States other than ADSs held by the entities set forth in the table above and certain other holders that we know to be non-residents of the United States, we estimate that approximately 44.1% of our outstanding ordinary shares (including ordinary shares underlying ADSs) were held in the United States by 92 holders of record. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:	17,956,385 (1)	$5.64 (2)	3,833,665 (3)
Total	**17,956,385**		**3,833,665**

(1) Includes shares issuable upon exercise of outstanding options under the 2017 Share Option Plan and shares issuable upon exercise of outstanding options and issuable upon settlement of outstanding restricted stock units under the 2018 Equity Incentive Plan.

(2) Gives effect to outstanding RSUs, which have no exercise price. Excluding the RSUs, the weighted average exercise price would be $5.64 per share.

(3) Following the adoption of the 2018 Equity Incentive Plan, no additional stock awards may be granted under the 2017 Share Option Plan. The number of shares of our common stock reserved for issuance under our 2018 Equity Incentive Plan automatically increases on October 1 of each year, from October 1, 2018 continuing through October 1, 2027, by 4% of the total number of shares of our common stock outstanding on September 30 of the same calendar year, or a lesser number of shares as may be determined by our Board.

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

Policies and Procedures for Related Person Transactions

We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we or any of our subsidiaries and any related person are, were or will be participants in which the amount involved exceeds $120,000 or which is unusual in its nature or conditions. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

For so long as we qualify as a foreign private issuer, a related person will be any:

- enterprise that directly or indirectly controls or is controlled by or is under common control with us;
- enterprise over which we have a significant influence or which has significant influence over us;
- individual owning, directly or indirectly, an interest in our voting power that gives them significant influence over us, and close members of any such individual's family;
- persons having authority or responsibility for planning, directing or controlling our activities, including directors and senior management and close members of such individuals' families; or

- enterprise in which a substantial interest in our voting power is owned, directly or indirectly, by any person described above or over which such a person is able to exercise significant influence, including enterprises owned by our directors or major shareholders and enterprises that have a member of key management in common with us.

If we cease to be a foreign private issuer, then, under our policy, a related person will be any:

- person who is, or at any time since the beginning of our last fiscal year was, a director or member of senior management of us or a nominee to become a director of us;
- security holder known by us to be the beneficial owner of more than 5% of any class of our voting securities;
- immediate family member of any of the foregoing; and
- firm, corporation or other entity in which any of the foregoing persons is an executive, partner or principal or similar control position or in which such person has a 5% or greater beneficial ownership interest.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, member of senior management and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy. In addition, under our Code of Ethics, our employees, members of senior management and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

Transactions with Our Principal Shareholders, Directors and Members of our Senior Management

The following is a description of related party transactions we have entered into since January 1, 2023 with our directors, members of our senior management and holders of more than 5% of our outstanding voting securities and their affiliates, whom we refer to as our related persons, in which the amount involved exceeds $120,000 and that are material to us, other than the compensation arrangements we describe in Item 11. “Executive Compensation”

License Agreement with Syncona

We entered into a license agreement with an investee of Syncona Portfolio Limited on September 2, 2020, a holder of more than 5% of our share capital. The terms of the agreement include a non-refundable license fee, payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales. During the year ended December 31, 2023, we received $0.4 million arising from the achievement of a development milestone. Consequently, we recognized license revenue of $0.4 million (net of foreign exchange differences).

2024 Underwritten Offering

In connection with our February 2024 underwritten offering, certain of our related parties purchased our ADSs from the underwriters at the public offering price of $6.00 per ADSs, and on the same terms as other investors in registered direct offering. The following table summarizes purchases of ADS by our related parties:

Related party	ADSs purchased	Total purchase price (in millions)
Paradigm BioCapital Advisors LP (1)	3,416,667	$ 28.0
Deep Track Capital, LP (2)	3,750,000	$ 30.0

(1) Paradigm BioCapital Advisors LP was a holder of more than 5% of our share capital as of December 31, 2023.
(2) Deep Track Capital, LP was a holder of more than 5% of our share capital as of December 31, 2023.

Agreements with Our Senior Management and Directors

We have entered into service agreements with the members of our senior management and non-executive directors. See Item 11, “Executive Compensation” These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the members of our senior management. However, the enforceability of the non-competition provisions may be limited under applicable law.

Indemnification Agreements

We have entered into a deed of indemnity with each of our directors and members of our senior management. These agreements and our Articles of Association require us to indemnify our directors and senior management to the fullest extent permitted by law.

Item 14. Principal Accountant Fees and Services

Ernst & Young LLP has served as our independent registered public accounting firm since September 2017 and has audited our consolidated financial statements for the years ended December 31, 2023 and 2022.

The following table shows the aggregate fees for services rendered by Ernst & Young LLP to us and our subsidiaries for the years ended December 31, 2023 and 2022.

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Audit fees	$ 1,227	$ 965
Audit-related fees	81	267
Total	**$ 1,308**	**$ 1,232**

Audit fees. Audit fees consisted of fees for the audit of our annual financial statements and other professional services provided in connection with the statutory and regulatory filings or engagements, including fees for the review of our interim financial information.

Audit-related fees. Audit related fees include fees for assurance reporting on our current and historical financial information included in our SEC registration statements in connection with our follow-on capital raises and our at-the-market facility program, including services that generally only the independent accountant can reasonably provide such as comfort letters.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee reviews and pre-approves the scope and the cost of audit services related to us and permissible non-audit services performed by the independent auditors, other than those for *de minimis* services which are approved by the audit committee prior to the completion of the audit. All of the services related to us provided by Ernst & Young LLP during the year ended December 31, 2023 were pre-approved by the audit committee.

PART IV

Item 15. Exhibit and Financial Statement Schedule

(a) 1. Financial Statements

See the financial statements beginning on page F-1 of this Annual Report.

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

		INCORPORATED BY REFERENCE			
EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT	SCHEDULE/ FORM	FILE NUMBER	EXHIBIT	FILE DATE
3.1	Articles of Association of Autolus Therapeutics plc.	Form F-1/A	333-224720	3.1	6/19/18
4.1	Deposit Agreement by and among the registrant, Citibank, N.A., as the Depositary bank and the holders and beneficial owners of ADSs issued thereunder.	Form F-1/A	333-224720	4.1	6/19/18
4.2	Form of American Depositary Receipt (included in exhibit 4.1).	Form F-1/A	333-224720	4.2	6/19/18
4.3	Description of Securities	Form 20-F	001-38547	2.4	3/3/20

4.4	Warrant issued to BXLS V – Autobahn L.P. dated November 6, 2021.	Form 6-K	001-38547	99.3	11/8/21
10.1†#	Supply Agreement, dated as of March 23, 2018, by and between the registrant and Miltenyi Biotec GmbH.	Form F-1/A	333-224720	10.2	6/8/18
10.2†#	Autolus Therapeutics plc 2018 Equity Incentive Plan.	Form F-1/A	333-224720	10.3	6/19/18
10.3+	Non-employee Sub Plan to the Autolus Therapeutics plc 2018 Equity Incentive Plan.	Form F-1/A	333-224720	10.4	6/19/18
10.4+	Management Incentive Compensation Plan.	Form F-1/A	333-224720	10.5	6/8/18
10.5+	Form of Deed of Indemnity between the registrant and each of its members of senior management and directors.	Form F-1/A	333-224720	10.6	6/8/18
10.6†#*	License Agreement, dated as of September 25, 2014 by and between the registrant and UCL Business Ltd., as amended on March 2, 2016, March 28, 2018.	Form F-1/A	333-224720	10.1	6/8/18
10.7†#*	Amendment to License Agreement, dated as of September 25, 2014 by and between the registrant and UCL Business Ltd., dated as of October 15, 2020.	Form F-1/A	001-38547	4.7	3/4/21
10.8	Autolus Therapeutics plc, Registration Rights Agreement, dated as June 26, 2018	Form 20-F	001-38547	2.3	11/23/18
10.9	Collaboration and Financing Agreement, dated as of November 6, 2021, between Autolus Limited and BXLS V — Autobahn L.P.	Form 20-F	001-38547	4.7	3/10/22
10.10	Securities Purchase Agreement by and between the Registrant and BXLS V – Autobahn L.P. dated November 6, 2021.	Form 6-K	001-38547	99.1	11/8/21
10.11	Registration Rights Agreement by and between the Registrant and BXLS V – Autobahn L.P. dated November 6, 2021.	Form 6-K	001-38547	99.2	11/8/21
10.12*†#	License and Option Agreement between the registrant and BioNTech SE, dated February 6, 2024.				
10.13	Securities Purchase Agreement between the registrant and BioNTech SE, dated February 6, 2024.	Form 8-K	001-38547	10.1	2/8/24
10.14	Registration Rights Agreement between the registrant and BioNTech SE, dated February 6, 2024.	Form 8-K	001-38547	10.2	2/8/24
10.15	Letter Agreement between the registrant and BioNTech SE, dated February 6, 2024.	Form 8-K	001-38547	10.3	2/8/24
10.16†	Lease Agreement, dated September 19, 2023, between Forge Life Sciences Nominee I Limited and Forge Life Sciences Nominee 2 Limited, Autolus Limited and Autolus Therapeutics plc relating to The Nucleus Marshgate, Stevenage.	Form 10-Q	001-38547	10.1	11/9/23
10.17†	Amendment 2 to Supply Agreement, dated as of September 27, 2023, by and between Autolus Limited and Miltenyi Biotec B.V. & Co. KG.	Form 10-Q	001-38547	10.2	11/9/23
21.1*	Subsidiaries of the registrant.				
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm				

24.1*	Power of Attorney (included on signature page)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Policy relating to recovery of erroneously awarded compensation, as required by applicable listing standards adopted pursuant to 17 CFR 240.10D-1
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ Indicates management contract or compensatory plan.

† Certain portions of the exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the SEC.

* Filed herewith.

** Furnished herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AUTOLUS THERAPEUTICS PLC

Date: March 21, 2024

By: /s/ Christian Itin, Ph.D.
Christian Itin, Ph.D.
Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned officers and directors of Autolus Therapeutics plc, hereby severally constitute and appoint Christian Itin and Alex Driggs our true and lawful attorneys with full power to any of them, and to each of them singly, to sign for us and in our names in the capacities indicated below to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities 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 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, and either of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Christian Itin, Ph.D. Christian Itin, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 21, 2024
/s/ Robert Dolski Robert Dolski	Chief Financial Officer *(Principal Financial Officer)*	March 21, 2024
/s/ Andrew Mercieca Andrew Mercieca	Vice President, Finance *(Principal Accounting Officer)*	March 21, 2024
/s/ John Johnson John Johnson	Chairman of the Board of Directors	March 21, 2024
/s/ Joseph Anderson, Ph.D. Joseph Anderson, Ph.D.	Director	March 21, 2024
/s/ Robert Azelby Robert Azelby	Director	March 21, 2024
/s/ Linda Bain Linda Bain	Director	March 21, 2024
/s/ John Berriman John Berriman	Director	March 21, 2024
/s/ Cynthia Butitta Cynthia Butitta	Director	March 21, 2024
/s/ Robert Iannone, M.D., M.S.C.E. Robert Iannone, M.D., M.S.C.E	Director	March 21, 2024
/s/ Elisabeth Leiderman, M.D. Elisabeth Leiderman, M.D.	Director	March 21, 2024
/s/ Martin Murphy, Ph.D. Martin Murphy, Ph.D.	Director	March 21, 2024
/s/ William Young William Young	Director	March 21, 2024

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Autolus Therapeutics plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Autolus Therapeutics plc (the Company) as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2023 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Autolus Therapeutics plc at December 31, 2023 and 2022, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Restatement of 2022 and 2021 Financial Statements

As discussed in Note 3 to the consolidated financial statements, the 2022 and 2021 consolidated financial statements have been restated to correct a misstatement.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Liabilities related to future royalties and sales milestones

Description of the matter

As explained in note 11 to the consolidated financial statements, the Company entered into a collaboration agreement with BXLS V- Autobahn L.P ("Blackstone") in 2021 for the development of certain CAR T therapy products for which the Company received an upfront payment and subsequently certain milestone payments which was initially recognized as a liability. The Company remeasures the liability as the present value of future royalties and sales milestones payable, when significant assumptions associated with the underlying cash flows change. The liability is sensitive to forecasts of future royalties and sales milestones payable, which are based on management estimates which include the probability of success of the clinical trial and regulatory approval ('POS') and the estimated selling prices of products in different territories.

Auditing the Company's measurement of the liability for future royalties and sales milestones, net is especially challenging because the calculation involves significant management judgement about future events, which are inherently uncertain. In particular, the measurement was sensitive to the Company's estimates of the timing and likelihood of regulatory approvals and pricing of the products on which royalties will be paid.

How we addressed the matter	To test the liability related to future royalties and sales milestones, net and the related financial model our audit procedures included among others, meeting with management and its expert to understand the basis for changes in the POS and forecast selling prices. We also evaluated the reasonableness of the POS assumption, with the assistance of a specialist, by assessing analysts' reports, industry standards and publicly available information for similar products. We evaluated the appropriateness of management's selling price assumptions by comparing the pricing of the Company's product with competitor pricing from publicly available information in different market segments. We evaluated the reasonableness of the underlying financial model by performing a roll-forward of the prior year valuation, performing certain sensitivity analysis on the significant assumptions and comparing it to the significant assumptions used by management. We also tested the clerical accuracy of the model.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Reading, United Kingdom

March 21, 2024

AUTOLUS THERAPEUTICS PLC

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	Note	December 31, 2023	2022
Assets			
Current assets:			
Cash and cash equivalents		$ 239,566	$ 382,436
Restricted cash		769	325
Prepaid expenses and other current assets	7	34,967	43,010
Total current assets		**275,302**	**425,771**
Non-current assets:			
Property and equipment, net	8	34,862	35,209
Prepaid expenses and other non-current assets		380	2,176
Operating lease right-of-use assets, net	18	60,791	23,210
Long-term deposits		983	1,832
Deferred tax asset	17	3,063	2,076
Total assets		**$ 375,381**	**$ 490,274**
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		103	531
Accrued expenses and other liabilities	10	39,581	40,797
Operating lease liabilities, current	18	5,053	5,038
Total current liabilities		**44,737**	**46,366**
Non-current liabilities:			
Operating lease liabilities, non-current	18	47,914	19,218
Liability related to future royalties and sales milestones, net	11, 23	170,899	125,900
Other long-term payables		357	116
Total liabilities		**263,907**	**191,600**
Commitments and contingencies	19		
Shareholders' equity:			
Ordinary shares, $0.000042 par value; 290,909,783 shares authorized at December 31, 2023 and 2022, 174,101,361 and 173,074,510 shares issued and outstanding at December 31, 2023 and 2022	13	8	8
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at December 31, 2023 and 2022	13	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at December 31, 2023 and 2022	13	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at December 31, 2023 and 2022	13	—	—
Additional paid-in capital		1,018,902	1,007,625
Accumulated other comprehensive loss		(28,992)	(38,898)
Accumulated deficit		(878,562)	(670,179)
Total shareholders' equity		**111,474**	**298,674**
Total liabilities and shareholders' equity		**$ 375,381**	**$ 490,274**

The accompanying notes are an integral part of these consolidated financial statements.

AUTOLUS THERAPEUTICS PLC

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

	Note	December 31, 2023	2022 (As Restated)	2021 (As Restated)
Grant income		$ —	$ 166	$ 823
License revenue	4	1,698	6,194	1,507
Operating expenses:				
Research and development	3	(130,481)	(117,354)	(110,839)
General and administrative		(46,745)	(31,899)	(31,865)
Loss on disposal of property and equipment		(3,791)	(515)	(676)
Impairment of operating lease right-of-use assets and related property and equipment		(382)	—	—
Total operating expenses, net		**(179,701)**	**(143,408)**	**(141,050)**
Other income (expense), net		2,861	2,038	(145)
Interest income		13,505	1,708	262
Interest expense	5	(45,067)	(8,905)	(1,105)
Total other expenses, net		**(28,701)**	**(5,159)**	**(988)**
Net loss before income tax		**(208,402)**	**(148,567)**	**(142,038)**
Income tax benefit (expense)	3, 17	19	(272)	(58)
Net loss attributable to ordinary shareholders		**(208,383)**	**(148,839)**	**(142,096)**
Other comprehensive income (loss):				
Foreign currency exchange translation adjustment		9,906	(30,328)	(2,709)
Total comprehensive loss		**$ (198,477)**	**$ (179,167)**	**$ (144,805)**
Basic and diluted net loss per ordinary share	15	$ (1.20)	$ (1.57)	$ (1.97)
Weighted-average basic and diluted ordinary shares	15	173,941,926	94,993,400	72,084,078

The accompanying notes are an integral part of these consolidated financial statements.

AUTOLUS THERAPEUTICS PLC

Consolidated Statements of Shareholders' Equity
(In thousands, except share amounts)

	Ordinary shares		Deferred Shares		Deferred B shares		Deferred C Shares					
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid in Capital	Accumulated other comprehensive loss	Accumulated deficit	Total
Balance at December 31, 2020	**52,346,231**	**$ 3**	**34,425**	**$ —**	**88,893,548**	**$ 118**	**1**	**$ —**	**$ 595,016**	**$ (5,861)**	**$ (379,244)**	**$ 210,032**
Issuance of ordinary shares, net of issuance costs	38,202,155	1	—	—	—	—	—	—	228,160	—	—	228,161
Share-based compensation expense	—	—	—	—	—	—	—	—	9,937	—	—	9,937
Vesting of restricted stock	163,375	—	—	—	—	—	—	—	—	—	—	—
Exercise of stock options	196,069	—	—	—	—	—	—	—	127	—	—	127
Issuance of warrants, net of transaction costs	—	—	—	—	—	—	—	—	9,868	—	—	9,868
Unrealized loss on foreign currency translation	—	—	—	—	—	—	—	—	—	(2,709)	—	(2,709)
Net loss attributable to ordinary shareholders	—	—	—	—	—	—	—	—	—	—	(142,096)	(142,096)
Balance at December 31, 2021	**90,907,830**	**$ 4**	**34,425**	**$ —**	**88,893,548**	**$ 118**	**1**	**$ —**	**$ 843,108**	**$ (8,570)**	**$ (521,340)**	**$ 313,320**
Issuance of ordinary shares, net of issuance costs	81,927,012	4	—	—	—	—	—	—	152,386	—	—	152,390
Share-based compensation expense	—	—	—	—	—	—	—	—	12,014	—	—	12,014
Vesting of restricted stock	76,804	—	—	—	—	—	—	—	—	—	—	—
Exercise of stock options	162,864	—	—	—	—	—	—	—	117	—	—	117
Unrealized loss on foreign currency translation	—	—	—	—	—	—	—	—	—	(30,328)	—	(30,328)
Net loss attributable to ordinary shareholders	—	—	—	—	—	—	—	—	—	—	(148,839)	(148,839)
Balance at December 31, 2022	**173,074,510**	**$ 8**	**34,425**	**$ —**	**88,893,548**	**$ 118**	**1**	**$ —**	**$ 1,007,625**	**$ (38,898)**	**$ (670,179)**	**$ 298,674**
Share-based compensation expense	—	—	—	—	—	—	—	—	11,250	—	—	11,250
Vesting of restricted stock unit awards net of shares withheld to cover tax withholding	1,006,382	—	—	—	—	—	—	—	—	—	—	—
Reversal of restricted share forfeited	10,362	—	—	—	—	—	—	—	—	—	—	—
Exercise of share options	10,107	—	—	—	—	—	—	—	27	—	—	27
Unrealized gain on foreign currency translation	—	—	—	—	—	—	—	—	—	9,906	—	9,906
Net loss attributable to ordinary shareholders	—	—	—	—	—	—	—	—	—	—	(208,383)	(208,383)
Balance at Balance at December 31, 2023	**174,101,361**	**$ 8**	**34,425**	**$ —**	**88,893,548**	**$ 118**	**1**	**$ —**	**$ 1,018,902**	**$ (28,992)**	**$ (878,562)**	**$ 111,474**

The accompanying notes are an integral part of these consolidated financial statements.

AUTOLUS THERAPEUTICS PLC

Consolidated Statements of Cash Flows
(In thousands)

	December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net loss attributable to ordinary shareholders	$ (208,383)	$ (148,839)	$ (142,096)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6,565	7,422	8,458
Loss on disposal of property and equipment	3,791	515	672
Share-based compensation net of amounts capitalized	11,204	12,014	9,937
Interest expense accrued on liability related to future royalties and sales milestones, net and cumulative catch-up adjustment	44,999	8,884	1,093
Foreign exchange differences	(7,604)	3,996	—
Non-cash operating lease expense	4,058	3,432	3,728
Loss on lease incentive and reassessment	—	—	9
Loss on termination of operating lease	95	—	—
Impairment of operating lease right-of-use assets and related property and equipment	382	—	—
Deferred income tax	(986)	(268)	(72)
Changes in operating assets and liabilities			
Decrease (increase) in prepaid expenses and other current assets	10,695	(10,962)	5,574
Decrease in prepaid expenses and other non-current assets	1,726	161	503
Decrease (increase) in long-term deposits	937	(5)	575
(Decrease) increase in accounts payable	(509)	22	(1,816)
(Decrease) increase in accrued expenses and other liabilities	998	16,007	(2,021)
(Decrease) increase in operating lease liability	(13,555)	(4,687)	(2,405)
Net cash used in operating activities	**(145,587)**	**(112,308)**	**(117,861)**
Cash flows from investing activities:			
Purchases of property and equipment	(10,986)	(10,841)	(8,857)
Net cash used in investing activities	**(10,986)**	**(10,841)**	**(8,857)**
Cash flows from financing activities:			
Proceeds of issuance of ordinary shares	—	163,854	245,900
Proceeds from exercise of share options	27	117	125
Proceeds from liability related to future royalties and sales milestones, net	—	70,000	50,000
Payments of equity issuance costs	(910)	(10,361)	(11,453)
Payments of issuance costs related to the liability related to the sale of future royalties and sales milestones, net	—	—	(509)
Net cash (used in) provided by financing activities	**(883)**	**223,610**	**284,063**
Effect of exchange rate changes on cash, cash equivalents and restricted cash	15,030	(28,376)	(754)
Net (decrease) increase in cash, cash equivalents and restricted cash	**(142,426)**	**72,085**	**156,591**
Cash, cash equivalents and restricted cash, beginning of period	**382,761**	**310,676**	**154,085**
Cash, cash equivalents and restricted cash, end of period	**$ 240,335**	**$ 382,761**	**$ 310,676**

AUTOLUS THERAPEUTICS PLC

Consolidated Statements of Cash Flows
(In thousands)

	December 31,		
	2023	**2022**	**2021**
Supplemental cash flow information			
Cash paid for taxes - primarily related to the United States of America	$ (551)	$ (471)	$ (364)
Supplemental non-cash flow information			
Property and equipment purchases included in accounts payable or accrued expenses	$ 433	$ 2,864	$ 3,712
Leased assets terminated and obtained in exchange for operating lease liabilities, net	$ 3	$ —	$ 28,517
Leased assets obtained in exchange for operating lease liabilities	$ 41,148	$ 9,785	$ 627
Capitalized share-based compensation, net of forfeitures	$ 46	$ (6)	$ —
Capitalized implementation costs included in accrued expenses	$ 564	$ 230	$ 100
Issuance costs included in accounts payable and accrued expenses	$ 272	$ 1,103	$ 245
Warrants issued in relation to Blackstone Agreements at relative fair value	$ —	$ —	$ 9,868
Reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:			
Cash and cash equivalents	$ 239,566	$ 382,436	$ 310,338
Restricted cash	769	325	338
Total cash, cash equivalents and restricted cash	**$ 240,335**	**$ 382,761**	**$ 310,676**

The accompanying notes are an integral part of these consolidated financial statements.

Note 1. Nature of the Business

Autolus Therapeutics plc and its subsidiaries (collectively "Autolus" or the "Company") is a biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer and autoimmune diseases. Using its broad suite of proprietary and modular T cell programming technologies, the Company is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize cancer cells, break down their defense mechanisms and attack and kill these cells. The Company believes its programmed T cell therapies have the potential to be best-in-class and offer cancer patients substantial benefits over the existing standard of care, including the potential for cure in some patients.

Autolus Therapeutics plc is registered in England and Wales. Its registered office is The MediaWorks, 191 Wood Lane, London, W12 7FP, United Kingdom.

The Company is a public limited company incorporated under the laws of England and Wales, and qualifies as a "foreign private issuer," as such term is defined in Rule 405 under the Securities Act of 1933, as amended (the "Securities Act"), and Rule 3b-4 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and, therefore, is not subject to the same requirements that are imposed upon U.S. domestic issuers by the Securities and Exchange Commission (the "SEC"). The Company has decided to voluntarily file periodic reports, such as annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K on U.S. domestic issuer forms, which are more detailed and extensive in certain respects, and which must be filed more promptly than the forms currently required for foreign private issuers. Although the Company has voluntarily chosen to file periodic reports and current reports on U.S. domestic issuer forms, the Company will maintain its status as a foreign private issuer and is not subject to certain other requirements imposed on U.S. domestic issuers including its officers, directors, and principal shareholders are not subject to the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and are presented in U.S. dollars. All intercompany accounts and transactions between the Autolus Therapeutics plc and its subsidiaries have been eliminated upon consolidation.

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, 2023, the Company held cash and cash equivalents of $239.6 million and a net loss attributable to ordinary shareholders for the year the ended December 31, 2023 of $208.4 million. As of December 31, 2023, the Company had an accumulated deficit of $878.6 million. The Company concluded with its existing cash and cash equivalents of $239.6 million together with the total aggregate gross proceeds received post year end of $600.0 million ($250.0 million and $350.0 million received from BioNTech SE and an underwritten offering, respectively as further details described in Note 24 - Subsequent events) that it can fund its operations for at least the next twelve months from the date of issuance of these financial statements and as such has prepared the consolidated financial statements on the going concern basis. As the Company continues to incur losses, the transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and achieving a level of revenues adequate to support its cost structure. Even if the Company's planned regulatory submissions for its products are approved, and the Company is successful in its commercialization efforts, additional funding will be needed before the Company is expected to reach cash breakeven.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses, share-based compensation including assessing the probability of meeting performance conditions, income taxes, initial fair value of warrants, and accrued interest expense on liability related to future royalties and sales milestones, net and related cumulative catch-up adjustment, initial lease term of the Company's new manufacturing facility (The Nucleus), and incremental borrowing rates related to the Company's leased properties. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manages its business as a single operating segment, which is the business of developing and commercializing CAR T therapies.

Cash and cash equivalents

The Company considers cash and cash equivalents in the consolidated financial statements to include cash and highly liquid investments at financial institutions. The Company invests in variety of short-term interest-bearing instruments including money market funds, which are subject to an insignificant risk of changes in value. Cash equivalents are primarily accessible on demand and have a weighted average maturity date of less than 95 days.

Restricted Cash

The Company's restricted cash consists of cash providing security for corporate credit cards, rental deposits relating to the sub-lease of facilities to third parties and cash deposited with a financial institution for the incorporation of the Company's newly incorporated Swiss subsidiary. The Company has a security deposit relating to entered into a credit card arrangement with one of its financial institutions amounting to $0.6 million. In October 2021, the Company entered into two sub-leasing agreements relating to the Enfield facility, which require aggregate rental deposits of $0.1 million to be held by the Company. The cash deposited with a financial institution for the incorporation of Company's newly incorporated Swiss subsidiary amounted to $0.1 million

Fair Value Measurements

The Company uses valuation approaches that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in of the following levels:

- 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 reported in the balance sheet for cash and cash equivalents, restricted cash, prepaid expenses and other assets, accounts payable and accrued expenses and other liabilities approximate their fair value because of the short-term nature of these instruments.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents and restricted cash. The Company places cash and cash equivalents and restricted cash with established financial institutions with strong credit ratings. The Company holds significant amounts of cash and cash equivalents that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements. The Company's cash and cash equivalents are held with multiple banks and financial institutions. Management monitors the credit rating of those banks and financial institutions on a regular basis. The Company has no significant off-balance-sheet risk or concentration of credit risk, such as foreign exchange contracts, options contracts, or other foreign hedging arrangements.

Implementation Costs in a Cloud Computing Arrangement

The Company's cloud computing arrangements primarily comprise hosting arrangements which are service contracts, whereby the Company gains remote access to use enterprise software hosted by the vendor or another third party on an as-needed basis for a period of time in exchange for a subscription fee. Implementation costs for cloud computing arrangements are capitalized if certain criteria are met and consist of internal and external costs directly attributable to developing and configuring cloud computing software for its intended use. These capitalized implementation costs are presented in the consolidated balance sheet in prepaid expenses and other assets, current and non-current, and are generally amortized over the fixed, non-cancellable term of the associated hosting arrangement on a straight-line basis.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized using the straight-line method over the estimated useful lives of the respective assets. As of December 31, 2023 and 2022, the Company's property and equipment consisted of office equipment, lab equipment, furniture and fittings, and leasehold improvements.

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:

Office equipment	3 years
Lab equipment	5 to 10 years
Furniture and fittings	5 years
Leasehold improvements	shorter of the lease term or the estimated useful life of the asset

Assets under construction consist of costs incurred with leasehold improvements and, once placed into service, will be depreciated over the shorter of the lease term or the estimated useful life of the asset. Upon retirement or sale, the cost of assets disposed of, and the related accumulated depreciation, are removed from the accounts and any resulting gain or loss is included in the statement of operations and other comprehensive loss.

Repairs and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred.

The Company routinely evaluates the useful life attributed to its assets.

Impairment of Long-Lived Assets

The Company evaluates an asset for potential impairment when events or changes in circumstances indicate the carrying value of the asset may not be recoverable. Recoverability is measured by comparing the carrying value of the asset to the expected future net undiscounted cash flows that the asset is expected to generate. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying value of the asset exceeds the fair value. The Company recognized an impairment of long-lived assets located in the United Kingdom amounting to $0.4 million for the year ended December 31, 2023. The Company did not recognize any impairment of long-lived assets for the year ended December 31, 2022 and 2021.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet, leases with terms of one year or less. Instead, these lease payments are recognized in the statements of operations on a straight-line basis over the lease term. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as incentives received, initial direct costs, or prepayments.

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in Topic 842, *Leases* ("ASC 842"), components of a lease should be split into three categories: lease components (*e.g.*, land, building, etc.) and non-lease components (*e.g.*, common area maintenance, consumables, etc). Many of the Company's leases contain variable non-lease components such as maintenance, taxes, insurance, and similar costs for the spaces it occupies. The Company expenses the variable lease payments in the period in which it incurs the obligation to pay such variable amounts and will be included in variable lease costs in the leases footnote disclosure. Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components.

For new and amended leases, the Company has elected the practical expedients to account for the lease and non-lease components for leases for classes of all underlying assets and allocate all of the contract consideration to the lease component only. The Company determined the underlying lease to be the predominant component, and therefore, the entire agreement was accounted for under ASC 842.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities during the adoption of ASC 842:

- As the Company's leases do not provide an implicit rate, it estimated the incremental borrowing rate for each lease based on a yield curve analysis, utilizing the interest rate derived from the fair value analysis of its existing leases and adjusting it for factors that appropriately reflect the profile of secured borrowing over the lease term. For leases existing as of the adoption date, the Company has utilized its incremental borrowing rate based on the remaining lease term as of the adoption date. For leases that commenced after the adoption date, the Company determined the incremental borrowing rate based on the lease term as determined at the commencement date of the lease.
- The expected lease terms include both contractual lease periods and, when applicable, cancellable option periods where failure to exercise such options would result in an economic penalty.
- Since the Company elected to account for the classes of underlying assets and its associated non-lease components as a single combined lease component, all contract consideration was allocated to the combined lease component.

Intangible Assets Subject to Amortization

The Company's intangible assets have been related to acquired software licenses with finite lives which are amortized over their useful lives and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If any indicators were present, the Company would test for recoverability by comparing the carrying amount of the asset to the net undiscounted cash flows expected to be generated from the asset. If those net undiscounted cash flows do not exceed the carrying amount (*i.e.*, the asset is not recoverable), the Company would perform the next step, which is to determine the fair value of the asset and record an impairment loss, if any. The Company evaluates the useful lives for these intangible assets each reporting period to determine whether events and circumstances warrant a revision in their remaining useful lives. At December 31, 2023 and 2022 these intangible assets were fully amortized.

Research and Development Costs

Research and development ("R&D") costs are expensed as incurred. R&D expenses consist of costs incurred in performing R&D activities, including salaries, share-based compensation and benefits, depreciation expense, third-party license fees, external costs of outside vendors engaged to conduct clinical development activities, clinical trials, costs to manufacture clinical trial materials and certain tax credits associated with research and development activities.

UK Research and Developments Tax Credits

As a company that carries out extensive R&D activities, the Company benefits from research and development tax credits in the UK. The Company claims UK research and development tax credits under the regimes for small or medium-sized enterprises ("SME R&D tax credit"), and UK Research and Development Expenditure Credit ("RDEC"), to the extent that the Company's projects are grant funded.

The UK research and development tax credits are fully refundable to the Company and are not dependent on current or future taxable income. As a result, the Company records the entire benefit from the UK research and development tax credits as a benefit, which is included in net loss before income tax and accordingly, not reflected as part of the income tax provision. If, in the future, any UK research and development tax credits generated are needed to offset a corporate income tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded as a reduction of research and development expenses.

The benefits from UK research and development tax credits are recognized in the statements of operations and comprehensive loss as a reduction of research and development expenses and represents the sum of the research and development tax credits recoverable in the UK.

The SME regime has been particularly beneficial to the Company, as under such program the trading losses that arise from the Company's qualifying R&D activities can be surrendered for a cash rebate of up to 33.35% of qualifying expenditure incurred prior to April 1, 2023 and decreasing to 18.6% after April 1, 2023. Additionally, the UK Government has enacted further changes to the SME regime on March 4, 2024 which include the introduction of a new rate for R&D intensive companies of 27% (which the Company may qualify for) and comes into effect for expenditures incurred after April 1, 2024. Qualifying expenditures largely comprise of employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects for which the Company do not receive income. A large proportion of costs in relation to the Company's pipeline research, clinical trials management and manufacturing development activities, all of which are being carried out by its wholly owned subsidiary Autolus Limited, are eligible for inclusion within these tax credit cash rebate claims.

Under the RDEC Program, tax credits for qualifying R&D expenditure incurred prior to April 1, 2023 are granted at a headline rate of 13% and can generate cash rebates of up to 10.5% of qualifying R&D expenditure. The headline rate of RDEC increased to 20% on April 1, 2023 and can generate cash rebates of up to 15% on qualifying R&D expenditure incurred from this date.

Amendments to the current SME and RDEC programs that are contained in the Finance Bill currently proceeding through the UK Parliament will take effect from periods on or after April 1, 2024 and will (i) (unless limited exceptions apply) introduce restrictions on the tax relief that can be claimed for expenditure incurred on sub-contracted R&D activities or externally provided workers, where such sub-contracted activities are not carried out in the UK or such workers are not subject to UK payroll taxes, and (ii) merge the SME regime and the RDEC regime into a single scheme which would generate net cash benefit of up to 15% of the qualifying expenditure for profit making companies and up to 16.2% for loss making companies.

The Company currently meet the conditions of the SME regime, but also can make claims under the RDEC regime to the extent that our projects are grant funded. In addition, the Company may meet the conditions of the R&D intensive scheme and may be able to make claims under merged SME R&D intensive regime. The Company may not be able to continue in the future to qualify as a small or medium-sized enterprise under the SME Regime, based on size criteria concerning employee headcount, turnover and gross assets. If the Company ceases to qualify under the SME regime, the Company may make a claim under the RDEC regime for periods ending December 31, 2024, or the merged R&D regime from period ending December 31, 2025. It should be noted, however, that the types of qualifying expenditure in respect of which the Company may make claims under the RDEC regime are more restricted than under the SME regime (for example, it may be the case that certain subcontracted costs in respect of which claims may be made under the SME regime do not qualify for relief under the RDEC regime).

R&D tax credits of $19.5 million, $24.6 million and $24.0 million were recognized for the years ended December 31, 2023, 2022 and 2021, respectively, and are recorded as offsets to research and development expense in our consolidated statement of operations and comprehensive loss.

Accrued Research and Development Expenses

As part of the process of preparing consolidated financial statements, the Company is required to estimate accruals for research and development expenses. This process involves reviewing and identifying services which have been performed by third parties on the Company's behalf and determining the value of these services. In addition, the Company makes estimates of costs incurred to date but not yet invoiced, in relation to external clinical research organizations and clinical site costs. The Company analyzes the progress of clinical trials, including levels of patient enrollment; invoices received and contracted costs, when evaluating the adequacy of the accrued liabilities for research and development. The Company makes judgments and estimates in determining the accrued balance in any accounting period.

Share-Based Compensation

The Company recognizes share-based compensation expense for equity awards based on the grant date fair value of the award. The Company recognizes share-based compensation expense for awards granted to employees and non-employees that have a graded vesting schedule based on a service condition only on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards (the "graded-vesting attribution method"), based on the estimated grant date fair value for each separately vesting tranche. For equity awards with a graded vesting schedule and a combination of service and performance conditions, the Company recognizes share-based compensation expense using a graded-vesting attribution method over the requisite service period when the achievement of a performance-based milestone is probable, based on the relative satisfaction of the performance condition as of the reporting date. For performance conditions related to regulatory approvals those regulatory approvals are deemed probable when actually achieved. The Company accounts for forfeitures as they occur.

The fair value of each share option grant is estimated on the date of grant using the Black-Scholes option pricing model. See Note 14, "Share-based compensation", for the Company's assumptions used in connection with share option grants made during the periods covered by these consolidated financial statements.

Assumptions used in the option pricing model include the following:

- *Expected volatility.* The Company lacks company-specific historical and implied volatility information for the Company's ADSs for expected terms greater than 5.5 years. Therefore, it uses a combination of the historical volatility of the ADSs and also the expected share volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as the Company has adequate historical data regarding the volatility of its own traded ADS price.
- *Expected term*. The expected term of the Company's share options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options.
- *Risk-free interest rate*. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods that are approximately equal to the expected term of the award.
- *Expected dividend.* Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.
- *Fair value of ordinary shares.* The fair market value of the Company's ADSs underlying the share option is equal to the closing price of the ADSs on the Nasdaq Global Select Market on the date the grant is approved by the Compensation Committee or delegate of the Compensation Committee.

Foreign Currency Translation

The Company maintains its accounting records in its functional currency, which is pound sterling. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net income (loss) for the respective periods. The Company recorded a foreign exchange gain of $2.6 million and $1.8 million for the year ended December 31, 2023 and 2022, respectively, and a foreign exchange loss of $2.3 million for the years ended December 31, 2021. Foreign exchange gains and losses are included in other income (expense), net in the consolidated statements of operations and comprehensive loss.

For financial reporting purposes, the financial statements of the Company have been translated into U.S. dollars. Assets and liabilities have been translated at the exchange rates at the balance sheet dates, while revenue and expenses are translated at the average exchange rates over the reporting period and shareholders' equity amounts are translated based on historical exchange rates as of the date of each transaction. Translation adjustments are not included in determining net income (loss) but are included in foreign exchange adjustment to other comprehensive loss, a component of shareholders' equity.

Patent Costs

The Company expenses patent prosecution and related legal costs as they are incurred and classifies such costs as general and administrative expenses in the accompanying statements of operations and comprehensive loss.

Grant Income

The Company has received research grants under which it is reimbursed for specific research and development activities. Payments received are recognized as income in the statements of operations and comprehensive loss over the period in which the Company recognizes the related costs. At the time the Company recognizes grant income, it has complied with the conditions attached to it and the receipt of the reimbursement is reasonably assured. The Company has received grants from the UK government, which are repayable under certain circumstances, including breach or noncompliance. For grants with refund provisions, the Company reviews the grant to determine the likelihood of repayment. If the likelihood of repayment of the grant is determined to be remote, then the grant is recognized as grant income. The Company has determined that the likelihood of any repayment events included in its current grants is remote.

Interest Income

Interest income arises on the Company's cash and cash equivalents including money market funds and short-term deposits.

License Revenue

The Company accounts for its revenues pursuant to the provisions of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). The Company has no products approved for commercial sale and have not generated any revenue from commercial product sales. The revenue to date has been generated principally from out-licensing agreements with a small number of the Company's customers.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

License Fees and Multiple Element Arrangements

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license at such time as the license is transferred to the licensee and the licensee is able to use, and benefit from, the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligations to determine whether the combined performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Appropriate methods of measuring progress include output methods and input methods. In determining the appropriate method for measuring progress, the Company considers the nature of service that the Company promises to transfer to the customer. When the Company decides on a method of measurement, the Company will apply that single method of measuring progress for each performance obligation satisfied over time and will apply that method consistently to similar performance obligations and in similar circumstances.

Customer Options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluate the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on any identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Contingent Research Milestone Payments

ASC Topic 606 constrains the amount of variable consideration included in the transaction price in that either all, or a portion, of an amount of variable consideration should be included in the transaction price. The variable consideration amount should be included only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The assessment of whether variable consideration should be constrained is largely a qualitative one that has two elements: the likelihood of a change in estimate, and the magnitude thereof. Variable consideration is not constrained if the potential reversal of cumulative revenue recognized is not significant, for example.

If the consideration in a contract includes a variable amount, the Company will estimate the amount of consideration in exchange for transfer of promised goods or services. The consideration also can vary if the Company's entitlement to the consideration is contingent on the occurrence or non-occurrence of a future event. The Company considers contingent research milestone payments to fall under the scope of variable consideration, which should be estimated for revenue recognition purposes at the inception of the contract and reassessed ongoing at the end of each reporting period.

The Company assesses whether contingent research milestones should be considered variable consideration that should be constrained and thus not part of the transaction price. This includes an assessment of the probability that all or some of the milestone revenue could be reversed when the uncertainty around whether or not the achievement of each milestone is resolved, and the amount of reversal could be significant.

U.S. GAAP provides factors to consider when assessing whether variable consideration should be constrained. All of the factors should be considered, and no factor is determinate. The Company considers all relevant factors when assessing whether variable consideration should be constrained

Royalty Revenue

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Accounts receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. Amounts collected on accounts receivable are included in net cash used by operating activities in the consolidated statements of cash flows. Accounts receivable are recorded within prepaid expenses and other current assets on the balance sheet.

Liability Related to Future Royalties and Sales Milestones, net and related interest expense accrued on liability related to future royalties and sales milestones, net and cumulative catch-up adjustment

The Company accounted for the Blackstone Collaboration Agreement (as defined in Note 11, "Liability relating to future royalties and sales milestones, net") as a liability. The carrying amount of the Blackstone Collaboration Agreement liability is based on the Company's estimate of the future royalties and sales milestones to be paid to Blackstone and the Blackstone Development Payments (as defined in the Blackstone Collaboration Agreement) to be received over the life of the arrangement as discounted using an effective interest rate. The excess estimated present value of future royalties and sales milestone payments over the initial carrying amount and future Blackstone Development Payments received, is recognized as a cumulative catch-up method within interest expense using the initial effective interest rate. The imputed rate of interest on the unamortized portion of the Blackstone Collaboration Agreement liability was approximately 15.80% as of December 31, 2023, 2022, and 2021, respectively.

At each reporting period, the Company assesses the estimated probability, timing and amount of any future royalty and sales milestone payments to be made by the Company and Blackstone Development Payments to be received from Blackstone over the term. There are a number of factors that could materially affect the probability, amount and timing of royalty and sales milestone payments to be made by the Company and Blackstone Development Payment to be received from Blackstone, most of which are not within the Company's control. The Blackstone Collaboration Agreement liability is recognized using significant unobservable inputs. These inputs are derived using internal management estimates developed based on third party data and reflect management's judgements, current market conditions surrounding competing products, and forecasts. The significant unobservable inputs include regulatory approvals, estimated patient populations, estimated selling price, estimated sales, estimated peak sales and sales ramp, timing of the expected launch and its impact on the royalties as well as the overall probability of a success. The Company may use a specialist third party valuation team in the determining the present value of the Blackstone Collaboration Agreement liability at each reporting date. Additionally, the transaction costs associated with the liability will be amortized to accrued interest expense over the estimated term of the agreements.

Income Taxes

The Company accounts for income taxes under the asset and liability method which includes the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the Company's financial statements. Under this approach, deferred taxes are recorded for the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the current year plus deferred taxes. Deferred taxes result from differences between the financial statements and tax bases of the Company's assets and liabilities and are adjusted for changes in tax rates and tax law when changes are enacted. The effects of future changes in income tax laws or rates are not anticipated.

The Company is subject to income taxes in the United Kingdom, the United States, Germany and Switzerland. The calculation of the Company's tax provision involves the application of tax law in multiple jurisdictions and requires judgement and estimates.

The Company evaluates the realizability of its deferred tax assets at each reporting date, and establishes a valuation allowance when it is more likely than not that all or a portion of its deferred tax assets will not be realized.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income of the same character and in the same jurisdiction. The Company considers all available positive and negative evidence in making this assessment, including, but not limited to, the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. In circumstances where there is sufficient negative evidence indicating that the Company's deferred tax assets are not more likely than not realizable, the Company establishes a valuation allowance.

The Company uses a two-step approach for recognizing and measuring uncertain tax positions. The first step is to evaluate tax positions taken or expected to be taken in a tax return by assessing whether they are more likely than not sustainable, based solely on their technical merits, upon examination, and including resolution of any related appeals or litigation process. The second step is to measure the associated tax benefit or each position as the largest amount that the Company believes is more likely than not realizable. Differences between the amount of tax benefits taken or expected to be taken in the Company's income tax returns and the amount of tax benefits recognized in its financial statements represent the Company's unrecognized income tax benefits, which it either records as a liability or reduction of deferred tax assets.

Un-surrendered UK losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of United Kingdom taxable profits.

Comprehensive Loss

The Company follows the provisions of the Financial Accounting Standards Board ("FASB") ASC Topic 220, *Comprehensive Income*, which establishes standards for the reporting and display of comprehensive income and its components. Comprehensive gain or loss is defined to include all changes in equity during a period except those resulting from investments by owners and distributions to owners.

Restructuring expenses

The Company records costs and liabilities associated with exit and disposal activities in accordance with FASB ASC Topic 420, *Exit or Disposal Cost Obligations* ("ASC 420"). Such costs are based on estimates of fair value in the period liabilities are incurred. The Company evaluates and adjusts these costs as appropriate for changes in circumstances as additional information becomes available. Refer to Note 22, "Severance Plan".

Net Loss per Share

Basic and diluted net loss per ordinary share is determined by dividing net loss by the weighted average number of ordinary shares outstanding during the period. For all periods presented, the outstanding but unvested restricted shares, unvested restricted stock units ("RSU"), share options and warrants have been excluded from the calculation, due their effects being anti-dilutive in nature. Therefore, the weighted average shares outstanding used to calculate both basic and diluted loss per share are the same for each period presented. Refer to Note 15, "Net loss per share".

Recently issued accounting pronouncements not yet adopted

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting: Improvements to Reportable Segment Disclosures. This ASU modified the disclosure and presentation requirements primarily through enhanced disclosures of significant segment expenses and clarified that single reportable segment entities must apply Topic 280 in its entirety. This guidance is effective for the Company for the year beginning January 1, 2024, with early adoption permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statement. The Company is currently assessing the impact of this guidance on its disclosures.

In December 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures. This ASU improves the transparency of income tax disclosure by requiring consistent categories and greater disaggregation of information in the rate reconciliation, and income taxes paid disaggregated by jurisdiction. This guidance is effective for the Company for the year beginning January 1, 2025, with early adoption permitted. The amendments should be applied on a prospective basis, with retrospective application permitted. The Company is currently assessing the impact of this guidance on its disclosures.

Note 3. Restatement of previously issued consolidated financial statements

In connection with the preparation of the Company's consolidated financial statements as of and for the year ended December 31, 2023, the Company discovered that in prior years it incorrectly accounted and presented its U.K SME tax credit in accordance with ASC 740 - *Income taxes*. The error resulted in an overstatement of both income tax benefit and research and development expense, and therefore total operating expenses, of $24.6 million and $24.0 million for the years ended December 31, 2022 and 2021, respectively.

In accordance with Staff Accounting Bulletin ("SAB") No. 99, "*Materiality*", and SAB No. 108, "*Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*", the Company evaluated these errors as material to its previously issued consolidated financial statements. As a result, the Company has restated its Consolidated Statement of Operations and Comprehensive Loss. There is no effect on the Company's Consolidated Balance Sheet, Consolidated Statements of Shareholders' Equity, or Consolidated Statements of Cash Flows as of and for the years ended December 31, 2022 or 2021. Furthermore, the error had no effect on the Company's net loss attributable to ordinary shareholders or basic diluted net loss per ordinary share.

The following table presents the effect of the restatement adjustments on the Company's Consolidated Statement of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021 (in thousands, except share and per share amounts):

	Year ended December 31, 2022		
	As previously Reported	Restatement adjustments	As Restated
Research and development expenses	$ (141,992)	$ 24,638	$ (117,354)
Total operating expenses, net	(168,046)	24,638	(143,408)
Income tax benefit (expense)	24,366	(24,638)	(272)
Basic and diluted net loss per ordinary share	$ (1.57)	$ —	$ (1.57)

	Year ended December 31, 2021		
	As previously Reported	Restatement adjustments	As Restated
Research and development expenses	$ (134,789)	$ 23,950	$ (110,839)
Total operating expenses, net	(165,000)	$ 23,950	$ (141,050)
Income tax benefit (expense)	23,892	(23,950)	$ (58)
Basic and diluted net loss per ordinary share	$ (1.97)	$ —	$ (1.97)

The Company has also restated its unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the quarterly periods ended March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30, 2023 and September 30, 2023. The unaudited Condensed Consolidated Statement Balance Sheet, Condensed Consolidated Statement of Changes in Equity and Condensed Consolidated Statement of Cash Flows for the periods ended March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30, 2023 and September 30, 2023 were not affected by the misstatement. Furthermore, the error had no effect on the Company's unaudited net loss attributable to ordinary shareholders or basic or diluted net loss per ordinary share for each of the above mentioned quarterly periods. Refer to Note 25, "Restatement of previously issued quarterly condensed consolidated financial statements (unaudited)" for further details.

Note 4. License revenue

Revenue comprises of license revenue only for the years ended December 31, 2023, 2022 and 2021:

Total revenue by geographical location (in thousands):

	Year Ended December 31,		
	2023	2022	2021
License revenue			
United Kingdom	$ 346	$ —	$ —
United States	1,352	6,194	1,507
Total License revenue	**$ 1,698**	**$ 6,194**	**$ 1,507**

Research, Option and License Agreement with Cabaletta:

On January 9, 2023, the Company entered into an Option and License Agreement (the "Cabaletta Agreement") with Cabaletta Bio Inc. ("Cabaletta"), pursuant to which the Company granted to Cabaletta a non-exclusive license to research, develop, manufacture, have manufactured, use, and commercialize products incorporating the Company's safety switch technology (the "RQR8 technology"). Upon the execution of the Cabaletta Agreement, the Company made available the RQR8 licensed know-how to Cabaletta for a non-refundable license fee of $1.2 million. The Company has no further material performance obligations related to the Cabaletta Agreement.

The Company further granted to Cabaletta the option to expand the rights and licenses granted under the Cabaletta Agreement to include the research, development, manufacture, use, or commercialization of licensed products up to a predetermined number of target options upon payment of an option exercise fee.

The Company identified the following material promises relating to the granting of a non-exclusive license for research, development, manufacturing and commercialization activities as well as the initial transfer of know-how and information to Cabaletta. The Company determined the option exercise fee is not offered at a significant and incremental discount. Accordingly, the option granted to Cabaletta does not represent a material right and, therefore, is not a performance obligation at the outset of the arrangement. The Company determined that the granting of the research license and the initial transfer of know-how were not distinct from one another and must be combined as a performance obligation, as Cabaletta requires the know-how to derive benefit from the license. Based on these determinations, the Company identified one distinct performance obligation at the inception of the contract.

The Company further determined that the license fee payable constituted the entirety of the consideration included in the transaction price at contract inception, which was allocated to the one performance obligation. The amount of the transaction price allocated to the performance obligation is recognized as or when the Company satisfies the performance obligation. The Company determined that the performance obligation was recognized at a point-in-time, upon the delivery of the transfer of know-how and research license to Cabaletta. The Company recognized total license revenue of $1.2 million related to the Cabaletta Agreement for the year ended December 31, 2023.

Upon execution of the Cabaletta Agreement, the transaction price included only the $1.2 million non-refundable license fee payable to the Company. The Company may receive further payments upon the exercise of the options for licensed targets, the achievement of certain development and sales milestones, as well as royalty payments based on net sales of each product covered by the licensed intellectual property.

Research, Option and License Agreement with an Investee of Syncona Portfolio Limited

The Company entered into a license agreement with an investee of Syncona Portfolio Limited on September 2, 2020 relating to the Company's RQR8 technology. The terms of the agreement include a non-refundable license fee, payments based upon achievement of clinical development and regulatory objectives, sales milestones payments and royalties on product sales. Upon the execution of the license agreement, the Company made available the RQR8 licensed know-how to investee of Syncona Portfolio Limited for a non-refundable license fee of $0.3 million. The Company has no further material performance obligations related to the agreement.

The Company identified the following material promises relating to the granting of a non-exclusive license for research, development, manufacturing and commercialization activities as well as the initial transfer of know-how and information to the investee of Syncona Portfolio Limited. The Company determined that the granting of the research license and the initial transfer of know-how were not distinct from one another and must be combined as a performance obligation, as the investee of Syncona Portfolio Limited required the know-how to derive benefit from the license. Based on these determinations, the Company identified one distinct performance obligation at the inception of the contract.

Upon execution of the license agreement, the transaction price included only the $0.3 million non-refundable license fee payable to the Company. The Company may receive further payments upon the achievement of certain development and sales milestones, as well as royalty payments based on net sales of each product covered by the licensed intellectual property.

During the year ended December 31, 2023, Company received variable consideration arising from the achievement of a development milestone amounting to $0.35 million. Consequently, the Company recognized license revenue of $0.35 million (net of foreign exchange differences).

Option and License Agreement with Bristol-Myers Squibb:

On October 3, 2022, the Company entered into an Option and License Agreement (the "BMS Agreement") with Bristol-Myers Squibb Company ("BMS"), pursuant to which the Company granted to BMS a non-exclusive license to research, develop, manufacture, have manufactured, use, and commercialize products incorporating the Company's RQR8 technology. Upon the execution of the BMS Agreement, the Company made available the RQR8 licensed know-how to BMS for a non-refundable upfront license fee of $3.5 million. The Company has no further material performance obligations related to the BMS Agreement, as discussed below. BMS have agreed to pay non-refundable development milestones and low single-digit royalties based on net sales of each product covered by the licensed intellectual property.

The Company further granted to BMS the option (the "Target Option") to expand the rights and licenses granted hereunder to include the research, development, manufacture, use, or commercialization of licensed products up to a predetermined number of licensed targets upon payment of an option exercise fee ("Option Exercise Fee").

The Company identified the following material promises in the arrangement: the granting of a non-exclusive license for research and preclinical development activities as well as the initial transfer of know-how and information to BMS. The Company determined that the Option Exercise Fee was not offered at a significant and incremental discount. Accordingly, the Commercial Option did not represent a material right and, therefore, was not a performance obligation at the outset of the arrangement. The Company determined that the granting of the research license and the initial transfer of know-how were not distinct from one another and must be combined as a performance obligation (the "BMS Combined Performance Obligation"). This is because BMS requires the know-how to derive benefit from the license. Based on these determinations, the Company identified one distinct performance obligation at the inception of the contract: the BMS Combined Performance Obligation. The Company further determined that the up-front payment of $3.5 million constituted the entirety of the consideration included in the transaction price at contract inception, which was allocated to the BMS Combined Performance Obligation. The amount of the transaction price allocated to the BMS Combined Performance Obligation is recognized as or when the Company satisfies the performance obligation. The Company determined that the BMS Combined Performance Obligation was recognized at a point-in-time, upon the delivery of the transfer of know-how and research license to BMS.

Upon execution of the BMS Agreement, the transaction price included only the $3.5 million up-front payment owed to the Company. The Company may receive further payments upon the exercise of the Target Option, the achievement of certain milestones, as well as royalty payments that reach low-single digit based on future net sales. The Company received an upfront non-refundable cash payment of $3.5 million in November 2022 and recognized license revenue of $3.5 million for the year ended December 31, 2022.

Research, Option and License Agreement with Moderna

On June 22, 2021, the Company entered into a Research, Option and License Agreement (the "Moderna Agreement") with ModernaTX, Inc. ("Moderna"), pursuant to which the Company granted to Moderna an exclusive research license to perform research and pre-clinical development activities relating to target sequences with respect to certain of the Company's research targets and products. The Company also granted Moderna on a research target-by-research target basis, the right to obtain an exclusive commercial license upon payment of a commercial option fee of $2.0 million (the "Commercial Option").

Pursuant to the Moderna Agreement, the Company received an upfront non-refundable cash payment of $1.5 million in October 2021 and is entitled to receive development milestones payments per product and in sales milestones payments per product from Moderna if certain clinical, regulatory and sales performance milestones are achieved. The Company is further eligible to receive royalties in the low to mid-single digits on net sales on a product-by-product basis.

The Company identified the following material promises in the arrangement: the granting of an exclusive license to research and preclinical development activities as well as the initial transfer of know-how and information to Moderna. The Company determined the Commercial Option fee was not offered at a significant and incremental discount. Accordingly, the Commercial Option did not represent a material right and, therefore, was not a performance obligation at the outset of the arrangement. The Company determined that the granting of the research license and the initial transfer of know-how were not distinct from one another and must be combined as a performance obligation (the "Moderna Combined Performance Obligation"). This is because Moderna requires the know-how to derive benefit from the research license. Based on these determinations, the Company identified one distinct performance obligation at the inception of the contract: the Moderna Combined Performance Obligation.

The Company further determined that the up-front payment of $1.5 million constituted the entirety of the consideration included in the transaction price at contract inception, which was allocated to the Combined Performance Obligation. The amount of the transaction price allocated to the Moderna Combined Performance Obligation is recognized as or when the Company satisfies the performance obligation. The Company determined that the Moderna Combined Performance Obligation was recognized at a point-in-time, upon the delivery of the transfer of know-how and research license to Moderna.

Upon execution of the Agreement, the transaction price included only the $1.5 million up-front payment was owed to the Company. The Company may receive further payments upon the exercise of the Commercial Option, the achievement of certain milestones, as detailed above, as well as royalty payments that reach mid-single digits based on future net sales. In September 2022, Moderna exercised its option, pursuant to the terms of the Moderna Agreement, to obtain the commercial license of the Company's proprietary binders against an undisclosed immuno-oncology target for the development and commercialization of mRNA therapeutics resulting in the Company recognizing $2.0 million of license revenue for the year ended December 31, 2022.

The future milestones, which represent variable consideration, were evaluated under the most likely amount method, and were not included in the transaction price, because the amounts were fully constrained as of December 31, 2023 and 2022, respectively. As part of the Company's evaluation of the constraint, it considered numerous factors, including that receipt of such milestones is outside the Company's control. Separately, any consideration related to development milestones, sales-based milestones, as well as royalties on net sales upon commercialization by Cabaletta, BMS, Moderna and the investee of Syncona Portfolio Limited, will be recognized when the related sales occur, and therefore, have also been excluded from the transaction price in accordance with the sales-based royalty exception. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

For the years ended December 31, 2023, 2022 and 2021, the Company has not recognized any variable consideration with regards to the development milestones, sales-based milestones which are included in the revenue generating license agreements with Cabaletta, BMS and Moderna. These development milestones are not yet probable and therefore no revenue has been recognized.

For the years ended December 31, 2023, 2022 and 2021 the Company has not recognized any royalty revenue from the license agreements that were executed in the current and prior periods.

Note 5. Interest expense

Interest expense consisted of the following (in thousands):

	Year Ended December 31,		
	2023	**2022**	**2021**
Interest expense accrued on liability related to future royalties and sales milestones, net (refer to Note 11)	$ 19,892	$ 8,005	$ 1,093
Cumulative catch-up adjustment arising from the liability related to future royalties and sales milestones, net (refer to Note 11)	25,107	879	—
Other interest expense	68	21	12
	$ 45,067	**$ 8,905**	**$ 1,105**

Note 6. Fair value measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	December 31, 2023			
	Total	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Financial assets				
Cash and cash equivalents:				
Money market funds	$ 184,635	$ 184,635	$ —	$ —
Total	**$ 184,635**	**$ 184,635**	**$ —**	**$ —**

	December 31, 2022			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash and cash equivalents:				
Money market funds	$ 28,593	$ 28,593	$ —	$ —
Total	**$ 28,593**	**$ 28,593**	**$ —**	**$ —**

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1.

Note 7. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2023	2022
Research and development claims receivable	$ 19,209	$ 24,685
Prepayments	8,638	12,337
VAT receivable	2,771	2,701
Deferred cost	1,787	1,494
Other receivable	1,515	1,435
Lease and lease deposit receivable	938	32
Accounts receivable	109	121
Other assets	—	203
Grant income receivable	—	2
Total prepaid expenses and other current assets	**$ 34,967**	**$ 43,010**

Note 8. Property and equipment, net

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

	December 31,	
	2023	2022
Lab equipment	$ 32,232	$ 31,188
Office equipment	3,777	3,573
Furniture and fittings	2,360	1,221
Leasehold improvements	12,728	11,688
Assets under construction	12,539	13,186
Less: accumulated depreciation	(28,774)	(25,647)
Total property and equipment, net	**$ 34,862**	**$ 35,209**

Depreciation expense recorded for the years ended December 31, 2023, 2022 and 2021 was $6.6 million, $7.3 million and $8.6 million, respectively.

Note 9. Intangible assets, net

The following table summarizes the carrying amount of the Company's intangible assets, net of accumulated amortization (in thousands):

	December 31,	
	2023	**2022**
Software licenses	$ —	$ 258
Less: accumulated amortization	—	(258)
Total intangibles assets, net	**$ —**	**$ —**

Software licenses have an estimated useful life of 3 years. Amortization expense for the years ended December 31, 2023, 2022 and 2021 was nil, $65,000 and $90,000, respectively.

Note 10. Accrued expenses and other liabilities

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

	December 31,	
	2023	**2022**
Research and development costs	$ 19,825	$ 26,478
Compensation and benefits	14,757	10,181
Professional fees	4,466	3,745
Other liabilities	533	393
Total accrued expenses and other liabilities	**$ 39,581**	**$ 40,797**

Research and development costs have decreased primarily due to a reduction in clinical trials related costs relating to the Company's product candidate obe-cel.

Note 11. Liability related to future royalties and sales milestones, net

Blackstone Agreements

On November 6, 2021, the Company concurrently entered into the following agreements with BXLS V - Autobahn L.P, (“Blackstone”) collectively called the “Blackstone Agreements”:

(i) Strategic Collaboration and Financing Agreement, (the “Blackstone Collaboration Agreement”);

(ii) Securities Purchase Agreement (the “Blackstone Securities Purchase Agreement”) - refer to Note 13. “Shareholders' equity”;

(iii) Warrant Agreement (the “Blackstone Warrant”) - refer to Note 12, “Warrants"; and

(iv) a Registration Rights Agreement (the “Blackstone Registration Rights Agreement”).

The Blackstone Agreements were entered into and in contemplation of one another and, accordingly, the Company assessed the accounting for these agreements in the aggregate.

Blackstone Collaboration Agreement

Pursuant to the Blackstone Collaboration Agreement, Blackstone agreed to pay the Company up to $150 million to support the continued development of the Company's CD19 CAR T cell investigational therapy product candidate, obecabtagene autoleucel (obe-cel), as well as next generation product therapies of obe-cel in B-cell malignancies. These payments include (i) an upfront payment of $50 million and (ii) up to $100 million payable based on the achievement of certain specified clinical, manufacturing and regulatory milestones (each such payment, a “Blackstone Development Payment” and collectively, the “Blackstone Development Payments”)

In November 2021, the upfront payment of $50 million was paid by Blackstone upon execution of the Blackstone Collaboration Agreement. In December 2022, two Blackstone Development Payments were paid by Blackstone of $35 million each as a result of (i) the joint steering committee's review of Autolus' interim analysis of pivotal FELIX Phase 2 clinical trial of obe-cel in relapsed/refractory (r/r) adult Acute Lymphoblastic Leukemia (ALL) and (ii) achievement of a pre-agreed manufacturing milestone as a result of completion of planned activities demonstrating the performance and qualification of the Company's obe-cel's manufacturing process. The remaining $30 million will be payable to the Company on the achievement on certain specified regulatory milestones. The Company considers the achievement of the specified regulatory milestone as probable when actually achieved.

In exchange for the Blackstone Development Payments, the Company agreed to make payments to Blackstone (the "Revenue Share Payments") equal to a mid-single digit royalty, subject to the Aggregate Cap (as defined in the Blackstone Collaboration Agreement) on payments under the Blackstone Collaboration Agreement, based on net sales anywhere in the world of (i) Collaboration Products in B-cell malignancies, (ii) subject to certain conditions set forth in the Blackstone Collaboration Agreement, its CD19 and CD22 CAR T cell investigational therapy product candidate known as AUTO3 in B-cell malignancies, and (iii) certain Collaboration Products to the extent developed or commercialized in indications other than a B-cell malignancy ("Obe-cel Franchise Products"). The Company is also obligated to make payments (the "Sales Milestone Payments"), subject to the Aggregate Cap, if certain cumulative net sales levels are achieved.

The Company, and all of its subsidiaries have provided, and all of its future subsidiaries will provide, a guaranty to Blackstone of its obligations under the Blackstone Collaboration Agreement. In addition, the Company has granted a security interest in its subsidiary Autolus Limited to Blackstone in (a) intellectual property that is necessary or useful for the development, manufacture, use, commercialization, import, or export of Collaboration Products (the "Autolus IP Collateral"), (b) a segregated and blocked cash collateral account that will be established following regulatory approval of any Collaboration Product, solely for the purpose of receiving remittance of Revenue Share Payments and Sales Milestone Payments and disbursement thereof to Blackstone as provided in the Blackstone Collaboration Agreement, (c) a segregated cash collateral account established solely for the purpose of receiving Blackstone Development Payments and disbursing them for use by the Company in accordance with the terms of the Blackstone Collaboration Agreement, (d) all assets or property of the Company related to or arising from the Collaboration Products in any B-cell malignancy or the obe-cel Franchise Products in any indication other than a B-cell malignancy, and (e) all proceeds and products of each of the foregoing (collectively referred to as the "Collateral"). The security interest will be maintained until the earlier of (i) such time at which cumulative payments made by the Company under the Blackstone Collaboration Agreement equal $150 million and (ii) the first commercial sale in the United States of obe-cel or any other Lead Product (as defined in the Blackstone Collaboration Agreement) selected to replace obe-cel following a Program Failure (as defined in the Blackstone Collaboration Agreement) (such time, the "Release Time").

The Blackstone Collaboration Agreement contains negative covenants that restrict the Company from, among other things, (a) granting liens or otherwise encumbering its assets that constitute Collateral, (b) paying dividends or making distributions on account or, or redeeming, retiring or purchasing any capital stock, (c) other than certain permitted licensing transactions, transferring to third parties rights to commercialize any Collaboration Product or the Autolus IP Collateral anywhere in the world and (d) selling, transferring or assigning any rights to receive payments of royalties, returns on net sales, revenue share or other compensation or license fees with respect to a Collaboration Product in a B-cell malignancy and/or obe-cel Franchise Product in any indication other than a B-cell malignancy. Each of the negative covenants is subject to exceptions and carve outs set forth in the Blackstone Collaboration Agreement. The negative covenants will fall away upon the Release Time.

Termination of the Blackstone Collaboration Agreement by Blackstone due to certain breaches of the Blackstone Collaboration Agreement or other actions by the Company will require the Company to make liquidated damage payments to Blackstone in excess of the Blackstone Development Payments.

The Company has accounted for the Blackstone Collaboration Agreement as a liability primarily due to the Company's significant continuing involvement in generating the royalty stream. If and when obe-cel is commercialized and royalties or sales milestones become payable, the Company will recognize the portion of royalties paid to Blackstone as a decrease to the Collaboration Agreement liability with a corresponding reduction in cash.

The Company concluded the Blackstone Agreements comprised of the following three units of accounting for the consideration received: (i) the Blackstone Collaboration Agreement, (ii) the purchase of ADSs, representing its ordinary shares, and (iii) Blackstone Warrants. The three units of accounting were recorded at relative fair value upon initial recognition and are not subsequently measured at fair value.

During 2021, the Company allocated the initial total gross proceeds arising from the Blackstone Collaboration Agreement and the Blackstone Securities Purchase Agreement along with the issuance of the Blackstone Warrant among the three units of accounting on a relative fair value basis at the time of the transaction as follows:

Units of Accounting	Gross proceeds *(in millions)*	Initial fair value *(in millions)*	Allocated consideration based on relative fair value *(in millions)*	Net allocated consideration based on relative fair value after transaction costs* *(in millions)*
Liability related to future royalties and sales milestones, net (Blackstone Collaboration Agreement)	$ 50.0	$ 49.6	$ 46.4	$ 45.9
ADSs, representing ordinary shares	100.0	100.0	93.6	91.6
Warrants	—	10.7	10.0	9.9
Total	**$ 150.0**	**$ 160.3**	**$ 150.0**	**$ 147.4**

* In addition, the total shared transaction costs of $1.7 million, relating to the Blackstone Agreement have been allocated to the three units of accounting on a relative fair value basis.

The Company allocated the consideration and issuance costs on a relative fair value basis to the Collaboration Agreement, securities purchased and warrants issued to Blackstone which resulted in the Blackstone Collaboration Agreement being initially recognized at $46.4 million (relative fair value of $45.9 million, net of issuance costs).

The two Blackstone Development Payments received during the year ended December 31, 2022 were allocated solely to the Blackstone Collaboration Agreement liability.

Changes to the Blackstone Collaboration Agreement liability related to future royalties and sales milestones are as follows:

	Amount in thousands
Balance at December 31, 2021	**$ 47,016**
Proceeds from Blackstone Development Payments received	70,000
Interest expense accrued on liability related to future royalties and sales milestones, net (included interest expense)	8,005
Cumulative catch-up adjustment (included in interest expense)	879
Balance at December 31, 2022	**$ 125,900**
Interest expense accrued on liability related to future royalties and sales milestones, net (included interest expense)	19,892
Cumulative catch-up adjustment (included in interest expense)	25,107
Balance at December 31, 2023	**$ 170,899**

Note 12. Warrants

On November 6, 2021, in connection with the Blackstone Agreement, pursuant to the Blackstone Warrant, the Company issued Blackstone a warrant to purchase up to 3,265,306 ADSs representing 3,265,306 of the Company's ordinary shares, at an exercise price of $7.35 per ADS. The Blackstone Warrant is exercisable in whole or in part until November 6, 2026.

The Blackstone Warrant mechanism does not create any obligation to transfer cash to the investor but a fixed amount of ordinary shares upon exercise. Therefore, the Company has accounted for the Blackstone Warrant as equity-classified instruments (recognized within additional paid-in capital), per ASC 815-40. The assessment considers whether the warrants are freestanding financial instruments, meet the definition of a liability or whether the warrants meet all of the requirements for equity classification, including whether the warrants are indexed to the Company's own shares, among other conditions for equity classification. On November 6, 2021, the Blackstone Warrant had a relative fair value of approximately $10.0 million. As a result, the Company recorded a discount on the Blackstone Collaboration Agreement of $3.6 million during the year ended December 31, 2021. In addition, the Company also applied an offset to additional paid-in capital in an amount of $6.4 million related to the issuance of the Company's ordinary shares arising from the Blackstone Securities Purchase Agreement. Refer to Note 13, "Shareholders' equity".

The fair value of each Blackstone Warrant issued was estimated on the date of issuance using the Black-Scholes option pricing model. The assumptions used in the Black Scholes option pricing model relating to the Blackstone Warrant issued in 2021 included the following:

Expected volatility. The Company lacks company-specific historical and implied volatility information for our ADSs for expected terms greater than 3.5 years. Therefore, the Company uses a combination of the historical volatility of its ADSs and also the expected share volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as the Company has adequate historical data regarding the volatility of its own traded security price.

- *Expected term*. The expected term of the Company's warrants has been determined utilizing the contractual term of the warrants.
- *Risk-free interest rate*. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of granting of the warrant for time periods that are approximately equal to the expected term of the award.
- *Expected dividend.* Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.
- *Fair value of ordinary shares.* The fair value of each ordinary share was based on the closing price of the Company's publicly traded ADSs as reported on date of issuance.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the warrants issued to Blackstone as at November 6, 2021 were as follows:

Expected warrant life (years)	5
Risk-free interest rate	1.04%
Expected volatility	80.23%
Expected dividend yield	0%

The Company determined the initial fair value of Blackstone Warrant using the Black-Scholes option pricing model to be $10.7 million.

Note 13. Shareholders' equity

Ordinary Shares

Each holder of ordinary shares is entitled to one vote per ordinary share and to receive dividends when and if such dividends are recommended by the board of directors and declared by the shareholders. As of December 31, 2023, the Company has not declared any dividends.

The Company has obtained shareholder approval to allot additional ordinary shares for a period of five years from June 2022 (being the date on which the Company's shareholders, at the Company's Annual General Meeting of Shareholders, approved an ordinary resolution containing the relevant authorization), up to a maximum nominal amount of $8,400, which authorization will need to be renewed upon expiration (*i.e.*, at least every five years) but may be sought more frequently for additional five-year terms (or any shorter period).

As of December 31, 2023, the Company's issued capital share consisted of i) 174,101,361 ordinary shares, with a nominal value of $0.000042 per share, (ii) 34,425 deferred shares, with a nominal value of £0.00001 per share, (iii) 88,893,548 B deferred shares, with a nominal value of £0.00099 per share and (iv) one C deferred share, with a nominal value of £0.000008. Each issued share has been fully paid.

Initial Public Offering and Impact of Corporate Reorganization

On June 18, 2018, Autolus Therapeutics Limited re-registered as a public limited company and its name was changed from Autolus Therapeutics Limited to Autolus Therapeutics plc.

On June 26, 2018, the Company closed its IPO. Upon the closing of the IPO, each separate class of ordinary shares of Autolus Therapeutics plc was converted into a single class of ordinary shares of Autolus Therapeutics plc as described further below.

Prior to the Company's June 2018 reorganization and IPO, the Company had issued series A preferred shares, ordinary B shares, and ordinary C shares to fund its operations and upon the completion of the IPO, the different classes of shares were converted into a single class of ordinary shares on a 3.185-for-1 basis and created various classes of deferred shares.

The following deferred share classes were created:

Deferred Shares - The 34,425 deferred shares, aggregate nominal value less than $1.00, existed in Autolus Limited and were re-created in Autolus Therapeutics plc as part of the share exchange to place Autolus Therapeutics as the ultimate parent entity. The Company was required to replicate the shares to ensure the existing share has the correct nominal value to ensure stamp duty mirroring relief is available on the subsequent share for share exchange. These deferred shares have no voting rights.

Deferred B Shares - The deferred shares were the product of the reorganization of the series A preferred shares and ordinary B shares into ordinary shares. The nominal residual value was utilized by management as the required £50,000 of share capital to re-register Autolus Therapeutics Limited as Autolus Therapeutics plc. The resulting 88,893,548 deferred shares, aggregate nominal value of $118,000, is presented as a separate class of equity on the balance sheet and statement of shareholder's equity. These deferred B shares have no voting rights.

Deferred C Share - The deferred share, nominal value less than $1.00, was created when the shares in the Company were redenominated from pounds sterling to U.S. Dollars as part of the capital reduction to deal with rounding issues that would otherwise have unbalanced the company's nominal share capital. This deferred C share has no voting rights.

February 2021 Public Offering

On February 12, 2021, the Company completed an underwritten public offering of 14,285,715 ADSs representing 14,285,715 ordinary shares at a public offering price of $7.00 per ADS. In addition, the underwriters exercised their right to purchase an additional 2,142,857 ADSs representing 2,142,857 ordinary shares, at a public offering price of $7.00 per ADS. Aggregate net proceeds to the Company, after underwriting discounts and offering expenses, were $106.9 million.

Blackstone Securities Purchase Agreement

On November 6, 2021, pursuant to the Securities Purchase Agreement (the "Blackstone Securities Purchase Agreement"), the Company sold 17,985,611 ADSs, representing 17,985,611 ordinary shares, at a private placement price of $5.56 per ADS to Blackstone, resulting in gross proceeds of $100 million. Aggregate net proceeds to the Company after offering expenses, were $98.0 million. Net allocated consideration based on relative fair value after deducting direct and allocated shared transaction costs relating to the issuance of ADSs, were $91.6 million. For further details of the Blackstone Agreements, see Note 11, "Liability related to future royalties and sales milestones, net" and Note 12, "Warrants".

December 2022 Public Offering

In December 2022, the Company completed an underwritten public offering of 81,927,012 ADSs representing 81,927,012 ordinary shares, which includes the partial exercise by the underwriters to purchase an additional 6,927,012 ADSs, at a public offering price of $2.00 per ADS. Aggregate net proceeds to the Company, after underwriting discounts and offering expenses, were $152.4 million.

February 2024 Private Placement with BioNTech SE and Underwritten Offering

Refer to Note 24, "Subsequent events" for further information.

Open Market Sale Agreement

In September 2020, the Company entered into an Open Market Sale Agreement, or the "Sales Agreement", with Jefferies LLC, or Jefferies, under which the Company could, at its option, offer and sell ADSs having an aggregate offering price of up to $100.0 million from time to time through Jefferies, acting as sales agent. Any such sales made through Jefferies could be made by any method that is deemed an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act, or in other transactions pursuant to an effective shelf registration statement on Form F-3. The Company agreed to pay Jefferies a commission of 3.0% of the gross proceeds of any sales of ADSs sold pursuant to the Sales Agreement. During the year ended December 31, 2021, the Company issued an aggregate of 3,787,972 ADSs under the Sales Agreement for net proceeds, after underwriting discounts and offering expenses, of $29.6 million. There were no similar sales in 2022 and 2023. The Sales Agreement expired in September 2023.

Note 14. Share-based Compensation

In February 2017, the Board adopted the 2017 Share Option Plan, or the 2017 Plan. The 2017 Plan was set to expire on February 21, 2027. The 2017 Plan provided for the grant of potentially tax-favored Enterprise Management Incentives, or EMI, options to the Company's UK employees and for the grant of options to its U.S. employees.

In June 2018, as part of the Company's reorganization and IPO, the Company's board of directors and shareholders approved the 2018 Equity Incentive Plan, or the 2018 Plan. The initial maximum number of ordinary shares that may be issued under the 2018 Plan was 3,281,622. This number consists of 3,025,548 new ordinary shares and 256,074 ordinary shares that would have otherwise remained available for future grants under the 2017 Plan. The number of ordinary shares reserved for issuance under the 2018 Plan will automatically increase on October 1st of each year, for a period of not more than ten years, commencing on October 1, 2018 and ending on (and including) October 1, 2027, by an amount equal to the lesser of (i) 4% of the total number of ordinary shares outstanding on September 30th of the same calendar year or (ii) such fewer number of ordinary shares as the board of directors may designate prior to the applicable October 1st date.

The updated maximum number of ordinary shares that may be issued under the 2018 Plan is 22,298,243 as of December 31, 2023. The total shares issued under the 2018 Plan may be authorized but unissued shares, shares purchased on the open market, treasury shares or ADSs.

Share options granted under the 2018 Plan and 2017 Plan, as well as restricted shares granted as employee incentives, typically vest over a four-year service period with 25% of the award vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining three-years, unless the award contains specific performance vesting provisions.

Share options granted under the 2018 Plan and 2017 Plan generally expire ten years from the date of grant. For certain senior members of management and directors, the board of directors has approved an alternative vesting schedule.

Share Option Valuation

The assumptions (see Note 2) used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees and directors during the years ended December 31, 2023, 2022 and 2021 were as follows:

	Year Ended December 31,		
	2023	2022	2021
Expected option life (years)	5.19 to 6.08	5.27 to 6.08	5.27 to 6.08
Risk-free interest rate	3.37% to 4.86%	2.20% to 4.23%	0.62% to 1.34%
Expected volatility	83.25% to 85.51%	78.73% to 84.79%	80.05% to 82.03%
Expected dividend yield	0%	0%	0%

Share Options

The table below summarizes Company's share option activity during the year ended December 31, 2023.

	Number of Options	Weighted-Average Exercise Price per share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value [1] (in thousands)
Outstanding as of December 31, 2022	10,310,800	$ 8.90	8.18	$ 96
Granted	8,783,330	2.29	—	36,412
Exercised	(10,107)	2.69	—	11
Forfeited	(487,607)	4.10	—	1,203
Expired	(640,031)	13.60	—	90
Outstanding as of December 31, 2023	17,956,385	$ 5.64	8.35	$ 48,968
Exercisable as of December 31, 2023	6,318,107	$ 10.48	6.95	$ 7,601
Vested and expected to vest as of December 31, 2023	17,956,385	$ 5.64	8.35	$ 48,968

(1) Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of common stock for those options in the money as of December 31, 2023

The total intrinsic value of options exercised was $0.01 million, $0.4 million, and $1.2 million for the years ended December 31, 2023, 2022, and 2021, respectively. The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's underlying ordinary shares for those share options that had exercise prices lower than the fair value of the Company's underlying ordinary shares. The total fair value of share options vested (including performance-based share options) amounted to $11.4 million, $11.1 million, and $13.0 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The weighted average grant-date fair value of share options granted was $1.69, $2.24 and $4.91 per option for the years ended December 31, 2023, 2022 and 2021 respectively.

As of December 31, 2023, the total unrecognized compensation expense related to unvested share options without performance conditions was $12.8 million, which the Company expects to recognize over a weighted average vesting period of 3.25 years.

Performance based share options

During the year ended December 31, 2021, the Company granted 1,602,500 share options with performance conditions related to specified regulatory milestones, of which 222,500 share options with performance conditions were forfeited. During the year ended December 31, 2021, 80,000 of these share options were modified to remove the performance conditions, thereby accelerating the vesting.

During the year ended December 31, 2022, the Company did not grant any share options with performance conditions. However, during the year ended December 31, 2022, 222,500 share options with performance conditions were forfeited. In addition, 120,000 performance-based share options were modified during the year ended December 31, 2022 to remove the performance conditions, thereby accelerating the vesting and resulting in associated share-based compensation expense of $0.3 million.

During the year ended December 31, 2023, the Company granted 107,600 share options with a specified regulatory performance condition. No performance-based share options were forfeited during the year ended December 31, 2023. In addition, during the year ended December 31, 2023, 478,750 performance-based share options vested upon the achievement of the relevant regulatory milestone.

As of December 31, 2023, 2022 and 2021, a performance condition related to these performance-based share options was deemed probable. As a result, $1.0 million, $1.1 million and $1.4 million share-based compensation expense was recognized for the years ended December 31, 2023, 2022 and 2021, respectively. As at December 31, 2023, the total unrecognized share-based compensation expense related to unvested share options with performance conditions was $3.1 million, which the Company expects to recognize over a weighted average vesting period of 2.33 years.

Restricted Stock Units

An RSU award represents the right to receive one of the Company's ADSs upon vesting of the RSU. The fair value of each RSU award is based on the closing price of the Company's ADSs on the date of grant. Prior to 2021, the Company historically granted RSU awards with service conditions that vest over a three-year service period with 50% of the award vesting one-and-half years from grant date and the remaining 50% of the award vesting at the end of the third year. In January 2021, the Company awarded RSU awards that contained a performance condition based on a condition related to a specified clinical milestone. These performance-based RSU awards vest upon achievement of the related performance condition. In March 2021, the Company awarded RSU awards with service conditions that vest over a four-year service period with 25% on the first anniversary of the grant date, and the balance vesting quarterly over the remaining three-years. In July 2021, the Company awarded RSU awards with service conditions that vest over a two-year period, with 100% of the award vesting on the second anniversary of the grant date.

In 2022, RSUs awarded during the year typically vest over a four-year service period, with 25% of the award vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining three years. However, in September 2022, the Company awarded RSU awards with service conditions that vest over an 11-month period, with 50% of the award vesting eight months from grant date and the remaining 50% of the award vesting at the end of the eleventh month. In addition, in December 2022, the Company awarded RSU awards with service conditions that vest over a 15 month period, with 50% of the award vesting twelve months from grant date and the remaining 50% of the award vesting at the end of the fifteenth month.

In July 2023, the Company granted 90,000 RSU awards with a performance condition related to a specified regulatory milestone. These performance-based RSU awards vest upon achievement of the related performance condition.

The following is a summary of the Company's RSU activity for the 2018 Plan for the year ended December 31, 2023:

	Number of restricted units	Weighted average grant date fair value
Unvested and outstanding at December 31, 2022	403,331	$ 3.50
Granted	90,000	2.54
Vested	(351,427)	3.34
Forfeited	(25,468)	2.65
Unvested and outstanding at December 31, 2023	**116,436**	**$ 3.43**

As of December 31, 2023, there was $0.1 million of unrecognized share-based compensation expense related to unvested RSUs without performance conditions, which are expected to be recognized over a weighted average period of 1.69 years.

The total fair value of share RSU awards vested (including performance-based RSU awards) amounted to $1.3 million, $1.5 million, and $1.5 million for the years ended December 31, 2023, 2022 and 2021, respectively.

Performance-based RSU awards

During the year ended December 31, 2021, the Company awarded an aggregate of 1,020,000 RSU awards with a performance condition related to a specified clinical milestone. As of December 31, 2021, the related clinical milestone performance condition was determined to be probable and accordingly, $4.4 million of share-based compensation expense was recognized.

During the year ended December 31, 2022, 617,500 of these RSU awards vested due to the achievement of a specified clinical milestone resulting in the recognition of $1.2 million of share-based compensation expense. A further 60,000 of these RSU awards were modified during the year ended December 31, 2022 by removing the performance condition, thereby accelerating the vesting and resulting in related share-based compensation expense of $0.2 million. An aggregate of 152,500 and 222,500 performance based RSU awards with performance conditions were forfeited during the year ended December 31, 2022 and 2021, respectively.

During the year ended December 31, 2023, the Company granted 90,000 RSU awards with performance condition related to a specified regulatory milestone. These performance-based RSU awards also vested during the year upon the achievement of the relevant regulatory milestone. This resulted in the recognition $0.2 million share-based compensation expense during the year ended December 31, 2023.

As of December 31, 2023 there was no unrecognized share-based compensation expense relating to performance based RSU awards.

During the year ended December 31, 2023, 57,624 RSU awards vested but were not issued as of December 31, 2023, and as such are not included in the Company's outstanding shares at December 31, 2023. 57,524 of these RSU awards were issued in February 2024.

Share-based compensation expense

Share-based compensation expense recorded as research and development and general and administrative expenses is as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Research and development	$ 6,732	$ 7,171	$ 5,241
General and administrative	4,472	4,849	4,696
Capitalized to intangible assets, net / property and equipment	46	(6)	—
Total share-based compensation expense	**$ 11,250**	**$ 12,014**	**$ 9,937**

Note 15. Net loss per share

Basic and diluted net loss per share attributable to ordinary shareholders was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2023	2022	2021
Numerator			
Net loss	$ (208,383)	$ (148,839)	$ (142,096)
Net loss attributable to ordinary shareholders - basic and diluted	**$ (208,383)**	**$ (148,839)**	**$ (142,096)**
Denominator			
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	173,941,926	94,993,400	72,084,078
Net loss per share - basic and diluted	**$ (1.20)**	**$ (1.57)**	**$ (1.97)**

For all periods presented, outstanding but unvested restricted shares, unvested RSUs, share options and warrants have been excluded from the calculation, because their effects would be anti-dilutive. Therefore, the weighted average number of ordinary shares used to calculate both basic and diluted loss per share are the same for all periods presented.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	December 31,		
	2023	2022	2021
Unvested RSUs	116,436	403,331	1,089,650
Share options	17,956,385	10,310,800	7,772,455
Warrants	3,265,306	3,265,306	3,265,306
Total	**21,338,127**	**13,979,437**	**12,127,411**

Note 16. License Agreements

University College London Business Ltd. (UCLB) License

In September 2014, the Company entered into an exclusive license agreement (the "License") with UCL Business Ltd. ("UCLB"), the technology transfer company of University College London ("UCL"), to obtain licenses to certain technology rights in the field of cancer therapy and diagnosis. In March 2016, the License was amended to include additional rights.

As part of the consideration for the License in September 2014, the Company issued 1,497,643 ordinary shares to UCLB. The Company paid upfront fees of £0.3 million and issued an additional 313,971 ordinary shares to UCLB when the License was amended in March 2016.

In March 2018, the License was further amended and restated to include a license to the Company's product candidate, obe-cel, for which UCL is conducting Phase 1 clinical trials in pediatric and adult ALL patients. The Company paid an upfront fee of £1.5 million for consideration for the amended and restated License and paid the additional £0.35 million in connection with UCLB's transfer of clinical data to the Company in December 2020. No equity was issued as part of the upfront fee consideration.

In October 2020, the License was further amended and restated to reflect the Company's election to have various patent rights assigned to the Company, and to include a license to new technology and further licenses to obe-cel for which UCL is conducting Phase 1 clinical trials in primary CNS Lymphoma patients.

Additionally, the Company may be obligated to make payments to UCLB under the amended and restated License upon the initiation of certain clinical activities in an aggregate amount of £0.18 million, the receipt of specified regulatory approvals in an aggregate amount of £37.5 million, the start of commercialization in an aggregate amount of £18.0 million, and the achievement of net sales levels in an aggregate amount of £51.0 million, as well as royalty payments based on possible future sales resulting from the utilization of the licensed technologies. On a per-product basis, these milestone payments range from £1.0 million to £18.5 million, depending on which T cell programming modules are used in the product achieving the milestone. The Company considers the regulatory approval and commercial milestones probable when actually achieved.

Under the terms of the license, the Company has the right to grant sub-licenses to third parties, subject to certain restrictions. If the Company receives any income in connection with such sublicenses, it must pay UCLB a percentage of the income allocable to the value of the sublicensed intellectual property rights ranging from the low twenties to mid-single digits percent, decreasing based on the development expenses incurred by us and the passage of time. During the year ended December 31, 2023, $0.2 million was payable to UCLB by the Company relating to the income allocable to the value of the sublicensed intellectual property rights. UCLB has retained the right to use the licensed T cell programming modules for academic research purposes at UCL and with other academic institutions, subject to certain restrictions.

Upon commercialization of any of the Company's products that use the in-licensed patent rights, the Company will be obligated to pay UCLB a flat royalty for each licensed product ranging from the low- to mid-single digits, depending on which technologies are deployed in the licensed product, based on worldwide annual net sales of each licensed product, subject to certain reductions, including for the market entry of competing products and for loss of patent coverage of licensed products. The Company may deduct from the royalties payable to UCLB one-half of any payments made to a third party to obtain a license to such third party's intellectual property that is necessary to exploit any licensed products. Once net sales of a licensed product have reached a certain specified threshold, the Company may exercise an option to buy out UCLB's rights to the remaining milestone payments, royalty payments, and sublicensing revenue payments for such licensed product, on terms to be negotiated at the time.

The License expires on a product-by-product and country-by-country basis upon the expiration of the royalty term with respect to each product in each country. The Company may unilaterally terminate the license agreement for any reason upon advance notice to UCLB. Either party may terminate the License for the uncured material breach by the other party or for the insolvency of the other party. If UCLB terminates the License following the Company's insolvency or the Company's material breach of the License, or if the Company terminates the License unilaterally, all rights and licenses granted to the Company will terminate, and all patent rights and know-how transferred to the Company pursuant to the License will revert back to UCLB, unless and to the extent the Company has exercised its option to acquire ownership of the licensed patent rights. In addition, UCLB has the right to negotiate with the Company for the grant of an exclusive license to the Company's improvements to the T cell programming modules the Company has licensed on terms to be agreed upon at the time.

Noile-Immune Biotech Inc.

In November 2019, the Company entered into an exclusive license agreement with Noile-Immune Biotech Inc. ("Noile") under which the Company will have the right to develop CAR T cell therapies incorporating Noile's PRIME (proliferation-inducing and migration-enhancing) technology. The PRIME technology is designed to improve proliferation and trafficking into solid tumors of both engineered CAR T cells as well as the patient's own T cells.

The Company paid an upfront fee and may be obligated to make additional payments to Noile upon the achievement of development milestones and receipt of regulatory approvals, product sales milestones, as well as royalty payments based on possible future sales resulting from the utilization of the licensed technology.

Miltenyi Biotech B.V. & Co. KG

In September 2023, the Company entered into a non-exclusive sublicense agreement with Miltenyi Biotech B.V. & Co. KG ("Miltenyi") under which the Company will have the right to develop, manufacture and use Miltenyi's or affiliates' sublicensed products. Under the agreement, the Company is obligated to make specified payments to Miltenyi upon the achievement of certain regulatory and clinical milestones. The Company recognized $0.4 million in aggregate relating to an upfront license payment and milestone payments that were deemed probable during the year ended December 31, 2023.

Note 17. Income Taxes

Loss before income tax benefit (expense) is as follows (in thousands):

	Year Ended December 31,		
	2023	2022 (As Restated)	2021 (As Restated)
UK	$ (209,766)	$ (149,455)	$ (142,736)
U.S.	1,082	722	664
Switzerland and Germany	282	166	34
Net loss before income taxes	**$ (208,402)**	**$ (148,567)**	**$ (142,038)**

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

	Year Ended December 31,		
	2023	2022 (As Restated)	2021 (As Restated)
U.S.			
Federal	$ (859)	$ (440)	$ (148)
State and local	(5)	(19)	(19)
UK	—	—	—
Switzerland and Germany	(104)	(26)	(1)
Total current tax benefit (expense)	**(968)**	**(485)**	**(168)**
U.S.			
Federal	1,002	218	162
State and local	(15)	(5)	(52)
UK	—	—	—
Switzerland and Germany	—	—	—
Total deferred tax benefit (expense)	**987**	**213**	**110**
Total income tax benefit (expense)	**$ 19**	**$ (272)**	**$ (58)**

The Company recorded an income tax benefit (expense) of $19.5 thousand, $0.3 million and $0.1 million, for the years ended December 31, 2023, 2022 and 2021, respectively.

A reconciliation of income tax benefit at the U.K statutory corporate income tax rate to the income tax benefit is as follows (in thousands):

	Year Ended December 31,		
	2023	2022 (As Restated)	2021 (As Restated)
Net loss before taxes	$ (208,402)	$ (148,567)	$ (142,038)
UK statutory tax rate	23.5%	19.0%	19.0%
Income tax benefit at UK statutory tax rate	(48,974)	(28,228)	(26,987)
Tax-exempt reimbursable tax credits included within research and development expense	(4,589)	(4,681)	(4,595)
Non-deductible expenses	31,268	16,900	13,984
Adjustments in respect of prior years	96	10	167
Valuation allowance changes affecting the provision for income taxes	21,245	15,670	15,745
Other, net	961	583	1,727
Foreign rate differential	(26)	18	17
Total income tax benefit (expense)	$ (19)	$ 272	$ 58
Current income tax benefit	968	485	168
Deferred income tax benefit	(987)	(213)	(110)
Effective rate of income tax	—%	(0.2)%	—%

The Company is headquartered in the United Kingdom and has subsidiaries in the United Kingdom, the United States, Germany and Switzerland. The Company incurs tax losses in the United Kingdom. The UK corporate income tax rate for the year ended December 31, 2023 was 23.5%, and was 19% for the years ended December 31, 2022 and 2021, respectively. On April 1, 2023, the U.K government increased and enacted the corporate rate from 19% to 25%. 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 income tax rate was 21% for the years ended December 31, 2023, 2022 and 2021, respectively.

Deferred tax assets and liabilities consisted of the following at December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Other differences	$ 14,834	$ 13,576
Tax losses	104,534	80,203
Fixed assets	6,653	4,252
Total deferred tax assets	126,021	98,031
Valuation allowances	(122,958)	(95,955)
Net deferred tax asset	**$ 3,063**	**$ 2,076**

Deferred tax assets resulting from loss carryforwards, fixed assets and retirement benefits, with total deferred tax assets increasing by $1.0 million in 2023. The Company has recorded a valuation allowance against the net deferred tax asset where the recoverability due to future taxable profits is unknown. The $3.1 million deferred tax asset balance is related to the Company's U.S. subsidiary entity.

At December 31, 2023, the Company had UK trading losses carryforward of $418.1 million. These losses are carried forward indefinitely under local law, but are subject to numerous utilization criteria and restrictions.

As required by the authoritative guidance on accounting for income taxes, the Company evaluates the realizability of deferred tax assets at each reporting date. Accounting for income taxes guidance requires that a valuation allowance be established when it is more likely than not that all or a portion of the deferred tax assets will not be realized. In circumstances where there is sufficient negative evidence indicating that the deferred tax assets are not more likely than not realizable, the Company establishes a valuation allowance.

The Company operates in multiple jurisdictions with complex tax and regulatory environment and its tax returns are periodically audited or subjected to review by tax authorities. The following table summarizes tax years that remain subject to examination by tax jurisdiction as of December 31, 2023:

Jurisdiction	Open Tax Years Based on Originally Filed Returns
United Kingdom	2021 - 2022
United States	2020 - 2022

Note 18. Leases

Operating Leases

In September 2017, the Company executed an arrangement with Cell Therapy Catapult Limited to lease a manufacturing suite at the Cell and Gene Therapy Catapult manufacturing center in Stevenage, United Kingdom for a term through May 2021, at which time the Company had the option to renew or terminate the lease. The lease had a six-month rent-free period. In December 2018, the Company executed an additional lease arrangement for additional manufacturing space for a term through September 2023, at which time the Company had the option to renew or terminate the lease. In addition, in May 2020, the Company executed an arrangement with Cell Therapy Catapult Limited to lease a different manufacturing suite at the Cell and Gene Therapy Catapult manufacturing center in Stevenage, United Kingdom for a term through April 2024. In July 2022 the Company and Cell Therapy Catapult Limited mutually agreed: (i) to extend the lease term of a manufacturing suite leased by the Company from April 2024 to February 2025, and (ii) to reduce the lease term of a different manufacturing suite leased by the Company from July 2024 to June 2023. In March 2023, the Company and Cell Therapy Catapult Limited mutually agreed: (i) to terminate the lease relating to the leased manufacturing suite which originally had a lease term until February 2025, (ii) to extend the lease term of one of the remaining manufacturing suites from June 2023 to August 2024, and (iii) to extend the lease term of a third manufacturing suite leased by the Company from September 2023 to August 2024.

The Company recognized a lease termination loss of $0.1 million, which is included in Other income (expense), net on the Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2023, related to the manufacturing suite terminated and exited on March 31, 2023. In addition, during the year ended December 31, 2023, the Company recognized a loss on disposal on leasehold improvements of $3.8 million arising from the manufacturing suite terminated and exited on March 31, 2023.

In October 2018, the Company executed an agreement to sublease office space in Rockville, Maryland for a term through October 2021. The Company then terminated the sublease in February 2020 and immediately entered into a five-year lease for the same space with the landlord. As a result of the sublease termination, the Company recognized a $0.2 million gain in other (expense) income in March, 2020. The lease related to this facility is classified as an operating lease. The Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

In January 2019, the Company executed a lease agreement with Whitewood Media Village GP Limited and Whitewood Media Village Nominee Limited to lease the fifth floor of MediaWorks including laboratory space. The Company has the option to terminate the lease in November 2026. In August 2021, MediaWorks became the Company's main corporate headquarters. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability. The lease agreement includes an option to lease additional space. The lease term is nine years and eleven months with an eighteen-month rent free period at the beginning of the lease term.

In January 2019, the Company executed a lease agreement to lease additional office and manufacturing space in Rockville, Maryland. The lease agreement required the Company to enter into a lease provided that the landlord completed the required leasehold improvements described in the agreement. The lease commenced in August 2020 for a term through June 2036. In March 2021, the Company announced plans to move the site of its global manufacturing headquarters to the United Kingdom from the United States. As a part of this strategy, the Company entered into a termination agreement with the landlord of its Rockville, Maryland property to terminate the lease for office and manufacturing space. As a result, the Company recognized a $2.0 million termination fee gain from the landlord, a $2.3 million gain from the removal of the leased right of use asset and corresponding lease liability, and expensed $2.4 million of leasehold improvements for the year ended December 31, 2021 within Other income (expense), net. The $2.0 million termination fee was received from the landlord in April 2021.

In February 2019, the Company agreed to enter into a fifteen-year lease for manufacturing space units located in Enfield, United Kingdom, provided that the landlord completed the required leasehold improvements described in the agreement. The Company executed these lease agreements for 3 manufacturing space units, each for fifteen-year lease terms upon such completion. The leases commenced in February 2019, with the option to terminate the lease in February 2029. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability. The Company reduced the right-of-use asset and lease liability based on the contractual option termination date. The Company expensed $4.1 million of leasehold improvements from assets under construction as of December 31, 2019 as a result of discontinuing the fit-out of the manufacturing facility. In March 2021, one of the units was split in two separate units and the Company surrendered one of those units back to the landlord. Upon the surrender of the unit, the Company recognized a $0.1 million gain in other (expense) income after recognizing a termination fee of $0.2 million. The Company has no further obligations for the surrendered unit and the right of use asset and lease liability which were recorded for this unit were written off during the year ended December 31, 2021. In October 2021, the Company subleased two of the three remaining units to third parties with lease terms ending in February 2029 and October 2026, respectively. Refer to "Sublease agreements" below for further details**.** The Company completed an asset impairment analysis of the right-of-use lease concluding the undiscounted cash flows exceeded the carrying value as of December 31, 2023.

In September 2021, the Company entered into an arrangement for lease with the landlord, Forge Life Sciences Nominee, an affiliate of the Reef Group, for the design, construction and lease of a new 70,000 square foot commercial manufacturing facility in Stevenage, United Kingdom. Under this arrangement, the landlord leased the facility, which is called The Nucleus, to the Company on agreed terms, upon satisfaction of certain conditions and completion of construction. Since November 2022, the landlord has handed over various portions of the facility to the Company until July 31, 2023. The Company was required to pay a pro-rated license fee for each portion of the facility for which the Company was granted access until the execution of a lease agreement. The Company cumulatively contributed $7.5 million as part as of landlord works and tenant contributions towards the lease as of December 31, 2023 resulting in these payments being taken into account in the determination of the right of use asset for this facility. On July 31, 2023, the landlord and its contractors accepted practical completion of The Nucleus. On September 19, 2023, the Company entered into a 20-year lease agreement with the landlord for The Nucleus. The Company made fit-out costs in other areas of the building and may be required to be removed at the end of the lease term. As a result, as of December 31, 2023, the Company has recognized an estimated Asset Retirement Obligation ("ARO") amounting to $0.2 million. The Company will continue to assess the ARO as more related assets are brought into use.

In September 2021, the Company also entered into a lease agreement for 2,762 square feet of laboratory and office space in Gaithersburg, Maryland, with a term until March 2024. In September 2023, the Company extended the original lease term to March 2027.

The following table shows the lease balance sheet classification of leases for the years ended December 31, 2023 and 2022 (in thousands):

	As of December 31,	
	2023	**2022**
Assets		
Operating lease right-of-use assets, net	**$ 60,791**	**$ 23,210**
Liabilities		
Current		
Operating lease liabilities, current	5,053	5,038
Non-current		
Operating lease liabilities, non-current	47,914	19,218
Total lease liabilities	**$ 52,967**	**$ 24,256**

The following table shows the lease costs for the years ended December 31, 2023, 2022 and 2021 (in thousands):

		Year ended December 31,		
Lease costs	**Statement of Operations classification**	**2023**	**2022**	**2021**
Operating lease costs	Operating expenses: research and development	$ 6,340	$ 3,733	$ 4,801
Variable costs	Operating expenses: research and development	1,041	769	1,144
Short term lease costs	Operating expenses: research and development	786	270	193
Operating lease costs	Operating expenses: general and administrative	956	984	1,178
Variable costs	Operating expenses: general and administrative	51	45	147
Short term lease costs	Operating expenses: general and administrative	90	86	12
Total lease costs		**$ 9,264**	**$ 5,887**	**$ 7,475**

	Year ended December 31,	
Other information	**2023**	**2022**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases (in thousands)	$ 10,407	$ 4,575
Weighted-average remaining lease term - operating leases (in years)	16 years	10.40 years
Weighted-average discount rate - operating leases	7.44 %	6.77 %

Future fixed payments for non-cancellable operating leases in effect as of December 31, 2023 are payable as follows:

Maturity of lease liabilities for the years ending December 31,	**Operating Leases** (in thousands)
2024	$ 7,937
2025	6,899
2026	6,667
2027	6,524
2028	5,803
Thereafter	57,038
Total lease payments	90,868
Less: imputed interest	(37,901)
Present value of lease liabilities	**$ 52,967**

Sublease agreements

In October 2021, the Company entered into separate two sublease agreements with two third parties for two manufacturing spaces in Enfield which is currently leased by the Company. The annual lease payments to be received for each of subleased units is £97,000 and £109,000, over lease terms from October 2021 to February 2029 and October 2026, respectively. In October 2021, the Company received $127,000 in rental deposits, arising from the sublease agreements which have been classified as restricted cash as of December 31, 2023 and 2022, respectively. Both sub-leases have been classified as operating leases. The Company recognized the sublease payments on a straight-line basis from the commencement of the sublease agreements.

The following table shows the sub-lease rental income for the years ended December 31, 2023, 2022 and 2021 (in thousands):

Sublease rental income	Statement of Operations classification	Year ended December 31, 2023	2022	2021
Sublease rental income	Other income (expense), net	$ 241	$ 240	$ 49
Total sublease rental income		**$ 241**	**$ 240**	**$ 49**

Future fixed receipts for non-cancellable operating subleases in effect as of December 31, 2023 are receivable as follows:

	Operating Leases (in thousands)
2024	$ 261
2025	261
2026	203
2027	123
2028	106
Total lease payments receivable	**$ 954**

Note 19. Commitments and Contingencies

License Agreements

The Company has entered into an exclusive license agreement, as amended, with UCLB (Refer to Note 16, “License Agreements”). In connection with the UCLB license agreement, the Company is required to make annual license payments and may be required to make payments upon the achievement of specified milestones. The Company has estimated the probability of the Company achieving each potential milestone in accordance with ASC 450, *Contingencies*.

In November 2019, the Company entered into an exclusive license agreement with Noile-Immune Biotech Inc. (“Noile”) under which the Company will have the right to develop CAR T cell therapies incorporating Noile’s PRIME (proliferation-inducing and migration-enhancing) technology. The Company may be obligated to make additional payments to Noile upon the achievement of development milestones and receipt of regulatory approvals, product sales milestones, as well as royalty payments based on possible future sales resulting from the utilization of the licensed technology.

In July 2022, the Company renegotiated a master services agreement with Adaptive Biotechnologies Corporation (“Adaptive”), under which Adaptive's assay is used to analyze patient samples from relapsed/refractory B Cell Acute Lymphoblastic Leukaemia (rrB-ALL) patients. Under the agreement, the Company is obligated to make specified payments to Adaptive upon the achievement and receipt of certain regulatory approvals and achievement of commercial milestones in connection with the Company's use of the Adaptive assay. During the year ended December 31, 2023, the Company recognized all contractual milestones relating to this contract which were deemed probable.

In August 2022, the Company entered into an agreement with Evercore Partners International LLP (“Evercore”) to act as advisors for the Company. The Company is obligated to make specified payments to Evercore upon the achievement of certain strategic transactions involving the Company. The Company became obligated to make a single low- to mid-million dollar payment upon the completion of the BioNTech Collaboration Agreement. (Refer to Note 24 - “Subsequent events”), which will be paid in the first quarter of 2024.

In September 2023, the Company entered into a non-exclusive sublicense agreement with Miltenyi Biotech B.V. & Co. KG (“Miltenyi”) under which the Company will have the right to develop, manufacture and use Miltenyi's or affiliates' sublicensed products. Under the agreement, the Company is obligated to make specified payments to Miltenyi upon the achievement of certain regulatory and clinical milestones. The Company recognized $0.4 million in aggregate relating to an upfront license payment and milestone payments that were deemed probable during the year ended December 31, 2023.

In November 2023, the Company entered into an agreement with goetzpartners securities Limited (“goetzpartners”) to act as advisors for the Company. The Company is obligated to make specified payments to goetzpartners upon the achievement of certain strategic transactions involving the Company. The Company became obligated to make a single low to mid million dollar payment upon the completion of the BioNTech Collaboration Agreement (Refer to Note 24 - “Subsequent events”), which was paid in the first quarter of 2024.

The Company has estimated the probability of the Company achieving each potential milestone in relation to the license agreements with UCLB, Noile, Miltenyi and agreements with Evercore and goetzpartners in accordance with ASC 450, *Contingencies*. The Company considers the regulatory approval, commercial milestones and execution of collaboration agreements probable when actually achieved. Furthermore, the Company considers clinical milestones recognizes clinical milestones when deemed probable. The Company concluded that, as of December 31, 2023, there were other no milestones for which the likelihood of achievement was currently probable.

Legal Proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. The Company was not a party to any litigation and did not have contingency reserves established for any liabilities as of December 31, 2023.

Capital Commitments

As of December 31, 2023, the Company's unconditional purchase obligations for capital expenditure totaled $4.3 million and include signed orders for capital equipment and capital expenditure for construction and related expenditure relating to its properties in the United Kingdom and the United States, of which the Company expects to incur $0.4 million within one year, and $3.9 million within one to four years.

Master Supply Commitments

In March 2018, the Company entered into a long-term supply agreement with Miltenyi Biotec GmbH, or Miltenyi, for the supply of Miltenyi's CliniMACS Prodigy instruments, reagents and disposables for the manufacture of the Company's programmed T cell therapies for preclinical and clinical use and, if approved, for commercial use, as well as support services. The supply agreement sets forth procedures to ensure continuity of supply to the Company of Miltenyi's products, both during the clinical phase and any future commercial phase of our product candidates. After the initial ten-year term of the agreement, the Company has two separate options to renew the agreement, each for an additional five-year term. The Company has a three-month firm commitment to purchase to reagents and disposables pursuant to the agreement.

As of December 31, 2023, the Company's unconditional purchase obligations for reagents and disposables totaled $0.6 million, which the Company expects to incur within one year.

Leases

Lease payments under operating leases as of December 31, 2023 and information about the Company's lease arrangements are disclosed in Note 18, "Leases".

Blackstone Strategic Collaboration and Financing Agreement

Refer to Note 11, "Liability related to future royalties and sales milestone, net" for further details about the Blackstone Collaboration Agreement.

Note 20. Employee Benefit Plans

In the United Kingdom and Switzerland, the Company makes contributions to defined contribution pension schemes on behalf of its employees. The Company expensed $2.0 million, $1.7 million and $1.6 million, in the years ended December 31, 2023, 2022 and 2021, respectively.

In the United States, the Company has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company matches employee contributions up to five percent of the employee's annual salary. The Company expensed $0.4 million, $0.3 million and $0.3 million in contributions in the years ended in the years ended December 31, 2023, 2022 and 2021, respectively. The Company pays all administrative fees related to the Plan.

Note 21. Geographic Information

Operations by geographic area

Revenue

Revenue recognized by geographic area are disclosed in Note 4, “Revenue”.

Major customers

During the year ended December 31, 2023, 76% and 20% of the Company’s license revenues were generated from Cabaletta, and an investee of Syncona Portfolio Limited, respectively.

Long-lived assets

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

	December 31,	
	2023	**2022**
United Kingdom	$ 94,033	$ 56,379
United States of America	1,620	2,040
Total long-lived assets	**$ 95,653**	**$ 58,419**

For the year ended December 31, 2023, the Company recognized an impairment of long-lived assets relating to the operating lease right-of-use assets and related property and equipment of $0.4 million related to a leased property in Stevenage, United Kingdom. There was no impairment recognized for the year ended December 31, 2022.

Note 22. Severance Plan

During January 2021 there was a restructuring program executed by the Company leading to a reduction in workforce and resulting in a corresponding severance charge of $1.2 million, which has been presented on a proportionate basis within research and development expenses and general and administration expenses.

There have been no similar severance charges incurred during the year ended December 31, 2023 and 2022.

Note 23. Related Party Transactions

Blackstone

On November 6, 2021, the Company concurrently entered into the Blackstone Agreements. Refer to Note 11, “Liability relating to future royalties and sales milestones, net”, Note 12, “Warrants” and Note 13, "Shareholders Equity”. Subsequent to the execution of the Blackstone Agreements, Blackstone became a related party as Blackstone owns more than 10% of the Company's outstanding voting securities and is therefore one of the principal owners of the Company. In addition, Blackstone received the right to nominate one director to the board of directors of the Company; William Young was appointed to the Company's board of directors as Blackstone’s designee pursuant to this right.

As of December 31, 2023, the carrying amount of the Blackstone Collaboration Agreement liability was $170.9 million, which included accrued interest expense and cumulative catch-up adjustment, of $45.0 million, $8.9 million and $1.1 million for the years ended December 31, 2023, 2022, and 2021, respectively. Refer to Note 11, “Liability related to sales of future royalties and sales milestone, net” for further details.

Syncona Portfolio Limited

Syncona Portfolio Limited is a related party as Syncona Portfolio Limited owns more than 10% of the Company's outstanding voting securities and is therefore one of the principal owners of the Company. In addition, a member of the Company's board of directors was the chair of the ultimate parent company of Syncona Portfolio Limited until November 2023.

In the Company's February 2021 public offering, Syncona Portfolio Limited purchased 3,571,428 ADSs, representing 3,571,428 ordinary shares. This purchase was made through the underwriters at the public offering price.

December 2022 public offering

In connection with the Company's December 2022 public offering, certain of the Company's related parties purchased the Company's ADSs from the underwriters at the public offering price of $2.00 per ADSs, and on the same terms as other investors in the Company's public offering. The following table summarizes purchases of ADS by the Company's related parties:

Related party	ADSs purchased	Total purchase price (in millions)
Syncona Portfolio Limited (1)	14,000,000	$ 28.0
Deep Track Capital, LP (2)	15,000,000	30.0
Qatar Investment Authority (3)	15,000,000	30.0
Armistice Capital, LLC (4)	10,000,000	20.0
Entities affiliated with Blackstone (5)	2,500,000	5.0
	56,500,000	**$ 113.0**

(1) Syncona Portfolio Limited is a holder of more than 10% of the Company's share capital.
(2) In connection with this transaction, Deep Track Capital, LP became a holder of more than 5% of the Company's share capital.
(3) In connection with this transaction, Qatar Investment Authority became a holder of more than 5% of the Company's share capital.
(4) In connection with this transaction, Armistice Capital, LLC became a holder of more than 5% of the Company's share capital.
(5) Entities affiliated with Blackstone collectively hold more than 10% of the Company's share capital.

Investee of Syncona Portfolio Limited

The Company entered into a collaboration agreement in 2020 with an investee of Syncona Portfolio Limited, a holder of more than 10% of the Company's share capital. The terms of the agreement include a non-refundable license fee, payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales. During the year ended December 31, 2023, Company received variable consideration arising from the achievement of a development milestone amounting to $0.4 million. Consequently, the Company recognized license revenue of $0.4 million. The Company did not recognize any license revenue for the year ended December 31, 2022 and 2021.

Note 24. Subsequent Events

The Company evaluated subsequent events through March 21, 2024, the date on which these consolidated financial statements were issued.

On February 6, 2024 (the "Execution Date"), the Company, through its wholly owned subsidiaries, Autolus Limited and Autolus Holdings (UK) Limited entered into a License and Option Agreement (the "License Agreement") with BioNTech SE ("BioNTech") pursuant to which the Company granted to BioNTech an exclusive, worldwide, sublicensable license (the "License") to certain binders and to exploit products that express in vivo such binders (collectively, the "Binder Licensed Products").

In addition to the License, under the License Agreement the Company has granted to BioNTech several time-limited options (the "Options") to acquire additional rights to specified clinical-stage product candidates, binders and technologies of the Company, described in more detail below. In the event that all Options are fully exercised, the Company would be eligible to receive maximum aggregate payments of up to $582.0 million pursuant to the License Agreement. This maximum amount includes upfront payments, the potential milestone payments for the Binder Licensed Products described below, all option exercise fees and potential milestone payments for licenses to optioned products and technologies, and additional payments that BioNTech may pay to the Company for an increased revenue interest with respect to the Company's product candidate obe-cel as described below.

License and Options

In consideration for the License and the Options, BioNTech made an initial payment to the Company of $10.0 million. The Company is eligible to receive milestone payments of up to $32 million in the aggregate upon the achievement of specified clinical development and regulatory milestones for each Binder Licensed Product that achieves such milestones. The Company is also eligible to receive a low single-digit royalty on net sales of Binder Licensed Products, subject to customary reductions, which reductions are subject to specified limits. The royalty will be increased if BioNTech, its affiliates or sublicensees commercialize a Binder Licensed Product in an indication and country in which the Company or its affiliates or licensees also commercializes a product containing the same binders. Under the License Agreement, BioNTech is solely responsible for, and has sole decision-making authority with respect to, at its own expense, the exploitation of Binder Licensed Products.

Under the terms of the License Agreement, the Company has agreed to grant BioNTech the following time-limited Options:

- an option to obtain exclusive rights to co-fund development costs of the Company's development-stage programs AUTO1/22 and AUTO6NG, in return for agreed upon economic terms, including an option exercise fee, milestone payments and a profit-sharing arrangement for each such product candidate, with additional options to co-promote or co-commercialize such product candidate;
- an option to obtain an exclusive worldwide license to exploit products that express certain additional binders in vivo or, with respect to certain binders, in an antibody drug conjugate (the "Binder Option");
- an option to obtain a co-exclusive worldwide license to exploit products that express in vivo the Company's modules for activity enhancement, with a non-exclusive right, in certain agreed instances, to exploit products that include Company's modules for activity enhancement but do not express in vivo such modules (the "Activity Enhancement Option"); and
- an option to obtain a non-exclusive worldwide license to exploit products that contain the Company's safety switches (the "Safety Switch Option" and, together with the Binder Option and the Activity Enhancement Option, the "Technology Options").

The option exercise fee for each Technology Option is a low seven-digit amount. Each of the Activity Enhancement Option and the Safety Switch Option must be exercised with respect to a given biological target or combination of targets. There is a cap on the total option exercise fee if multiple options are exercised with respect to a given target.

There is also a cap on milestone payments across all agreements entered into as the result of BioNTech exercising one or more of the Technology Options and a cap on the royalty rate payable on any given product for which multiple Options are exercised.

Obe-cel Product Revenue Interest

Under the License Agreement, BioNTech has also agreed to financially support the expansion of the clinical development program for, and planned commercialization of obe-cel. In exchange for the grant of rights to future revenues from the sales of obe-cel products, BioNTech made an upfront payment to the Company of $40 million. The Company will pay BioNTech a low single-digit percentage of annual net sales of obe-cel products, which may be increased up to a mid-single digit percentage in exchange for milestone payments of up to $100 million in the aggregate on achievement of certain regulatory events for specific new indications upon BioNTech's election.

Manufacturing and Commercial Agreement

Under the terms of the BioNTech License Agreement, the Company has agreed to grant BioNTech the option to negotiate a joint manufacturing and commercial services agreement pursuant to which the parties may access and leverage each other's manufacturing and commercial capabilities, in addition to Autolus' commercial site network and infrastructure, with respect to certain of each parties' CAR T products, including BioNTech's product candidate BNT211 (the "Manufacturing and Commercial Agreement"). The Manufacturing and Commercial Agreement, if entered into, would also grant BioNTech access to the Company's commercial site network and infrastructure.

Securities Purchase Agreement, Registration Rights Agreement and Letter Agreement

Concurrently with the execution of the BioNTech License Agreement, the Company and BioNTech entered into a Securities Purchase Agreement (the "Purchase Agreement") pursuant to which the Company sold to BioNTech American Depositary Shares ("ADSs"), each representing one ordinary share, with a nominal value of $0.000042 per share, of the Company (the "Ordinary Shares") in a private placement transaction (the "Private Placement"). On February 13, 2024, the Company completed the Private Placement of 33,333,333 ADSs representing 33,333,333 ordinary shares at an offering price of $6.00 per ADS. Aggregate gross proceeds to the Company, before underwriting discounts and offering expenses, were $200.0 million.

In the event that BioNTech and the Company enter into a Manufacturing and Commercial Agreement (as defined above) within 18 months of the Initial Closing, BioNTech will purchase additional ADSs (the "Subsequent ADSs" and, together with the Initial ADSs, the "Private Placement ADSs"), not to exceed 15,000,000 ADSs, for an aggregate purchase price of up to $20 million. The total number of Subsequent ADSs that may be issued is subject to additional limitations and restrictions.

The Purchase Agreement contains customary representations, warranties, and covenants of each of the Company and BioNTech.

Concurrently with entry into the Purchase Agreement, the Company and BioNTech entered into a letter agreement (the "Letter Agreement") providing BioNTech with certain additional rights and subjecting BioNTech's investment in the Company to certain restrictions. Pursuant to the Letter Agreement, BioNTech received the right to nominate a director to the Company's board of directors. If BioNTech acquires beneficial ownership of at least 30% of the issued and outstanding Ordinary Shares of the Company within five years of the Execution Date, BioNTech will have the right to designate an additional director who shall be independent. BioNTech's director nomination rights under the Letter Agreement shall automatically terminate upon BioNTech's ownership of Ordinary Shares dropping below certain specified percentages. Additionally, pursuant to the Letter Agreement, BioNTech has the right to purchase equity securities sold by the Company in bona fide financing transactions in amounts that are based on BioNTech maintaining specified ownership thresholds following such financing transactions.

Pursuant to the Letter Agreement, subject to specified exceptions, BioNTech may not sell the Private Placement ADSs without the Company's approval for a period of six months following the applicable closing date for such ADSs.

The Letter Agreement terminates upon the earlier of (a) the later of (i) three years from the Execution Date and (ii) such time as no securities of the Company are held by BioNTech or its affiliates and (b) the consummation of a change of control transaction involving the Company.

The Company and BioNTech also entered into a registration rights agreement (the "Registration Rights Agreement") pursuant to which the Company has agreed to file a registration statement with the SEC to register the resale of the Private Placement ADSs. The foregoing descriptions of the License Agreement, the Purchase Agreement, the Registration Rights Agreement and the Letter Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements.

February 2024 Underwritten Offering

On February 12, 2024, the Company completed an underwritten offering of 58,333,336 ADSs representing 58,333,336 ordinary shares at an offering price of $6.00 per ADS. Aggregate gross proceeds to the Company, before underwriting discounts and offering expenses, were $350.0 million.

Note 25. Restatement of previously issued quarterly condensed consolidated financial statements (unaudited)

The Company has restated its unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the quarterly periods ended March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30, 2023 and September 30, 2023. The unaudited Condensed Consolidated Statement Balance Sheet, Condensed Consolidated Statement of Changes in Equity and Condensed Consolidated Statement of Cash Flows for the periods ended March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30, 2023 and September 30, 2023 were not affected by the restatement. Furthermore, the error had no effect on the Company's unaudited net loss to ordinary shareholders or basic or diluted net loss per ordinary share for any of the above mentioned quarterly periods.

Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share and per share amounts)

	March 31	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 343,027	$ 268,558
Restricted cash	328	334
Prepaid expenses and other current assets	50,530	40,571
Total current assets	**393,885**	**309,463**
Non-current assets:		
Property and equipment, net	34,667	31,017
Prepaid expenses and other non-current assets	465	2,119
Operating lease right-of-use assets, net	26,861	17,366
Long-term deposits	1,821	1,983
Deferred tax asset	2,272	2,000
Intangible assets, net	—	46
Total assets	**$ 459,971**	**$ 363,994**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	353	153
Accrued expenses and other liabilities	34,463	24,513
Operating lease liabilities, current	4,821	4,174
Total current liabilities	**39,637**	**28,840**
Non-current liabilities:		
Operating lease liabilities, non-current	22,495	15,081
Liability related to future royalties and sales milestones, net	130,805	48,806
Other long-term payables	114	124
Total liabilities	**193,051**	**92,851**
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 290,909,783 and 200,000,000 shares authorized at March 31, 2023 and 2022, 173,074,510 and 90,907,941 shares issued and outstanding at March 31, 2023 and 2022	8	4
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2023 and 2022	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2023 and 2022	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at March 31, 2023 and 2022	—	—
Additional paid-in capital	1,010,041	845,448
Accumulated other comprehensive loss	(33,257)	(16,025)
Accumulated deficit	(709,990)	(558,402)
Total shareholders' equity	**266,920**	**271,143**
Total liabilities and shareholders' equity	**$ 459,971**	**$ 363,994**

Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share and per share amounts)

Condensed Consolidated Balance Sheets (Unaudited)	June 30 2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 307,500	$ 216,437
Restricted cash	332	325
Prepaid expenses and other current assets	47,533	42,198
Total current assets	**355,365**	**258,960**
Non-current assets:		
Property and equipment, net	36,857	33,794
Prepaid expenses and other non-current assets	295	1,888
Operating lease right-of-use assets, net	54,251	15,230
Long-term deposits	1,864	1,835
Deferred tax asset	2,360	2,244
Intangible assets, net	—	25
Total assets	**$ 450,992**	**$ 313,976**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	3,878	162
Accrued expenses and other liabilities	30,954	31,360
Operating lease liabilities, current	6,231	3,995
Total current liabilities	**41,063**	**35,517**
Non-current liabilities:		
Operating lease liabilities, non-current	44,707	13,208
Liability related to future royalties and sales milestones, net	135,764	50,615
Other long-term payables	122	115
Total liabilities	**221,656**	**99,455**
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 290,909,783 shares authorized at June 30, 2023 and 2022, 173,680,872 and 90,909,783 shares issued and outstanding at June 30, 202 and 2022	8	4
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at June 30, 2023 and 2022	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at June 30, 2023 and 2022	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at June 30, 2023 and 2022	—	—
Additional paid-in capital	1,012,709	848,370
Accumulated other comprehensive loss	(27,957)	(33,510)
Accumulated deficit	(755,542)	(600,461)
Total shareholders' equity	**229,336**	**214,521**
Total liabilities and shareholders' equity	**$ 450,992**	**$ 313,976**

Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share and per share amounts)

Condensed Consolidated Balance Sheets (Unaudited)	September 30 2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 256,415	$ 163,053
Restricted cash	434	315
Prepaid expenses and other current assets	51,533	48,943
Total current assets	**308,382**	**212,311**
Non-current assets:		
Property and equipment, net	34,637	32,474
Prepaid expenses and other non-current assets	136	1,718
Operating lease right-of-use assets, net	59,403	13,235
Long-term deposits	943	1,688
Deferred tax asset	2,597	2,396
Intangible assets, net	—	8
Total assets	**$ 406,098**	**$ 263,830**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	661	334
Accrued expenses and other liabilities	31,388	34,669
Operating lease liabilities, current	5,491	3,815
Total current liabilities	**37,540**	**38,818**
Non-current liabilities:		
Operating lease liabilities, non-current	46,967	11,310
Liability related to future royalties and sales milestones, net	140,778	52,443
Other long-term payables	295	105
Total liabilities	**225,580**	**102,676**
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 290,909,783 shares authorized at September 30, 2023 and 2022, 173,936,794 and 91,132,356 shares issued and outstanding at September 30, 2023 and 2022	8	4
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at September 30, 2023 and 2022	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at September 30, 2023 and 2022	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at September 30, 2023 and 2022	—	—
Additional paid-in capital	1,015,577	851,824
Accumulated other comprehensive loss	(33,794)	(47,564)
Accumulated deficit	(801,391)	(643,228)
Total shareholders' equity	**180,518**	**161,154**
Total liabilities and shareholders' equity	**$ 406,098**	**$ 263,830**

Restated Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31, 2023			Three Months Ended March 31, 2022		
	As previously reported	Impact of adjustment	As Restated	As previously reported	Impact of adjustment	As Restated
Grant income	$ —		$ —	$ 166		$ 166
License revenue	1,292		1,292	—		—
Operating expenses:						
Research and development	(31,344)	3,956	(27,388)	(33,963)	5,598	(28,365)
General and administrative	(9,284)		(9,284)	(7,987)		(7,987)
Loss on disposal of property and equipment	(3,768)		(3,768)	—		—
Total operating expenses, net	**(43,104)**	**3,956**	**(39,148)**	**(41,784)**	**5,598**	**(36,186)**
Other income (expense), net	782		782	860		860
Interest income	3,446		3,446	28		28
Interest expense	(4,905)		(4,905)	(1,790)		(1,790)
Total other expenses, net	**(677)**	**—**	**(677)**	**(902)**	**—**	**(902)**
Net loss before income tax	**(43,781)**	**3,956**	**(39,825)**	**(42,686)**	**5,598**	**(37,088)**
Income tax benefit	3,970	(3,956)	14	5,624	(5,598)	26
Net loss attributable to ordinary shareholders	**(39,811)**	**—**	**(39,811)**	**(37,062)**	**—**	**(37,062)**
Other comprehensive income (loss):						
Foreign currency exchange translation adjustment	5,641		5,641	(7,455)		(7,455)
Total comprehensive loss	**$ (34,170)**	**$ —**	**$ (34,170)**	**$ (44,517)**	**$ —**	**$ (44,517)**
Basic and diluted net loss per ordinary share	$ (0.23)	$ —	$ (0.23)	$ (0.41)	$ —	$ (0.41)
Weighted-average basic and diluted ordinary shares	173,825,825	173,825,825	173,825,825	90,914,175	90,914,175	90,914,175

Restated Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30, 2023			Three Months Ended June 30, 2022		
	As previously reported	Impact of adjustment	As Restated	As previously reported	Impact of adjustment	As Restated
Grant income	$ —		$ —	$ —		$ —
License revenue	—		—	—		—
Operating expenses:						
Research and development	(36,742)	3,510	(33,232)	(38,212)	7,418	(30,794)
General and administrative	(11,122)		(11,122)	(8,269)		(8,269)
Loss on disposal of property and equipment	(23)		(23)	—		—
Total operating expenses, net	**(47,887)**	**3,510**	**(44,377)**	**(46,481)**	**7,418**	**(39,063)**
Other income (expense), net	482		482	(1,331)		(1,331)
Interest income	3,403		3,403	89		89
Interest expense	(5,020)		(5,020)	(1,810)		(1,810)
Total other expenses, net	**(1,135)**	**—**	**(1,135)**	**(3,052)**	**—**	**(3,052)**
Net loss before income tax	**(49,022)**	**3,510**	**(45,512)**	**(49,533)**	**7,418**	**(42,115)**
Income tax benefit (expense)	3,470	(3,510)	(40)	7,474	(7,418)	56
Net loss attributable to ordinary shareholders	**(45,552)**	**—**	**(45,552)**	**(42,059)**	**—**	**(42,059)**
Other comprehensive income (loss):						
Foreign currency exchange translation adjustment	5,300		5,300	(17,485)		(17,485)
Total comprehensive loss	**$ (40,252)**	**$ —**	**$ (40,252)**	**$ (59,544)**	**$ —**	**$ (59,544)**
Basic and diluted net loss per ordinary share	$ (0.26)	$ —	$ (0.26)	$ (0.46)	$ —	$ (0.46)
Weighted-average basic and diluted ordinary shares	173,860,491	173,860,491	173,860,491	90,931,964	90,931,964	90,931,964

Restated Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30, 2023			Three Months Ended September 30, 2022		
	As previously reported	Impact of adjustment	As Restated	As previously reported	Impact of adjustment	As Restated
Grant income	$ —		$ —	$ —		$ —
License revenue	406		406	2,369		2,369
Operating expenses:						
Research and development	(37,237)	4,919	(32,318)	(37,632)	6,147	(31,485)
General and administrative	(10,611)		(10,611)	(8,231)		(8,231)
Impairment of operating lease right-of-use assets and related property and equipment	(382)		(382)	—		—
Total operating expenses, net	**(47,824)**	**4,919**	**(42,905)**	**(43,494)**	**6,147**	**(37,347)**
Other income (expense), net	(1,597)		(1,597)	(3,740)		(3,740)
Interest income	3,646		3,646	165		165
Interest expense	(5,014)		(5,014)	(1,850)		(1,850)
Total other expenses, net	**(2,965)**	**—**	**(2,965)**	**(5,425)**	**—**	**(5,425)**
Net loss before income tax	**(50,789)**	**4,919**	**(45,870)**	**(48,919)**	**6,147**	**(42,772)**
Income tax benefit	4,940	(4,919)	21	6,152	(6,147)	5
Net loss attributable to ordinary shareholders	**(45,849)**	—	**(45,849)**	**(42,767)**	—	(42,767)
Other comprehensive income (loss):						
Foreign currency exchange translation adjustment	(5,837)		(5,837)	(14,054)		(14,054)
Total comprehensive loss	**$ (51,686)**	**$ —**	**$ (51,686)**	**$ (56,821)**	**$ —**	**$ (56,821)**
Basic and diluted net loss per ordinary share	$ (0.26)	$ —	$ (0.26)	$ (0.47)	$ —	$ (0.47)
Weighted-average basic and diluted ordinary shares	173,984,101	173,984,101	173,984,101	91,240,801	91,240,801	91,240,801

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

LICENSE AND OPTION AGREEMENT

BY AND AMONG

AUTOLUS LIMITED

AUTOLUS HOLDINGS (UK) LIMITED

AND

BIONTECH SE

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LICENSE AND OPTION AGREEMENT

This **LICENSE AND OPTION AGREEMENT** ("**Agreement**") is entered into this 6th day of February, 2024 ("**Execution Date**"), subject to Section 13.1(a), by and among (a) **AUTOLUS LIMITED**, a company organized under the laws of England and Wales, with company number 09115837, and its registered office address at The Mediaworks, 191 Wood Lane, London, England, W12 7FP, (b) **AUTOLUS HOLDINGS (UK) LIMITED**, a company organized under the laws of England and Wales, with company number 11365111, and its registered office address at The Mediaworks, 191 Wood Lane, London, England, W12 7FP ((a) and (b) collectively "**Autolus**"); and (c) **BIONTECH SE,** a corporation organized and existing under the laws of Germany, registered with the commercial register of the lower court (Amtsgericht) of Mainz under HRB 48720 and having its place of business at An der Goldgrube 12, D-55131 Mainz, Germany ("**BioNTech**"). Autolus and BioNTech are each referred to individually as a "**Party**" and together as the "**Parties**."

RECITALS

WHEREAS, Autolus is a clinical stage biotechnology company that owns or otherwise controls certain products and technologies applicable to CAR-T cell therapy;

WHEREAS, BioNTech is a biotechnology company with expertise in the research, development, and commercialization of drug products;

WHEREAS, pursuant to the terms and conditions of this Agreement, Autolus desires to grant, and BioNTech desires to accept, certain rights, options and licenses to develop, manufacture and commercialize products on the terms, and subject to the conditions, set out below;

WHEREAS, simultaneously with entering into this Agreement, Autolus and BioNTech are entering into (a) that certain securities purchase agreement (the "**Share Purchase Agreement**"), pursuant to which Autolus will sell to BioNTech, and BioNTech will purchase from Autolus, Autolus's ordinary shares in the form of American depository shares, all in accordance with the terms and conditions set forth in the Share Purchase Agreement, and (b) that certain side letter agreement and that certain registration rights agreement pursuant to which Autolus will grant BioNTech certain rights (including registration rights) in connection with BioNTech's purchase of Autolus's ordinary shares in the form of American depository shares; and

WHEREAS, the Share Purchase Agreement contemplates a staggered signing and Initial Closing (as defined in the Share Purchase Agreement), and save as specifically provided herein, the terms of this Agreement shall become effective as of the Initial Closing.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the Parties agree as follows.

1. DEFINITIONS

Definitions. The terms in this Agreement with initial letters capitalized have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

1.1 "**Accounting Standards**" means IFRS (International Financial Reporting Standards) or U.S. GAAP (Generally Accepted Accounting Principles), as generally and consistently applied by a Party, its Affiliates, Sublicensees or Autolus Licensees (as applicable).

1.2 "**Acquirer**" means any Person that becomes an Affiliate of a Party following the Effective Date as a result of an Acquisition. "Acquirer" does not include any Person that was an Affiliate of a Party prior to such Acquisition.

1.3 "**Acquisition**" means, with respect to a Party or an Affiliate, from and after the Effective Date: (a) a merger, consolidation or similar transaction involving such Person, in which the shareholders of such Person immediately prior to such transaction cease to control (as defined in Section 1.11) such Person after such transaction; (b) a sale, transfer or other disposition of all or substantially all of the business or assets of such Person to a Third Party; or (c) a sale of a controlling (as defined in Section 1.11) interest of such Person to a Third Party. Notwithstanding the foregoing, a sale of stock of such Person to underwriters in an underwritten public offering of such Person's stock solely for the purpose of financing does not constitute an Acquisition.

1.4 "**Activity Enhancement Licensed IP**" means the Activity Enhancement Licensed Know-How and the Activity Enhancement Licensed Patents.

1.5 "**Activity Enhancement Licensed Know-How**" means all Know-How, including [***], that is (a) Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Exploitation of the Activity Enhancement Licensed Technology, or (ii) the Exploitation of such Activity Enhancement Licensed Technology in an Activity Enhancement Licensed Product. Notwithstanding the foregoing, the Activity Enhancement Licensed Know-How excludes [***], except [***].

1.6 "**Activity Enhancement Licensed Patents**" means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) Activity Enhancement Licensed Technology, (ii) Activity Enhancement Licensed Know-How, or (iii) the Exploitation of such Activity Enhancement Licensed Technology or Activity Enhancement Licensed Know-How in an Activity Enhancement Licensed Product.

1.7 "**Activity Enhancement Licensed Products**" means any pharmaceutical or biologic product that includes any Activity Enhancement Licensed Technology. For the purposes of this Agreement, [***], and *provided further* that such [***].

1.8 "**Activity Enhancement Licensed Technology**" means each module listed in Schedule 1.8.

1.9 "**Activity Enhancement Option**" means the options granted by Autolus to BioNTech in Section 6.3(d) and Section 6.3(e).

1.10 "**ADC**" means an antibody-drug conjugate, being a pharmaceutical or biologic product that contains an antibody, or an antibody derivative, that can be linked directly or indirectly to a payload such as a chemical moiety. Such antibody or antibody derivative and payload [***]. For these purposes, "antibody derivative" includes antibodies that have (a) been modified via isotype switching; (b) undergone a modification of effector function; (c) been adapted to enable the antibody to carry payloads; (d) been altered to change the expression characteristics, stability or biological half-life of the antibody; (e) been mutated using an affinity maturation strategy designed to modify the affinity of either the variable regions and/or the constant regions of the antibody for any ligands, antigens or receptors; or (f) been modified or combined to bind additional moieties. Antibody derivatives may be full length antibodies, monoclonal and polyclonal antibodies, and multispecific antibodies (*e.g.*, bi-specific antibodies), as well as antibody fragments and antibody-like fragments (including Fab, Fab', F(ab')2, Fv fragments, scFv, diabodies,

linear antibodies and single-chain antibodies). Antibodies and antibody derivatives can be of any origin, whether human, humanized, chimeric or otherwise.

1.11 "**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" shall mean, direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest, in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%) and, in such case, such lower percentage shall be substituted in the preceding sentence; *provided*, that such foreign investor has the power to direct the management and policies of such entity.

1.12 "**Antitrust Laws**" means the Sherman Act, as amended, the Clayton Act, as amended, the HSR Act, the Federal Trade Commission Act, as amended, and all other applicable laws and regulations (including non-U.S. laws and regulations) issued by a governmental authority that are designed or intended to preserve and protect competition, prohibit and restrict monopolization, attempted monopolization, restraint of trade and abuse of dominant position, or to prevent acquisitions, mergers or other business combinations and similar transactions, the effect of which may be to lessen or impede competition or to tend to create or strengthen a dominant position or to create a monopoly.

1.13 "**Applicable Data Protection Law**" means all Applicable Laws in any jurisdiction relating to privacy or the processing or protection of Personal Data, including the General Data Protection Regulation (EU) 2016/679 (EU GDPR), the UK Data Protection Act 2018, the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the UK Data Protection Act 2018), the e-Privacy Directive (2002/58/EC), the UK Privacy and Electronic Communications Regulations 2003 (SI 2003 No. 2426) as amended and the comparable Applicable Laws in other jurisdictions and all guidance issued by any applicable data protection authority, including the Information Commissioner's Office statutory data sharing code of practice which came into force on 5 October 2021, as updated or amended from time to time.

1.14 "**Applicable Law**" means all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, cantonal, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time.

1.15 "**Audited Party**" has the meaning set out in Section 10.5(a).

1.16 "**Auditing Party**" has the meaning set out in Section 10.5(a).

1.17 "**Auditor**" has the meaning set out in Section 10.5(a).

1.18 "[***]" has the meaning set out in [***].

1.19 "**Autolus Indemnitees**" has the meaning set out in Section 16.2.

1.20 "**Autolus IP**" means (a) [***] Licensed IP, (b) [***] Licensed IP, (c) Safety Switch Licensed IP, (d) Activity Enhancement Licensed IP, and (e) [***] Licensed IP.

1.21 "**Autolus Know-How**" means all Know-How included within the Autolus IP.

1.22 "**Autolus Licensees**" means a licensee or sublicensee (regardless of how many tiers of (sub)licensee there are) of Autolus or any of its Affiliates; *provided* that, notwithstanding any provision to the contrary set forth in this Agreement, distributors and wholesalers will not be considered Autolus Licensees.

1.23 "**Autolus Patents**" means (a) [***] Licensed Patents, (b) [***] Licensed Patents, (c) Safety Switch Licensed Patents, (d) Activity Enhancement Licensed Patents, and (e) [***] Licensed Patents.

1.24 "**Autolus Product**" means an AUTO1/22 Product, AUTO6NG Product, and Obe-cel Product, in each case in the form in which such product exists as of the Effective Date.

1.25 "**Autolus's Knowledge**" means the [***] knowledge [***], of any of: [***].

1.26 "**AUTO1/22 Next Gen Product**" means any AUTO1/22 Product Developed by Autolus or its Affiliates to [***].

1.27 "**AUTO1/22 Product**" means Autolus's proprietary autologous CAR-T Cell Therapy targeting CD19 and CD22 in the form under Development as of the Effective Date, as more particularly set forth on Schedule 1.27, together with any new dosage forms, strengths, methods of manufacture, or methods of administration thereof and any improvements or modifications of such products, but excluding any AUTO1/22 Next Gen Product.

1.28 "**AUTO6NG Next Gen Product**" means any AUTO6NG Product Developed by Autolus or its Affiliates to [***].

1.29 "**AUTO6NG Product**" means Autolus's proprietary autologous CAR-T Cell Therapy targeting GD2 in the form under Development as of the Effective Date, as more particularly set forth on Schedule 1.29, together with any new dosage forms, strengths, methods of manufacture, or methods of administration thereof and any improvements or modifications of such products, but excluding any AUTO6NG Next Gen Product.

1.30 "[***]" means [***].

1.31 "[***]" has the meaning [***].

1.32 "[***]" has the meaning [***].

1.33 "**Available**" has the meaning set out in Section 6.4(b).

1.34 "**Availability Notice**" has the meaning set out in Section 6.4(b).

1.35 "**Background IP**" has the meaning set out in Section 11.1.

1.36 "**Baseball Arbitration**" means the baseball arbitration procedure set out in Schedule 1.36.

1.37 "[***]" means [***].

1.38 "[***] **Licensed Binder**" means (a) that certain Binder of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.39 "[***] **Licensed IP**" means the [***] Licensed Know-How and the [***] Licensed Patents.

1.40 "[***] **Licensed Know-How**" means all Know-How, including [***], that is (a) Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Development of the [***] Licensed Binder, or (ii) the Exploitation of such Binder in a [***] Licensed Product. Notwithstanding the foregoing, the [***] Licensed Know-How [***].

1.41 "[***] **Licensed Patents**" means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) the [***] Licensed Binder, (ii) the [***] Licensed Know-How, or (iii) the Exploitation of the [***] Licensed Binder in a [***] Licensed Product.

1.42 "[***] **Licensed Product**" means any pharmaceutical or biologic product that expresses In Vivo one or more [***] Licensed Binder(s), including any dosage strengths, presentations, formulations or methods of administration. For the purposes of this Agreement, [***], and *provided further* that ***].

1.43 "[***] **Option**" has the meaning set out in Section 6.3(b).

1.44 "[***] **Option Period**" has the meaning set out in Section 6.1.

1.45 "**Binder**" means a protein domain that is capable of binding an antigen.

1.46 "[***]" has the meaning set out in [***].

1.47 "**BioNTech Indemnitees**" has the meaning set out in Section 16.1.

1.48 "**Biosimilar Product**" means, in a particular country with respect to a particular [***] Licensed Product, a product that: (a) has received all necessary approvals by the applicable Regulatory Authorities in such country to place on the market such product as a biopharmaceutical product; (b) is marketed or sold by a Third Party that has not obtained the rights to such product as a Sublicensee or distributor of, or through any other contractual relationship with, BioNTech or any of its Affiliates or Sublicensees; and (c) is approved as a "biosimilar" (in the United States) or a "similar biological medicinal product" (in the EU) or using a comparable procedure in other countries whereby the [***] Licensed Product is the "reference medicinal product" and an expedited Regulatory Approval process for the approval of generic versions of biological products is used based on Applicable Laws and once all regulatory exclusivities and intellectual property rights for the [***] Licensed Product have expired.

1.49 "[***]" means [***].

1.50 "**BNT211**" has the meaning set out in Section 3.1(a).

1.51 "**Business Day**" means a day other than a Saturday, Sunday, or a bank or other public holiday in London, England or Mainz, Germany.

1.52 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; *provided*, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first such three (3)-month period thereafter; and (b) the final Calendar Quarter of the Term shall extend from the first day of such three (3)-month period until the last day of the Term.

1.53 "**Calendar Year**" means a period of twelve (12) consecutive calendar months ending on December 31; *provided*, that: (a) the first Calendar Year of the Term shall extend from the Effective Date to December 31; and (b) the final Calendar Year of the Term shall extend from January 1 until the last day of the Term.

1.54 "**CAR**" means a chimeric antigen receptor.

1.55 "**CAR-T**" means a T-cell incorporating a CAR.

1.56 "**CAR-T Cell Therapy**" means a therapy comprising a T-cell that [***].

1.57 "[***]" means a protein product of the [***] molecule gene.

1.58 "[***]" means a protein product of the [***] molecule gene.

1.59 "[***] **Buyer**" has the meaning set out in Section 1.70.

1.60 "[***] **Licensed Binder**" means (a) that certain Binder of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.61 "[***] **Licensed Binder**" means (a) that certain Binder of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.62 "[***] **Binder** [***] **Patent**" means any Patents (a) Controlled by BioNTech or its Affiliates and (b) that claim or Cover [***] Licensed Binder and/or a [***] Licensed Binder that were made by or on behalf of BioNTech, its Affiliates, Sublicensees, or their Subcontractors unless [***].

1.63 "[***] **Competing Product**" has the meaning set out in Section 9.2(c).

1.64 "[***] **License**" has the meaning set out in Section 5.1(a).

1.65 "[***] **Licensed IP**" means the [***] Licensed Know-How and the [***] Licensed Patents.

1.66 "[***] **Licensed Know-How**" means all Know-How that is (a) Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Development of a [***] Licensed Binder and/or a [***] Licensed Binder, or (ii) the Exploitation of a [***] Licensed Product. Notwithstanding the foregoing, the [***] Licensed Know-How excludes [***].

1.67 "[***] **Licensed Patents**" means all Patents that are (a) are Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) that claim or Cover (i) a [***] Licensed Binder and/or a [***] Licensed Binder, (ii) [***] Licensed Know-How, or (iii) the Exploitation of such Binders in a [***] Licensed Product.

1.68 "[***] **Licensed Product**" means any pharmaceutical or biologic product that expresses In Vivo one or more [***] Licensed Binder(s) and/or [***] Licensed Binder(s), including any dosage strengths, presentations, formulations or methods of administration. For the purposes of this Agreement, [***] and *provided further* that [***]. For clarity, [***].

1.69 "[***] **Royalty Term**" means, on a [***] Licensed Product-by-[***] Licensed Product and country-by-country basis, the period commencing on the date of First Commercial Sale of such [***] Licensed Product in such country and expiring on [***].

1.70 "[***] **Transaction**" means [***] to a Third Party (the "[***] **Buyer**").

1.71 "**CDR**" means complementarity determining sequences.

1.72 "**Claim**" or "**Claims**" means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature whatsoever.

1.73 "**Clinical Study Report**" means the final clinical study report containing the results of a [***], in the form in which it is provided to Autolus by the Sponsor (or prepared by Autolus, if Autolus is the Sponsor).

1.74 "**Clinical Trial**" means any human clinical study or trial of a product, including Phase 1 Trials, Phase 2 Trials, Pivotal Trials, Phase 3 clinical trials and Phase 4 clinical trials or any other equivalent, combined or other trial a product is administered to a human subject.

1.75 "**Co-Exclusive**" means each of BioNTech and Autolus and their respective Affiliates may practice the Activity Enhancement Licensed IP with respect to products owned or controlled by such Party or one of its Affiliates, and that neither Party nor any of its Affiliates may grant Third Parties, [***], any right or license to practice the Activity Enhancement Licensed IP with any products other than products owned or controlled by such Party or one of its Affiliates.

1.76 "**Combination Product**" means: (a) a Revenue-Bearing Product in combination with [***] other therapeutically active ingredients; (b) a co-packaged Revenue-Bearing Product containing [***] separate pharmaceutical products (one of which is a Revenue-Bearing Product) in the same presentation; or (c) a Revenue-Bearing Product used as part of a treatment regimen where such Revenue-Bearing Product is approved for use with other pharmaceutical or biologic products (whether or not each such pharmaceutical or biologic product is sold separately) and sold for a single price. For the avoidance of doubt, [***].

1.77 "**Commercialize**" means to market, promote, distribute, import, export, offer to sell or sell a product or conduct other commercialization activities with respect to a product, including activities relating to marketing, promoting, distributing, importing, exporting, offering for sale or selling a product, and "**Commercialization**" has a correlative meaning. Commercialize and Commercialization do not include Manufacture, Manufactured or Manufacturing or Develop, Development or Developed.

1.78 "**Commercially Reasonable Efforts**" means, with respect to a Party's activities, such [***] efforts to undertake an activity as [***] would normally use to accomplish a similar objective under similar circumstances, with respect to a product that is of similar market and economic potential as the applicable product, and at a similar stage in its development or product life as such product, taking into account [***].

1.79 "**Competitive Infringement**" has the meaning set out in Section 11.4(b).

1.80 "**Confidential Information**" means all Know-How and other proprietary information and data of any kind, including of a financial, scientific, commercial or technical nature that the Disclosing Party has supplied or otherwise made available to the Recipient Party, whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data (including Personal Data), designs or formulae in relation to this Agreement.

1.81 "**Control**" or "**Controlled**" means with respect to any Know-How, material, Patent, or other property right, the possession of the right, whether directly or indirectly, and whether by ownership, license, covenant not to sue, or otherwise (other than by operation of the license and other grants in this Agreement), for a Party or its Affiliates to grant a license, sublicense, or other right to or under such Know-How, material, Patent, or other property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party, *provided* that, neither such Party nor its Affiliates shall be deemed to "Control" any Know-How, material, Patent, or other property right that: (a) [***] of such Party, to the extent that [***] (i) [***], or (ii) [***], in each case ((i) or (ii)), except if ***], or (b) [***], *unless*, [***] such Know-How, material, Patent, or other property right ***] Know-How, material, Patent, or other property right [***], and such license [***] the license or sublicense is under any Know-How, material, Patent [***], or other property right, and [***], as applicable.

1.82 "**Cover**" means, on a country-by-country basis, with respect to a particular subject matter at issue [***] and one or more claim(s) in a relevant Patent, that, in the absence of ownership of, or a license under, such Patent, the Exploitation of such subject matter in such country would infringe one or more issued Valid Claims of such Patent, or, as to a pending claim included in such Patent, the Exploitation of such subject matter would infringe such Patent if such pending claim were to issue in an issued patent, in such country.

1.83 "**Data Package**" means, with respect to the AUTO1/22 Product, AUTO6NG Product, AUTO1/22 Next Gen Product and AUTO6NG Next Gen Product, [***].

1.84 "**Develop**" or "**Development**" means drug research and development activities, including test method development and stability testing, assay development and audit development, toxicology, formulation, quality assurance/quality control development, technical development, process development, statistical analysis, pre-clinical and Clinical Trials, packaging development, regulatory affairs, and the preparation, filing and prosecution of Regulatory Filings. "**Developed**" has a correlative meaning. Develop, Development and Developed do not include Manufacture, Manufactured or Manufacturing or Commercialize or Commercialization.

1.85 "**Development Plan Trigger Notice**" has the meaning set out in Section 4.3.

1.86 "**Disclosing Party**" has the meaning set out in Section 12.1.

1.87 "**Dispute**" has the meaning set out in Section 17.2.

1.88 "**Dollars**" or "**$**" means the lawful currency of the United States.

1.89 "**Drug Approval Application**" means (a) a New Drug Application, submitted to the FDA pursuant to 21 CFR § 314.50 ("**NDA**"); (b) a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act and the regulations promulgated thereunder ("**BLA**"); (c) an application for authorization to market or sell a biological or pharmaceutical product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., including, with respect to the European Union, a marketing authorization application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure ("**MAA**"); or (d) with respect to any biological or pharmaceutical product for which an NDA, BLA or MAA has been approved by the applicable Regulatory Authority, an application to supplement or amend such NDA, BLA or MAA to expand the approved label for such biological product to include use of such biological product for an additional Indication.

1.90 "**Effective Date**" means the date of the Initial Closing.

1.91 "**Execution Date**" has the meaning set forth in the preamble.

1.92 "**EMA**" means the European Medicines Agency or any successor entity thereto.

1.93 "**Evaluation**" has the meaning set out in Section 6.1.

1.94 "**Exploit**" or "**Exploitation**" means to make, have made, import, have imported, export, have exported, use, have used, sell, have sold, offer for sale, or have offered for sale, including to research, Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of.

1.95 "**Failure to Develop**" has the meaning set out in Section 4.6(b).

1.96 "**Failure to Develop Notice**" has the meaning set out in Section 4.6(b).

1.97 "**Failure to Develop Period**" has the meaning set out in Section 4.6(b).

1.98 "**FDA**" **means** the U. S. Food and Drug Administration or any successor entity thereto.

1.99 "**Field**" means the treatment and prophylaxis of diseases and conditions in humans.

1.100 "**First Commercial Sale**" means, with respect to an Obe-cel Product, or [***] Licensed Product, as the case may be, in a country, the first arm's length sale for monetary value: (a) in respect to Obe-cel Products, of such Obe-cel Product by Autolus, its Affiliates, or Autolus Licensees, or (b) in respect of [***] Licensed Products by BioNTech, its Affiliates, or their Sublicensees, as applicable to a Third Party for end use or consumption in such country following Regulatory Approval for sale of such Obe-cel Product or [***] Licensed Product in such country. Sales prior to receipt of Regulatory Approval for such product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.101 "**Foreign Investment Laws**" means any Applicable Laws that are designed or intended to screen, prohibit, restrict or regulate actions by Persons seeking to acquire rights in or control over domestic equities, securities, entities, assets, land or other interests in order to address national security or public order goals.

1.102 "**FTE**" means a full time equivalent person-year based upon a total of [***] working hours per Calendar Year of scientific or technical work carried out by a duly qualified employee of Autolus on or directly related to the work to be conducted under the Agreement. The portion of a FTE billable by Autolus for one (1) individual during a given accounting period shall be determined by dividing the number of hours worked directly by said individual on the work to be conducted under the Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on [***]; *provided* that hours worked will not be counted by any multiplier (*e.g.*, overtime or time-and-a-half).

1.103 "**FTE Rate**" means the rate of FTE costs incurred by Autolus, which for the purpose of this Agreement shall be [***] per FTE per Calendar Year. Beginning on [***], and on [***] of each subsequent Calendar Year during the Term, the FTE Rate is subject to annual adjustment by the percentage increase in the [***] in the preceding Calendar Year.

1.104 "**Gatekeeper**" means a mutually agreed independent Third Party patent attorney.

1.105 "**GLP**" means the good laboratory practice standards set out in Schedules 1 and 2 of Directive 2004/10/EC and Directive 2004/9/EC, or the equivalent Applicable Law in the relevant jurisdiction.

1.106 "**Government Official**" means: (a) any officer, employee (including physicians, hospital administrators or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital; (b) any candidate for political office, any political party or any official of a political party; or (c) any person acting in an official capacity on behalf of any of the foregoing.

1.107 "**Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.108 "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as codified at 15 U.S.C. §18a, as may be amended from time to time, and the rules and regulations promulgated thereunder.

1.109 "**HSR Clearance**" means the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act with respect thereto with respect to any Technologies Option or other option exercise.

1.110 "**HSR Filing**" means filings by Autolus or BioNTech with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form, together with all required documentary attachments thereto with respect to any Technologies Option or other option exercise.

1.111 "**IND**" means an Investigational New Drug application in the U.S. filed with the FDA or the corresponding application for the investigation of pharmaceutical or biologic products in any other country or group of countries, as defined in Applicable Law and filed with the Regulatory Authority of a given country or group of countries.

1.112 "**Indemnified Parties**" has the meaning set out in Section 16.3.

1.113 "**Indemnifying Party**" has the meaning set out in Section 16.3.

1.114 "**Indication**" means a separate and distinct disease or medical condition in humans, and [***], for which [***] with [***], as applicable.

1.115 "**Inflation Reduction Act**" means 42 U.S.C. §§ 1320f et seq., (or any amended or successor act).

1.116 "**Initial Closing**" has the meaning given to it in the Share Purchase Agreement.

1.117 "**Initial Tech Transfer Package**" means all Know-How, [***], that are in the possession of Autolus or its Affiliates at the Effective Date, that form part of the (a) [***] Licensed Know-How, (b) [***] Licensed Know-How, (c) Activity Enhancement Licensed Know-How, (d) Safety Switch Licensed

Know-How, or (e) [***] Licensed Know-How and [***], or [***], in the format held by Autolus or its Affiliates on the Effective Date.

1.118 "**Initiation**" means, (a) with respect to a Phase 1 Trial, the first dosing of the [***] human subject in such Phase 1 Trial, and (b) with respect to any other Clinical Trial, the first dosing of the [***] human subject in such Clinical Trial.

1.119 "**Insolvency Event**" means, in relation to either Party, any of the following: (a) that a Party admits in writing to that the other Party that is has or will cease to function as a going concern by suspending or discontinuing its business; (b) that Party shall commence any case, proceeding or other action (i) under any existing or future law of any jurisdiction relating to bankruptcy, insolvency, reorganization or relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, trustee, custodian, conservator or other similar official for it or for all or any substantial part of its assets, or any such Party shall make a general assignment for the benefit of its creditors; (c) there shall be commenced against such Party any case, proceeding or other action of a nature referred to in clause (b) above that (1) results in the entry of an order for relief or any such adjudication or appointment or (2) remains undismissed, undischarged or unbonded for a period of [***]; (d) any case, proceeding or other action has been commenced against such Party seeking issuance of a warrant of attachment, execution, distraint or similar process against all or any substantial part of its assets that results in the entry of an order for any such relief that shall not have been vacated, discharged, or stayed or bonded pending appeal within [***] from the entry thereof; or (e) such Party shall take any action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in clauses (b), (c) or (d) above.

1.120 "**Internal Program**" means an internal Autolus research program for which Autolus or any of its Affiliates has [***].

1.121 "**Intra-Group License**" means that certain License Agreement, dated [***], by and between Autolus Limited and Autolus Holdings (UK) Limited.

1.122 "**In Vivo**" means [***] in which [***] in any [***].

1.123 "**In Vivo AE Licensed Products**" has the meaning set out in Section 6.3(d).

1.124 "**JSC**" has the meaning set out in Section 2.2(a).

1.125 "**Know-How**" means all information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, formulations, compositions, products or to their Manufacture, Development, registration, use, Commercialization or other Exploitation, or methods of assaying or testing them or processes for their Manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data (including Personal Data), instructions, processes, formulae, expertise and information, regulatory filings and copies thereof, relevant to the Development, Manufacture, registration, use, Commercialization or other Exploitation of or which may be useful in studying, testing, Developing, producing or formulating products, or intermediates for the synthesis thereof.

1.126 "[***]" has the meaning set out in [***].

1.127 "**Losses**" has the meaning set out in Section 16.1.

1.128 "**Major Markets**" means any of [***].

1.129 "**Manufacture**" means, with respect to a compound or product, activities directed to the sourcing and purchasing of materials, producing, manufacturing, supplying, processing, compounding, filling, finishing, packing, packaging, labeling, leafleting, quality assurance, quality control testing and release, shipping, storage, and sample retention of such compound or product. "**Manufactured**" and "**Manufacturing**" have correlative meanings. Manufacture and Manufacturing do not include Develop or Developed or Commercialize or Commercialization.

1.130 "**MCSA**" has the meaning set out in Section 3.1(a).

1.131 "**MCSA Negotiation Period**" has the meaning set out in Section 3.1(a).

1.132 "**Module Option**" means (a) the Safety Switch Option, or (b) the Activity Enhancement Option.

1.133 "**Module Option Period**" has the meaning set out in Section 6.1.

1.134 "**Negotiation Trigger Notice**" has the meaning set out in Section 4.4(a).

1.135 "**Net Sales**" means, (i) with respect to any Obe-cel Product, the gross amounts [***] by Autolus, its Affiliates or Autolus Licensees to Third Party customers for sales of such Obe-cel Product, or (ii) with respect to any [***] Licensed Product, the gross amount [***] by BioNTech, its Affiliates or Sublicensees to Third Party customers for sales of such [***] Licensed Product, in each case ((i) and (ii)) less the following to the extent reasonable and customary and paid, incurred, or otherwise taken and not reimbursed by any Third Party in accordance with applicable Accounting Standards with respect to such sales;

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***],

(f) [***]; and

(g) [***].

Notwithstanding any provision to the contrary set forth in this Agreement, [***]. Net Sales will only be determined on the first sale by a Selling Party to (1) [***] or (2) [***]. Notwithstanding the foregoing, amounts received or invoiced by a Selling Party for the sale of such Revenue-Bearing Product to [***] for resale will not be included in the computation of Net Sales hereunder, and the amounts invoiced by [***] on such resale to [***] will be included in the computation of Net Sales hereunder. For purposes of determining Net Sales, a Revenue-Bearing Product will be deemed to be sold when [***]. Net Sales will be accounted for in accordance with the applicable Accounting Standards. A particular deduction may only

be accounted for once in the calculation of Net Sales. Net Sales will exclude any Revenue-Bearing Product made available to the patient [***].

In the event that the Revenue-Bearing Product is sold as part of a Combination Product, the Net Sales of such Revenue-Bearing Product, for the purposes of determining royalty payments, shall be determined by [***].

In the event that the weighted average sale price of the Revenue-Bearing Product when sold separately in finished form can be determined but the weighted average sale price of the other active compound(s)/active ingredient(s) when sold separately in finished form cannot be determined, Net Sales shall be calculated by [***].

In the event that the weighted average sale price of the other active compound(s)/active ingredient(s) when sold separately in finished form can be determined but the weighted average sale price of the Revenue-Bearing Product when sold separately in finished form cannot be determined, Net Sales, shall be calculated by ***].

In the event that the weighted average sale price of both the Revenue-Bearing Product and the other active compound(s)/active ingredient(s) in the Combination Product, in each case, when sold separately in finished form, cannot be determined, the Net Sales of the Revenue-Bearing Product shall be determined by [***], *provided* that, [***].

The weighted average sale price for a Revenue-Bearing Product, other active compound(s)/active ingredient(s), or Combination Product ***]. When determining the weighted average sale price of a Revenue-Bearing Product, other active compound(s)/active ingredient(s), or Combination Product, the weighted average sale price shall be calculated by [***]. Any overpayment or underpayment due to [***] will be [***].

1.136 "**Next Gen Development Plan Trigger Notice**" has the meaning set out in Section 4.8(b).

1.137 "**Next Gen Negotiation Trigger Notice**" has the meaning set out in Section 4.8(c).

1.138 "**Next Gen Notification Period**" has the meaning set out in Section 4.8(b).

1.139 "**Next Gen Option Exercise Notice**" has the meaning set out in Section 4.12(a).

1.140 "**Next Gen Product**" means (a) AUTO1/22 Next Gen Product or (b) AUTO6NG Next Gen Product, as applicable.

1.141 "**Next Gen Product Agreement**" has the meaning set out in Section 4.8(c).

1.142 "**Next Gen Product Development Plan**" has the meaning set out in Section 4.8(b).

1.143 "**Next Gen Product Negotiation Period**" has the meaning set out in Section 4.9.

1.144 "**Next Gen Product Option**" has the meaning set out in Section 4.8(a).

1.145 "**Next Gen Product Option Period**" means, on a Next Gen Product-by-Next Gen Product basis, the [***].

1.146 "**Nominated Target**" has the meaning set out in Section 6.4(b).

1.147 "**Nomination Notice**" has the meaning set out in Section 6.4(b).

1.148 "**Obe-cel Buyer**" has the meaning set out in Section 1.153.

1.149 "**Obe-cel Milestone 1**" has the meaning set out in Section 7.4(a).

1.150 "**Obe-cel Milestone 2**" has the meaning set out in Section 7.4(a).

1.151 "**Obe-cel Milestone 3**" has the meaning set out in Section 7.4(a).

1.152 "**Obe-cel Product**" means the autologous CD19 CAR-T Cell Therapy known as obecabtagene autoleucel or obe-cel, as further set out in Schedule 1.152, regardless of the brand name under which it is sold, Indication, or dose.

1.153 "**Obe-cel Product Transaction**" means the [***] to a Third Party (the "**Obe-cel Buyer**").

1.154 "**Obe-cel Revenue Interest**" has the meaning set out in Section 7.5.

1.155 "**Obe-cel Revenue Interest Term**" means, on a [***], with respect to [***] Obe-cel Product by Autolus, its Affiliates or Autolus Licensees, the period commencing on [***] and [***].

1.156 "**OP/NGOP Buyer**" has the meaning set out in Section 1.159.

1.157 "**Option Product Development Plan**" has the meaning set out in Section 4.3.

1.158 "**Option Product**" means each of (a) AUTO1/22 Product and (b) AUTO6NG Product.

1.159 "**Option Product or Next Gen Option Product Transaction**" means the [***] to a Third Party (the "**OP/NGOP Buyer**").

1.160 "**Option Product Right**" has the meaning set out in Section 4.7(a).

1.161 "**Other AE Licensed Products**" has the meaning set out in Section 6.3(e).

1.162 "[***]" means [***].

1.163 "[***]" means [***].

1.164 "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications and any and all rights to claim priority thereto, (b) all patent applications filed either from such patents, patent applications, or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, continued prosecution applications and reissue 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 or other patents resulting from post-grant proceedings ((a), (b), and (c)), and (e) any similar patent rights, including so-called pipeline protection or any importation, revalidation, confirmation, or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.165 "**Paying Party**" has the meaning set out in Section 10.6(b)(i).

1.166 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.167 "**Personal Data**" shall mean any information collected or received by Autolus and provided to BioNTech as a Data Package pursuant to this Agreement and that relates to an identified or identifiable natural person in accordance with Applicable Data Protection Law.

1.168 "**Phase 1 Trial**" means a human clinical trial of a product that satisfies the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.169 "**Phase 2 Trial**" means a human clinical trial of a product that satisfies the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.170 "**Phase 3 Trial**" means a human clinical trial of a product that satisfies the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations), regardless of where such clinical trial is conducted.

1.171 "**Pivotal Trial**" means a human clinical trial of a product, the principal purpose of which is a determination of safety and efficacy in the target patient population in order to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling and the filing for Regulatory Approval, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(c), as amended.

1.172 "**Product Agreement**" has the meaning set out in Section 4.4(a).

1.173 "**Product Negotiation Period**" has the meaning set out in Section 4.4(b).

1.174 "**Product Option**" has the meaning set out in Section 4.1.

1.175 "**Product Option Exercise Notice**" has the meaning set out in Section 4.5(a).

1.176 "**Product Option Period**" means the period commencing on [***] and ending on (a) with respect to AUTO1/22 Product, [***] and (b) with respect to the AUTO6NG Product, [***]; *provided*, that if BioNTech provides a Development Plan Trigger Notice pursuant to Section 4.3, then the Product Option Period for the applicable Option Product shall [***].

1.177 "[***]" means [***].

1.178 "**Qualified Indication**" means any of [***].

1.179 "**Receiving Party**" means has the meaning set out in Section 10.6(b)(ii).

1.180 "**Recipient Party**" has the meaning set out in Section 12.1.

1.181 "**Regulatory Approval**" means, with respect to a product in any country or other jurisdiction, any approval (including, where required, pricing and reimbursement approvals), registration,

license or authorization from a Regulatory Authority in such country or other jurisdiction that is necessary to market and sell such product in such country or jurisdiction, including in the US, an EUA.

1.182 "**Regulatory Authority**" means any governmental agency or authority responsible for granting Regulatory Approvals for biopharmaceutical products, including the FDA, EMA, European Commission and any corresponding national or regional regulatory authorities.

1.183 "[***]" means, [***].

1.184 "**Regulatory Filings**" means, with respect to a product, any submission to a Regulatory Authority of any appropriate regulatory application with respect to such product, including any submission to a regulatory advisory board, Drug Approval Application, and any supplement or amendment thereto, including any IND, or the corresponding application in any other country or group of countries with respect to such product.

1.185 "**Research and Development Collaboration Agreement**" has the meaning set out in Section 3.2.

1.186 "**Reserved Target**" has the meaning set out in Section 6.4(c).

1.187 "**Restricted Target**" the meaning set forth in Section 6.4(d).

1.188 "[***]" have the meaning set forth in [***].

1.189 "**Revenue-Bearing Product**" means (a) Obe-cel Product when Autolus or its Affiliate, or an Autolus Licensee is the Selling Party or (b) [***] Licensed Product when BioNTech, its Affiliate, or a Sublicensee is the Selling Party.

1.190 "**ROFN Period**" has the meaning set out in Section 4.7(a).

1.191 "**Safety Switch Field**" means any and all uses, subject to the limitations set out in Schedule 1.191, Part B.

1.192 "**Safety Switch Licensed IP**" means the Safety Switch Licensed Know-How and the Safety Switch Licensed Patents.

1.193 "**Safety Switch Licensed Know-How**" means all Know-How, including [***], that is (a) Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (i) the Exploitation of the Safety Switch Licensed Technology, or (ii) the Exploitation of such Safety Switch Licensed Technology in a Safety Switch Licensed Product. Notwithstanding the foregoing, [***].

1.194 "**Safety Switch Licensed Patents**" means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) the Safety Switch Licensed Technology, (ii) the Safety Switch Licensed Know-How, or (iii) the Exploitation of such Safety Switch Licensed Technology in a Safety Switch Licensed Product.

1.195 "**Safety Switch Licensed Product**" means any pharmaceutical or biologic product, in any form, that contains or incorporates any Safety Switch Licensed Technology. For the purposes of this Agreement, [***], and *provided further* that [***].

1.196 "**Safety Switch Licensed Technology**" means each regulatable control module listed in Schedule 1.191, Part A.

1.197 "**Safety Switch Option**" has the meaning set out in Section 6.3(c).

1.198 "**Sales Tax**" means any sales, goods, services, value-added, turnover, consumption, use or similar tax and any tax charged on the import or export of any goods or services.

1.199 "**Selling Party**" means (a) with respect to Obe-cel Product, Autolus, its Affiliates or Autolus Licensees, as applicable and (b) with respect to any [***] Licensed Product, BioNTech, its Affiliates or Sublicensees, as applicable.

1.200 "**Share Purchase Agreement**" has the meaning set out in the recitals to this Agreement.

1.201 "**Sponsor**" means the sponsor of the [***] of the applicable Option Product or Next Gen Product.

1.202 "**Subcommittee**" has the meaning set out in Section 2.4.

1.203 "**Subcontractor**" has the meaning set out in Section 5.3

1.204 "**Sublicensee**" means a Third Party to whom BioNTech or any of its Affiliates has granted a sublicense of any of its rights under this Agreement to Exploit [***] Licensed Products; *provided* that, notwithstanding any provision to the contrary set forth in this Agreement, Subcontractors, distributors and wholesalers will not be considered Sublicensees.

1.205 "**Target**" means one or more biological targets identified by BioNTech in respect of which BioNTech wishes to exercise any Module Option, *provided* that, other than in respect of [***], if [***].

1.206 "[***]" has the meaning set out in [***].

1.207 "**Tax**" or "**Taxes**" means any taxes, duties, levies or imposts and other charges in the nature of tax and all related withholding or deductions.

1.208 "**Technologies License Agreement**" has the meaning set out in Section 6.5.

1.209 "**Technologies Option**" means (a) the [***] Option, (b) the Safety Switch Option, (c) the Activity Enhancement Option, or (d) [***] Option, as applicable.

1.210 "**Technologies Option Buyer**" has the meaning set out in Section 1.217.

1.211 "**Technologies Option Exercise Fee**" has the meaning set out in Section 6.6.

1.212 "**Technologies Option Exercise Fee Cap**" has the meaning set out in Section 6.6.

1.213 "**Technologies Option Exercise Notice**" has the meaning set out in Section 6.5.

1.214 "**Technologies Option IP**" means (a) the [***] Licensed IP, (b) the Safety Switch Licensed IP, (c) Activity Enhancement Licensed IP, and (d) [***] Licensed IP.

1.215 "**Technologies Option Period**" means the period of time commencing on the Effective Date and ending on the later of the expiration of (a) the [***] Option Period, (b) the Module Option Period, and (c) [***] Option Period.

1.216 "**Technologies Option Technology**" means the [***] Licensed Binder, [***] Licensed Binder, Safety Switch Licensed Technology, Activity Enhancement Licensed Technology, and [***] Licensed Binder.

1.217 "**Technologies Option Transaction**" means the [***] to a Third Party (the "**Technologies Option Buyer**").

1.218 "**Term**" has the meaning set out in Section 13.1(b).

1.219 "**Territory**" means worldwide.

1.220 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.221 "**Third Party Evaluator**" means Subcontractors performing activities in connection with the research or development of products being researched or developed, in whole or in part, by or on behalf of BioNTech or its Affiliates alone or in conjunction with a Third Party collaborator.

1.222 "**Transferred Materials**" has the meaning set out in Section 6.2(a).

1.223 "[***]" means [***].

1.224 "[***]" means [***].

1.225 "[***]" means [***].

1.226 "[***] **Field**" means (a) the Field and (b) [***].

1.227 "[***] **Licensed Binder**" means (a) any of the Binders of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.228 "[***] **Licensed Binder**" means (a) any of the Binders of [***], and (b) [***], provided that clause (b) shall not include any Binder that (i) [***], or (ii) [***].

1.229 "[***] **Licensed IP**" means the [***] Licensed Know-How and the [***] Licensed Patents.

1.230 "[***] **Licensed Know-How**" means all Know-How, including [***], that is (a) Controlled by Autolus or its Affiliates, as of the Effective Date or during the Term, and (b) necessary or reasonably useful for (a) the Development of the [***] Licensed Binder and/or the [***] Licensed Binder, or (b) the Exploitation of such Binders in a [***] Licensed Product, or [***]. Notwithstanding the foregoing, [***].

1.231 "[***] **Licensed Patents**" means all Patents, including Patents that Cover [***], that (a) are Controlled by Autolus or any of its Affiliates, as of the Effective Date or during the Term, and (b) claim or Cover (i) the [***] Licensed Binder or the [***] Licensed Binder, (ii) the [***] Licensed Know-How, or (iii) the Exploitation of the [***] Licensed Binder and/or the [***] Licensed Binder in a [***] Licensed Product or [***].

1.232 "[***] **Licensed Product**" means any pharmaceutical or biologic product (a) that expresses In Vivo, or (b) is an ADC that contains, in each case of (a) and (b), the [***] Licensed Binder and/or the [***] Licensed Binder, including any dosage strengths, presentations, formulations or methods of administration, but excluding a [***]. For the purposes of this Agreement, [***] and *provided further* that [***]. For clarity, [***].

1.233 "[***] **Option**" has the meaning set out in Section 6.3(a).

1.234 "[***] **Option Period**" has the meaning set out in Section 6.1.

1.235 "[***]" means [***].

1.236 "[***]" means [***].

1.237 "[***]" means [***].

1.238 "[***]" has the meaning set forth in [***].

1.239 "**United States**" **or** "**U.S.**" means the United States of America, its territories and possessions.

1.240 "**Upfront Payment**" has the meaning set out in Section 7.3.

1.241 "**Upstream License Agreement**" means [***].

1.242 "**Valid Claim**" means [***] of: (a) a [***] Patent [***], which [***] and [***] and [***], *provided* that such [***] to which such [***] patent [***] is [***], excluding, however, any [***] that [***], and *provided further* that from and after such [***], unless and until [***], and [***]; or (b) any [***] Patent for which [***] any of the following: [***]; or [***], and *provided further*, that in no event will any [***] with respect to [***]. For the purposes of this Agreement, [***] shall be subject to subparagraphs (a) or (b) hereof, or [***]. For the purpose of this definition, [***].

2. SCOPE AND GOVERNANCE

2.1 **Collaboration Overview.** Under and pursuant to the terms of this Agreement: (a) the Parties shall discuss [***] (i) one or more agreements with respect to manufacturing and commercial services pursuant to Section 3.1 and (ii) a potential research and development collaboration agreement pursuant to Section 3.2; (b) Autolus shall grant BioNTech certain exclusive options to obtain certain exclusive rights to certain agreed programs Controlled by Autolus, pursuant to Article 4; (c) Autolus shall grant BioNTech an exclusive license to [***] Licensed Binders and [***] Licensed Binders pursuant to Article 5; (d) Autolus shall grant BioNTech options to obtain licenses related to (i) [***] Licensed Binders and [***] Licensed Binders, (ii) Safety Switch Licensed Technology, (iii) Activity Enhancement Licensed Technology, and (iv) [***] Licensed Binders, each in accordance with Article 6; (e) Autolus shall pay to BioNTech the Obe-cel Revenue Interest pursuant to Section 7.5; and (f) BioNTech shall pay the license payment to Autolus set out in Section 9.1, purchase shares in Autolus set out in the Share Purchase Agreement, as further set out in the Recitals, and make the other payments set out under this Agreement in accordance with the terms hereof.

2.2 **Joint Steering Committee**.

(a) Within [***], the Parties shall establish a joint steering committee (the "**JSC**") to provide a forum for communication between the Parties and to oversee the relationship between the Parties; *provided*, *however*, that the JSC shall have no authority to amend this Agreement. The JSC is formed to aid in the exchange of information and discussions by the Parties [***]. The JSC shall disband upon the later of (i) [***], and (ii) [***]; *provided*, that upon BioNTech's written request, the term of the JSC shall continue for [***] beyond such period.

(b) The JSC shall be comprised of an equal number of representatives from each of Autolus and BioNTech. The exact number of such representatives shall be [***] for each Party, or such other number as the Parties may agree. Autolus and BioNTech shall each designate one of its JSC members as co-chairperson of the JSC. Each Party may replace any or all of its representatives or appoint a proxy at any time by giving prior written notification to the other Party. Each Party may, in its reasonable discretion, invite other employees and agents of such Party who are under written obligations of confidentiality to attend meetings of the JSC.

(c) From [***] until [***], the JSC will hold meetings on a [***] basis, and thereafter shall hold meetings [***], in each case unless otherwise agreed by the Parties. All meetings will be held by videoconference, telephone, web conference, or face to face, unless otherwise agreed by the JSC. The co-chairpersons of the JSC will set the agenda for meetings of the JSC. The co-chairpersons will issue minutes of each meeting of the JSC [***] following each meeting. The minutes will be considered as accepted if, within [***] following receipt, no one has objected in writing (including by electronic mail) to the co-chairpersons disputing the accuracy of such minutes. The minutes of each JSC meeting are the Confidential Information of both Parties.

(d) The JSC will:

(i) review and discuss Autolus's [***] updates provided under Section 4.2(a), any Data Package provided under Section 4.2(b), and any commencement by Autolus of Development activities on any Next Gen Product notified under Section 4.2(c);

(ii) following delivery of any Development Plan Trigger Notice or Next Gen Development Plan Trigger Notice, review and discuss the Option Product Development Plan or Next Gen Development Plan (as applicable), in accordance with Section 4.3 and Section 4.8(c) respectively;

(iii) review the [***] updates provided by BioNTech pursuant to Section 6.2(d);

(iv) review and discuss the report regarding the Obe-cel Product set forth in Section 7.1, and any updates to such report;

(v) review and discuss [***] updates on Development of Obe-cel Product with respect to Indications other than [***];

(vi) during the [***], including Autolus's [***] updates provided under Section 8.2;

(vii) review and discuss any [***] under Section 3.1(b), and oversee [***] pursuant to Section 3.1(b);

(viii) review and discuss each report provided by BioNTech under Section 5.11;

(ix) review and discuss [***];

(x) perform other responsibilities specifically assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time.

(e) Without prejudice to any obligation on Autolus to provide any of the information referenced for review and discussion at the JSC on particular timelines elsewhere in this Agreement, Autolus shall ensure that such information for discussion and review will be made available to BioNTech in writing reasonably in advance of each JSC meeting.

(f) The Parties will [***].

2.3 **Alliance Managers**. Within [***], each Party shall appoint an individual (who is not a member of the JSC) who possesses a general understanding of this Agreement to act as the alliance manager for such Party ("**Alliance Manager**"). Each Alliance Manager may attend meetings of the JSC as a nonvoting observer and the Alliance Managers may bring to the attention of the JSC any matters or issues such Alliance Manager reasonably believes should be discussed. The Alliance Managers will be a key point of contact for the Parties regarding the contractual and business aspects of the collaboration during the Term. Each Party may replace its Alliance Manager at any time by giving prior written notification to the other Party.

2.4 **Subcommittees**. The JSC may establish one or more subcommittees of the JSC (each a "**Subcommittee**"). Each Subcommittee shall be established on mutually agreed terms, and have agreed specific responsibilities, *provided*, that no Subcommittee shall have the authority to amend this Agreement or any other agreement.

3. COLLABORATION AGREEMENTS

3.1 **Manufacturing and Commercial Services Agreement**.

(a) During the period commencing on the Effective Date and ending on the eighteen (18) month anniversary of the Effective Date ("**MCSA Negotiation Period**"), the Parties shall [***] negotiate the terms of and execute a joint manufacturing and commercial services agreement ("**MCSA**") pursuant to which (i) Autolus may obtain access to BioNTech's manufacturing and commercial site services capabilities for Autolus's CAR-T products, and (ii) BioNTech may obtain access to Autolus's manufacturing and commercial site services capabilities for BioNTech's CAR-T products, including the product known as BNT211 ("**BNT211**"), including, in each case, [***]. The MCSA will reflect the terms set forth on Schedule 3.1.

(b) During the MCSA Negotiation Period, Autolus (1) shall provide updates to the JSC on the progress of its Manufacturing facilities to allow BioNTech to monitor the progress of such facilities and (2) [***]. For the avoidance of doubt, subject to Autolus reserving the requisite capacity for BioNTech, (i) this Section 3.1(b) does not prevent, inhibit or otherwise affect Autolus's ability to Manufacture any product that has been Developed by Autolus or its Affiliates (including Obe-cel Product), whether for sale by itself or any Third Party, (ii) [***], and (iii) [***] after [***], the Parties shall [***], which shall [***].

(c) Autolus will [***] ensure that its manufacturing facility is ready and available to manufacture BNT211 by [***] such that the batches produced at Autolus's manufacturing facility can be [***], subject to (i) Section 3.1(d), (ii) BioNTech fulfilling its obligations in [***], and (iii) BioNTech [***]. If a Party's performance of its obligations under [***] is adversely affected in a material manner by

the other Party's failure to perform its obligations under this Agreement, then the impact of such performance failure will be taken into account in determining whether such first Party has used the required efforts to perform any such affected obligations, but only to the extent such other Party's performance failure is the cause of such first Party's failure to meet such obligations and such first Party continues to use the required efforts to reduce the impact of the other Party's performance failure.

(d) If the MCSA is not entered into within [***] following [***], then the timeline of [***] in Section 3.1(c) shall be [***].

(e) If upon expiry of the MCSA Negotiation Period, the Parties are unable to agree the terms of the MCSA, BioNTech may, in its sole discretion, refer the terms of the MCSA for resolution using Baseball Arbitration, which referral must occur within [***] of expiry of the MCSA Negotiation Period. If (i) BioNTech does not refer the terms of the MCSA for resolution using Baseball Arbitration within [***] of expiry of the MCSA Negotiation Period, or (ii), BioNTech chooses not to enter into the MCSA within [***] after the arbitrator has given a final decision in Baseball Arbitration then, without any further action required on the part of either Party, the obligations set out in Section 3.1(a), Section 3.1(b) and Section 3.1(c) shall expire and, if an MCSA has not been entered into by such date, then there shall be no further obligation to continue negotiations on either Party and Autolus, at its sole discretion, may enter into an agreement with a Third Party pursuant to which Autolus would Manufacture a Third Party's CAR-T Cell Therapy.

3.2 **Research and Development Collaboration Agreement**. During [***], the Parties shall discuss [***] the terms, including financial terms, of a research and development collaboration agreement regarding products that utilize the expertise of both Parties ("**Research and Development Collaboration Agreement**"), *provided* that neither Party is required to enter into such Research and Development Collaboration Agreement, and the obligation to discuss shall expire at the end of such [***] period.

4. PRODUCT OPTIONS

4.1 **Product Options**. With effect from the Effective Date, Autolus hereby grants to BioNTech, on an Option Product-by-Option Product basis, the exclusive option to obtain the exclusive right to co-fund certain development costs in respect of the relevant Option Product in return for a [***] profit sharing arrangement, and to obtain the exclusive option to co-promote and co-commercialize the Option Product, in each case, for all oncology Indications and subject to and as further set out in this Article 4 and Schedule 4.4(a) (each, a "**Product Option**").

4.2 **Provision of Data**.

(a) Autolus shall, within [***], deliver to BioNTech, all information and data received or otherwise Controlled by Autolus in relation to the Development of the Option Products, [***], in the formats such information and data are held by Autolus [***]. During the applicable Product Option Period, Autolus shall provide additional data received by or otherwise Controlled by Autolus in relation to the Development of the Option Products to BioNTech [***] following such data becoming available to Autolus. Autolus will provide the JSC with updates on the progress of the Sponsor's activities in relation to such Option Product or Next Gen Product, as applicable, every [***] during the applicable (i) Product Option Period for each Option Product, and, (ii) Next Gen Product Option Period for each Next Gen Product. Autolus will also provide the JSC with updates on the progress of the Development of each Option Product and Next Gen Product [***] from [***] until the end of the Product Option Period for the applicable Option Product and from [***] until the end of the Next Gen Product Option Period for the applicable Next Gen Product. Autolus shall, during the applicable Product Negotiation Period on an Option Product-by-Option Product basis and, during the applicable Next Gen Product Negotiation Period on a Next Gen

Product-by-Next Gen Product basis, on BioNTech's request, request from the Sponsor any additional relevant data that the Sponsor has in relation to the Option Products or Next Gen Products, as applicable, which has not been provided to Autolus. On BioNTech's request during the applicable Product Negotiation Period or Next Gen Product Negotiation Period, Autolus will [***] facilitate access for BioNTech to the Sponsor's principal investigators working on the Development of the applicable Option Products and Next Gen Products. Autolus will [***] provide BioNTech with [***] (1) of AUTO6NG Product during the applicable Product Option Period and any applicable ROFN Period, and (2) of any Next Gen Product during the applicable Next Gen Product Option Period. To the extent that any data to be provided under this Section 4.2(a), Section 4.2(b) or Section 4.7(b) constitutes Personal Data, Autolus shall only be obliged to deliver such Personal Data to BioNTech to the extent to which it can be delivered in compliance with Applicable Data Protection Law. If the current formats are not compatible with the transfer of such information and data to BioNTech in compliance with Applicable Data Protection Law, then Autolus shall [***] (A) to obtain such information and data in an anonymized or other format that (x) can be transferred to BioNTech and (y) results in the applicable information and data no longer constituting Personal Data under Applicable Data Protection Law, or (B) to facilitate an appropriate data transfer agreement under which such data can be provided to BioNTech in compliance with Applicable Data Protection Law, *provided* that [***].

(b) Autolus shall deliver to BioNTech the applicable Data Package: (i) within [***] after [***], with respect to the AUTO1/22 Product, (ii) [***], with respect to the AUTO6NG Product, or (iii) during the applicable Next Gen Product Option Period, [***]. Autolus shall provide reasonable assistance to BioNTech in analyzing each Data Package, at BioNTech's written request and [***].

(c) If Autolus commences Development activities on any Next Gen Product during the Next Gen Product Option Period, it shall inform BioNTech [***].

4.3 **Development Plan**. On an Option Product-by-Option Product basis, at any time during the applicable Product Option Period after BioNTech has received the relevant Data Package pursuant to Section 4.2(b), BioNTech may notify Autolus in writing that it wishes to receive a Development plan for such Option Product (a "**Development Plan Trigger Notice**"). Within [***] after Autolus receives a Development Plan Trigger Notice, Autolus shall provide to BioNTech a reasonably detailed written Development plan and associated budget for the applicable Option Product (the "**Option Product Development Plan**"). The Option Product Development Plan would include [***]. Upon BioNTech's request, the Parties, through the JSC, would discuss the Option Product Development Plan and associated budget and Autolus shall [***]. For clarity, [***]. If BioNTech provides a Development Plan Trigger Notice, and Autolus does not, at such time, intend to Develop further such Option Product, then Section 4.7 applies. For the period from provision of the Data Package until the earlier of: (i) the relevant Product Option Period expires without a Development Plan Trigger Notice being received by Autolus, (ii) [***] after BioNTech's receipt of the applicable Option Product Development Plan, if no Negotiation Trigger Notice is received by Autolus, or (iii) expiry of the Product Negotiation Period and any period during which a Baseball Arbitration procedure is ongoing with respect to such Option Product, Autolus shall not grant a Third Party rights to Exploit the relevant Option Product without BioNTech's prior written consent, [***].

4.4 **Negotiation of Product Agreement**.

(a) **Negotiation Trigger Notice**. Within [***] after BioNTech's receipt of the Option Product Development Plan, BioNTech may notify Autolus in writing that it wishes to enter into exclusive negotiations with Autolus to finalize the terms of and execute an agreement in respect of the Exploitation of a particular Option Product for the treatment of one or more oncology Indications, providing for co-funding and [***] profit share arrangements and an exclusive option for BioNTech to co-promote and co-commercialize (each a "**Negotiation Trigger Notice**"), which agreement shall include the terms set out in

Schedule 4.4(a) (each a "**Product Agreement**"). The Option Product Development Plan would be included as an initial Development plan to the Product Agreement.

(b) **Negotiation of Product Agreement**. The Parties shall, on an Option Product-by-Option Product basis, negotiate exclusively [***] for a period of [***] from the date of Autolus's receipt of the Negotiation Trigger Notice ("**Product Negotiation Period**"), to agree the definitive terms of the applicable Product Agreement. If the anticipated start date for the Development activities included in the Option Product Development Plan is more than [***] after BioNTech's receipt of the Option Product Development Plan, the Parties would [***].

(c) **Referral to Baseball Arbitration**. If, upon expiry of the applicable Product Negotiation Period, the Parties are unable to agree the terms of such Product Agreement, BioNTech may, in its sole discretion, refer the terms of the Product Agreement ([***]) for resolution using Baseball Arbitration, which referral must occur within [***] of expiry of the applicable Product Negotiation Period.

4.5 **Option Exercise.**

(a) **Option Exercise Notice**. Within [***] after (i) the Parties have agreed on a Product Agreement for the applicable Option Product or (ii) the arbitrator has given a final decision in Baseball Arbitration, as applicable, BioNTech may notify Autolus in writing that it wishes to execute the applicable Product Agreement (a "**Product Option Exercise Notice**"). If BioNTech provides such a Product Option Exercise Notice, then the Parties shall execute such Product Agreement within [***] after Autolus's receipt of the Product Option Exercise Notice.

(b) **Option Exercise Fee**. BioNTech shall pay Autolus the applicable option exercise fee set forth below for the corresponding Product Agreement within [***] after the receipt of an invoice from Autolus following the execution of such Product Agreement:

Option Product	Option Exercise Fee
AUTO1/22	[***]
AUTO6NG	[***]

4.6 **Failure to Exercise Option or Rejection of Baseball Arbitration**.

(a) If:

(i) Autolus does not receive a Development Plan Trigger Notice during the applicable Product Option Period, or

(ii) Autolus does not receive a Negotiation Trigger Notice within [***] after BioNTech's receipt of an Option Product Development Plan, or

(iii) the Parties fail to enter into a Product Agreement during the applicable Product Negotiation Period and BioNTech does not refer such matter for resolution using Baseball Arbitration in the period described in Section 4.4(c), or

(iv) Autolus does not receive a Product Option Exercise Notice within [***] after the Parties have agreed on a Product Agreement for the applicable Option Product or the arbitrator has given a final decision in Baseball Arbitration, or

(v) BioNTech chooses not to enter into the applicable Product Agreement within [***] after the Parties have agreed on a Product Agreement for the applicable Option Product or the arbitrator has given a final decision in Baseball Arbitration,

then in each case of (i)–(v), with effect from the date of expiry of such period, and without any further action required on the part of either Party, the applicable Product Option shall expire and then the terms of this Article 4 shall no longer apply to such Option Product and, without limiting the generality of the foregoing, Autolus may commence Development of such Option Product or enter into an agreement with a Third Party for such Option Product, on terms determined at Autolus's sole discretion without further reference to BioNTech, save as provided in Section 4.6(b).

(b) If Autolus elects to commence Development of an Option Product in accordance with Section 4.6(a)(ii)–(v) where Autolus received a Development Plan Trigger Notice, but for which the Parties have not entered into a Product Agreement, (i) Autolus shall, on BioNTech's written request during the [***] from the date of expiry of the applicable period in Section 4.6(a), provide BioNTech with a report on Autolus's Development spend under the applicable Development Plan reconciled against the budget for the applicable Development Plan, and [***] (a "**Failure to Develop**"), Autolus will notify BioNTech in writing (a "**Failure to Develop Notice**") and the provisions of Section 4.2(b) and Section 4.8 shall apply to any Next Gen Product of such Option Product, for which Autolus obtains, within [***] after the BioNTech's receipt of the Failure to Develop Notice (the "**Failure to Develop Period**"), sufficient data and information to provide BioNTech with a Data Package.

4.7 **Rights of BioNTech if Autolus does not wish to Develop.**

(a) If Autolus notifies BioNTech pursuant to Section 4.3 that it does not, at the time of receipt by Autolus of a Development Plan Trigger Notice, intend to Develop further such Option Product, then Autolus shall and hereby does grant BioNTech (i) a right of first negotiation, as set out in this Section 4.7, in relation to such Option Product if Autolus intends (1) [***], or (2) [***] ((1) and (2) collectively, an "**Option Product Right**"), and (ii) the right to negotiate a Product Agreement in accordance with Sections 4.3–4.6 if Autolus intends to Develop such Option Product itself or with or through any Affiliate, in the case of both (i) and (ii) for a period of [***] commencing on the date of receipt by Autolus of the applicable Development Plan Trigger Notice (the "**ROFN Period**"), subject to and as further set out in Section 4.7(b). Notwithstanding the foregoing, the rights in this Section 4.7 do not apply to an Acquisition of Autolus or its Affiliate. For clarity, Section 4.7 remains in full force and effect following an Acquisition of Autolus or its Affiliate.

(b) If Autolus notifies BioNTech pursuant to Section 4.3 that it does not, at the time of receipt by Autolus of a Development Plan Trigger Notice, intend to Develop further such Option Product, and thereafter during the ROFN Period Autolus intends to Develop such Option Product itself or with or through any Affiliate or to grant any Third Party an Option Product Right, then, prior to commencing such Development or engaging in discussions or entering into any agreement with any Third Party for the grant of such rights (a "**Restricted Act**"), Autolus shall provide BioNTech with prior written notice and all material information and data relating to such Option Product then in its possession (to the extent not previously provided pursuant to Section 4.2) and, (i) in the event that Autolus intends to grant any Third Party an Option Product Right, for a period of [***] after receipt of such notice and information, BioNTech has an exclusive right of first negotiation to enter into a definitive agreement with Autolus granting BioNTech rights in relation to such Option Product, and during such [***], Autolus would negotiate [***]

with BioNTech and would not perform any Restricted Act, and (ii) in the event that Autolus intends to Develop such Option Product itself or with or through any Affiliate, to an option on the terms set out in Schedule 4.4(a), in which case the provisions of Sections 4.3–4.6 shall apply, *mutatis mutandis*, *provided* that BioNTech provides a Development Plan Trigger Notice to Autolus within [***] of receiving written notice and all material information and data from Autolus regarding Autolus's proposed further Development of such Option Product.

(c) Notwithstanding the ROFN Period, if the Parties fail to enter into a definitive agreement prior to (i) in the case of Autolus intending to Develop such Option Product through the grant of any Option Product Rights to any Third Party, the expiration of the [***] period set forth in Section 4.7(b), and (ii) in the case of Autolus intending to Develop such Option Product itself or with or through any Affiliate, the date of expiry of the applicable period set forth in Sections 4.6(a)(i)–4.6(a)(v), *mutatis mutandis*, then (1) for a period of [***] after the ROFN Period, Autolus will notify BioNTech if Autolus intends to grant a Third Party a Product Option Right, and (2) all of the terms of this Section 4.7 shall no longer apply to such Option Product and, for clarity, and without limiting the generality of the foregoing, Autolus may commence Development of such Option Product, engage in discussions with a Third Party or enter into an agreement with a Third Party for such Option Product, on terms determined at Autolus's sole discretion.

4.8 **Next Generation Products Option.**

(a) **Next Gen Product Option and Next Gen Product Development Plan**. Autolus hereby grants to BioNTech, on a Next Gen Product-by-Next Gen Product basis, the exclusive option in relation to any Next Gen Product for which Autolus provides BioNTech with a Data Package pursuant to Section 4.2(b), to obtain the exclusive right to co-fund certain development costs in respect of the relevant Next Gen Product in return for a [***] profit sharing arrangement, in each case, for all oncology Indications, and obtain the exclusive option to co-promote and co-commercialize such Next Gen Product for all oncology Indications, in each case, subject to and as set out in this Section 4.8 ("**Next Gen Product Option**").

(b) **Next Gen Product Development Plan.** At any time during the [***] period after BioNTech's receipt of a Data Package for a Next Gen Product pursuant to Section 4.2(b) (the "**Next Gen Notification Period**"), BioNTech may notify Autolus in writing that it wishes to receive a Development plan for such Next Gen Product (a "**Next Gen Development Plan Trigger Notice**"). Within [***] after Autolus receives a Next Gen Development Plan Trigger Notice, Autolus shall provide to BioNTech a reasonably detailed written Development plan and associated budget for the applicable Next Gen Product (the "**Next Gen Product Development Plan**"). The Next Gen Product Development Plan would include [***]. Upon BioNTech's request, the Parties, through the JSC, would discuss the Next Gen Product Development Plan and associated budget and Autolus shall [***]. For clarity, [***]. For the period from receipt by Autolus of a Next Gen Development Plan Trigger Notice until the earlier of (i) [***] after BioNTech's receipt of the applicable Next Gen Product Development Plan, if no Next Gen Negotiation Trigger Notice is received by Autolus, or (ii) the expiry of the Next Gen Product Negotiation Period and any period during which a Baseball Arbitration procedure is ongoing with respect to such Next Gen Product, Autolus shall not grant a Third Party rights to Exploit the relevant Next Gen Product without BioNTech's prior written consent, [***].

(c) **Negotiation Trigger Notice**. Within [***] after BioNTech's receipt of the Next Gen Product Development Plan, BioNTech may notify Autolus in writing that it wishes to enter into exclusive negotiations with Autolus to agree the terms of and execute an agreement in respect of the Exploitation of the applicable Next Gen Product for the treatment of one or more oncology Indications, providing for co-funding and [***] profit share arrangements and an exclusive option for BioNTech to co-

promote and co-commercialize (each a "**Next Gen Negotiation Trigger Notice**"), which agreement shall include the terms set out in Schedule 4.4(a) (each a "**Next Gen Product Agreement**"). The Next Gen Product Development Plan would be included as an initial Development plan to the Next Gen Product Agreement.

4.9 **Negotiation of Next Gen Product Agreement**. The Parties shall, on a Next Gen Product-by-Next Gen Product basis, negotiate exclusively [***] for a period of [***] from the date of Autolus's receipt of the Next Gen Negotiation Trigger Notice to agree the definitive terms of the applicable Next Gen Product Agreement (such period and any mutually agreed extension, the "**Next Gen Product Negotiation Period**"), to agree the definitive terms of the applicable Next Gen Product Agreement. If the anticipated start date for the Development activities included in the Next Gen Product Development Plan is more than [***] after BioNTech's receipt of the Next Gen Product Development Plan, the Parties would [***].

4.10 **Referral to Baseball Arbitration**. If, upon expiry of the applicable Next Gen Product Negotiation Period, the Parties are unable to agree the terms of such Next Gen Product Agreement, BioNTech may, in its sole discretion, refer the terms of the Next Gen Product Agreement ([***]) for resolution using Baseball Arbitration, which referral must occur within [***] of expiry of the applicable Next Gen Product Negotiation Period.

4.11 **Failure to Exercise Option or Rejection of Baseball Arbitration**. If:

(a) Autolus does not receive a Next Gen Development Plan Trigger Notice during the applicable Next Gen Notification Period, or

(b) Autolus does not receive a Next Gen Negotiation Trigger Notice within [***] after BioNTech's receipt of a Next Gen Product Development Plan, or

(c) the Parties fail to enter into a Next Gen Product Agreement during the applicable Next Gen Product Negotiation Period and BioNTech does not refer such matter for resolution using Baseball Arbitration in the period described in Section 4.10, or

(d) Autolus does not receive a Next Gen Option Exercise Notice within [***] after the Parties have agreed on a Next Gen Product Agreement for the applicable Next Gen Product or the arbitrator has given a final decision in Baseball Arbitration, or

(e) BioNTech chooses not to enter into the applicable Next Gen Product Agreement within [***] after the Parties have agreed on a Next Gen Product Agreement for the applicable Next Gen Product or the arbitrator has given a final decision in Baseball Arbitration,

then in each case of (a)–(e), with effect from the date of expiry of such period, and without any further action required on the part of either Party, the applicable Next Gen Product Option shall expire and then the terms of this Article 4 shall no longer apply to such Next Gen Product and, without limiting the generality of the foregoing, Autolus may commence Development of such Next Gen Product or enter into an agreement with a Third Party for such Next Gen Product, on terms determined at Autolus's sole discretion without further reference to BioNTech.

4.12 **Next Gen Option Exercise.**

(a) **Option Exercise Notice**. Within [***] after (i) the Parties have agreed on a Next Gen Product Agreement for the applicable Next Gen Product or (ii) the arbitrator has given a final decision

in Baseball Arbitration, as applicable, BioNTech may notify Autolus in writing that it wishes to execute the applicable Next Gen Product Agreement (a "**Next Gen Option Exercise Notice**"). If BioNTech provides such a Next Gen Option Exercise Notice, then the Parties shall execute such Next Gen Product Agreement within [***] after Autolus's receipt of the Next Gen Option Exercise Notice.

(b) **Next Gen Option Exercise Fee**. BioNTech shall pay Autolus the applicable option exercise fee set forth below for the corresponding Next Gen Product Agreement within [***] after the receipt of an invoice from Autolus following the execution of such Next Gen Agreement:

Next Gen Product	Option Exercise Fee
AUTO1/22	[***]
AUTO6NG	[***]

4.13 **If Autolus does not wish to Develop**. If BioNTech provides a Next Gen Development Plan Trigger Notice, and Autolus does not, at such time, intend to Develop further such Next Gen Product, then Autolus shall provide BioNTech with written notice and all material information and data relating to such Next Gen Product then in Autolus's possession and, for a period of [***] after receipt of such notice and information, BioNTech has a right of first negotiation to such Next Gen Product to obtain rights in such Next Gen Product. During such [***], Autolus may not perform any Development, engage in discussions or enter into any agreement with any Third Party for the grant of any rights in relation to such Next Gen Product.

5. LICENSE TO [***] AND [***] BINDERS

5.1 **License Grant**. Subject to the terms and conditions of this Agreement, with effect from the Effective Date, Autolus hereby grants to BioNTech:

(a) an exclusive (including as to Autolus and its Affiliates), sub-licensable (subject to Section 5.3), payment-bearing, worldwide license under the [***] Licensed IP (i) to Develop the [***] Licensed Binder and the [***] Licensed Binder in connection with a [***] Licensed Product, and (ii) to Exploit [***] Licensed Products directed to [***], in each case of (i) and (ii), in the Field in the Territory ("[***] **License**"); and

(b) a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the [***] Licensed IP to research and Develop (only up to and including [***]) a CAR-T Cell Therapy; *provided* that [***]; *provided further* that [***].

5.2 **Right of Negotiation**. If BioNTech, its Affiliates or Sublicensees wishes to Exploit any [***] Licensed Product in combination with a CAR-T Cell Therapy that [***] (the "**Autolus [***] CAR-T**"), then prior to [***], BioNTech shall provide Autolus with prior written notice and grants, and shall procure the grant of, to Autolus, for a period of [***] after receipt of such notice, a right of first negotiation to, [***], negotiate and enter into an agreement with BioNTech, its Affiliate or Sublicensee (as applicable) for Autolus or its Affiliate to be BioNTech's partner for such combination therapy, whereby [***] Licensed Product would be used in combination with such Autolus [***] CAR-T. Prior to or during such [***] period, BioNTech, its Affiliates and Sublicensees shall [***].

5.3 **Sublicense Rights; Subcontracting**. Subject to the terms and conditions of this Agreement, BioNTech may sublicense the rights granted to it by Autolus under Section 5.1, including in

connection with subcontracting to Third Parties whose business is to provide services to other entities, including contract research organizations, contract laboratory testing providers, contract manufacturing organizations, contract sales force providers, contract employees, and scientific, regulatory or other expert consultants and professional advisors ("**Subcontractor**") the rights or performance of tasks and obligations with respect to the Exploitation of [***] Licensed Products; *provided* that:

(a) BioNTech is not permitted to grant a sublicense under the rights granted to it by Autolus under Section 5.1 that permits the Sublicensee to Develop or otherwise use a [***] Licensed Binder and/or a [***] Licensed Binder:

(i) for any purpose *other than* [***], and

(ii) for any purpose *other than* [***] under: (1) [***] described in clause (i), or (2) [***] described in clause (i), *provided* that, if [***], then unless [***];

(b) any such sublicenses shall be in writing and be consistent with the applicable terms and conditions of this Agreement;

(c) BioNTech shall remain responsible for the performance of all of its Sublicensees to the same extent as if such activities were conducted by BioNTech, and, as between the Parties, BioNTech shall remain responsible for any payments due to Autolus under this Agreement with respect to activities of any Sublicensees; and

(d) within [***] after the execution of any sublicense agreement with a Sublicensee, BioNTech shall provide Autolus with a copy of such sublicense agreement, *provided* that BioNTech may redact any terms of such sublicense agreement (i) [***] or (ii) [***].

5.4 **Retention of Rights**. Autolus hereby expressly reserves the right to practice, and to grant licenses under, the [***] Licensed IP outside the scope of the licenses granted to BioNTech pursuant to Section 5.1.

5.5 **No Implied Licenses**. Except as expressly provided in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication, estoppel, or otherwise, under or to any Patents, Know-How, information, or other intellectual property owned or controlled by the other Party. BioNTech shall not, nor shall it permit any of its Affiliates or Sublicensees to, practice any Patents or Know-How licensed to it by Autolus outside the scope of the licenses granted to it under this Agreement, except as permitted under Applicable Law.

5.6 **Scope**. For clarity, subject to the terms of this Agreement (including Section 5.1 and Section 5.2), the licenses granted to BioNTech by Autolus to Exploit [***] Licensed Products extend to BioNTech being able to Exploit [***] Licensed Products in conjunction with BioNTech's own products, product components, or other technologies or Third Party products, product components, or other technologies, in each case, whether through co-formulation, co-packaging, co-administration, or any other use as part of a Combination Product or combination therapy.

5.7 [***]. In the event that [***], BioNTech hereby grants to Autolus a non-exclusive, [***] irrevocable, perpetual license in the Field in the Territory under [***] Binder [***] Patent in the field of [***] only in the Territory solely for Autolus, its Affiliates and Autolus Licensees to Exploit [***] in the field of [***] in the Territory. Any sublicenses shall be in writing and be consistent with the applicable terms and conditions of this Agreement. As used in this Section **Error! Reference source not found.**, "[***]" means [***].

5.8 **Transfer of Know-How**. [***], Autolus shall transfer, disclose and otherwise make available to BioNTech the Initial Tech Transfer Package. If, following such initial transfer BioNTech notifies Autolus, in writing, of any specific (a) [***] Licensed Know-How, (b) [***] Licensed Know-How, (c) Activity Enhancement Licensed Know-How, (d) Safety Switch Licensed Know-How or (e) [***] Licensed Know-How, in Autolus's or its Affiliates' Control, or Autolus identifies such Know How, in each case which has not previously been provided to BioNTech ([***]), then Autolus shall [***] disclose to BioNTech such Know-How. At BioNTech's written request [***], Autolus shall provide reasonable assistance to BioNTech in analyzing and understanding the (i) [***] Licensed Know-How, (ii) [***] Licensed Know-How, (iii) Activity Enhancement Licensed Know-How, (iv) Safety Switch Licensed Know-How, (v) [***] Licensed Know-How, and (vi) Initial Tech Transfer Package, including making relevant personnel available to BioNTech, which may include [***]. Autolus shall, if requested [***], make no fewer than [***] FTEs, who shall be scientific or technical personnel of Autolus, available to BioNTech for [***]. For the avoidance of doubt, [***] the Initial Tech Transfer Package, the [***] Licensed Know-How, [***] Licensed Know-How, Activity Enhancement Licensed Know-How, Safety Switch Licensed Know-How or [***] Licensed Know-How.

5.9 **Development and Commercialization**. BioNTech is responsible for conducting, at its sole expense, the Development and Commercialization of [***] Licensed Products in the Field in the Territory.

5.10 **[***] Licensed Product Diligence**. BioNTech shall use Commercially Reasonable Efforts: to (a) [***], and (b) [***].

5.11 **Reporting Obligations**. BioNTech shall, within [***] after [***] until [***], provide Autolus with a written report summarizing, [***] in respect of the [***] Licensed Binder, the [***] Licensed Binder, and [***] Licensed Products. All information and reports provided to Autolus pursuant to this Section 5.11 shall be deemed the Confidential Information of BioNTech hereunder.

5.12 **Regulatory Matters**.

(a) **Regulatory Filings**. As between the Parties, BioNTech has the sole responsibility for preparing and submitting all Regulatory Filings and all Drug Approval Applications for all [***] Licensed Products in the Field in each country within the Territory. At the request of BioNTech [***], Autolus shall provide such assistance as is [***] for BioNTech to prepare and submit Regulatory Filings for [***] Licensed Products in the Field. BioNTech shall own and maintain all Regulatory Filings and Regulatory Approvals for [***] Licensed Products in the Field. [***], BioNTech shall notify Autolus of [***].

(b) **Adverse Event Reporting**. Within [***], the Parties will discuss whether a pharmacovigilance agreement, governing each Party's respective obligations with respect to adverse event reporting, monitoring, maintenance of safety databases and submissions to Regulatory Authorities and other similar obligations with respect to [***] Licensed Products [***]. If a [***], then within [***], the Parties shall [***]. Such [***]. Notwithstanding any other provisions of this Agreement, if [***], or [***] Licensed Product, or [***], then such Party shall provide the other Party with [***].

(c) **Recalls**. As between the Parties, BioNTech has the sole right to determine whether and how to implement a recall or other market withdrawal of a [***] Licensed Product in the Field in each country within the Territory.

6. TECHNOLOGIES OPTIONS

6.1 **Non-Exclusive License Grant**. Subject to the terms and conditions of this Agreement and during the applicable Technologies Option Period, Autolus hereby grants to BioNTech a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the Technologies Option IP for BioNTech's internal research purposes to evaluate whether BioNTech wishes to exercise a Technologies Option in respect of all or part of the Technologies Option Technology ("**Evaluation**"). For the avoidance of doubt, BioNTech shall conduct the Evaluation solely in relation to (a) Activity Enhancement Licensed Products in the Field (and, with respect to Other AE Licensed Products, solely with respect to a Target that has been pre-cleared pursuant to Section 6.4), (b) [***] Licensed Products in the Field, (c) Safety Switch Licensed Products in the Safety Switch Field, and (d) [***] Licensed Products in the [***] Field. Such license shall commence on the Effective Date and shall expire: (i) in respect to the [***] Option, on the [***] (the "[***] **Option Period**"), (ii) in respect to the [***] Option, on the [***] (the "[***] **Option Period**"), and (iii) in respect to each Module Option, on the [***] (the "**Module Option Period**"). BioNTech shall ensure that any sublicenses of the rights under this Section 6.1 to Third Party Evaluators shall be in writing and be consistent with the applicable terms and conditions of this Agreement. BioNTech shall remain responsible for the performance of all of its Third Party Evaluators to the same extent as if such activities were conducted by BioNTech.

6.2 **Transfer of Technologies Option Technology**.

(a) [***], Autolus shall transfer to BioNTech such of the Technologies Option Technology, and in such quantities, as set out in Schedule 6.2 ("**Transferred Materials**"). BioNTech shall use the Transferred Materials and all Technologies Option Technology solely for the purposes of the Evaluation and for no other purpose. The Transferred Materials and all tangible embodiments of the Technologies Option Technology shall (i) at all times remain solely under the control of BioNTech or one of its Affiliates or Third Party Evaluators, (ii) be used in compliance with Applicable Laws, (iii) not be used by or delivered by BioNTech to or for the benefit of any Third Party, other than a Third Party Evaluator, without the prior written consent of Autolus, and (iv) not be used by BioNTech for any research or testing involving human subjects.

(b) BioNTech, its Affiliates, and its Third Party Evaluators shall not attempt to reverse engineer, design around, deconstruct or in any way determine the structure or composition of the Transferred Materials without the prior written consent of Autolus, but it is acknowledged that as part of the Evaluation, BioNTech may [***]. BioNTech shall [***] and nothing in this Agreement restricts [***]. Autolus shall [***] and nothing in this Agreement restricts [***], unless and until [***]. BioNTech shall [***] in writing, providing [***]. BioNTech [***]. If any [***], neither Party shall be permitted to: (i) [***]; or (ii) [***], in each case (i) and (ii), unless and until a Technologies License Agreement regarding the Technologies Option Technology to which such [***] relates is executed, whereupon the terms of such Technologies License Agreement shall govern the Parties rights to use and Exploit [***].

(c) The Transferred Materials supplied to BioNTech are for experimental use only and are provided "as is" with no warranties of any kind, express or implied, including any warranty of merchantability or fitness for a particular purpose. Save as set forth in Article 15, the Technologies Option Technology supplied to BioNTech are for experimental use only and are provided "as is" with no warranties of any kind, express or implied, including any warranty of merchantability or fitness for a particular purpose. To the extent the Transferred Materials comprise cell lines, [***].

(d) BioNTech shall provide Autolus with [***] updates on [***]. Each such update will be provided [***], and BioNTech shall [***].

(e) When BioNTech has completed the Evaluation, following the expiry of the Technologies Option Period without a Technologies License Agreement having been entered into, BioNTech shall [***] return to Autolus or destroy, at Autolus's instruction, any remaining Transferred Materials and cease all use of the Technologies Option Technology.

6.3 **Options**. Autolus grants to BioNTech, with effect from the Effective Date, the option (which is an exclusive option, solely with respect to (1) the [***] Option, (2) the [***] Option and (3) the option for a Co-Exclusive license in respect of the In Vivo AE Licensed Products), during the Technologies Option Period, to receive, in any combination, one or more of the following licenses, which (i) with respect to the [***] Option is solely exercisable in respect of [***], (ii) with respect to the [***] Option is solely exercisable in respect of [***], and (iii) with respect to each Module Option is exercisable on a Target-by-Target basis in respect of a specified Target, without a cap on the number of times that BioNTech may exercise a Module Option:

(a) (i) an exclusive, payment-bearing, license under the [***] Licensed IP (1) to Develop the [***] Licensed Binder and the [***] Licensed Binder in connection with a [***] Licensed Product, and (2) to Exploit [***] Licensed Products directed to [***], in each case of (1) and (2), in the [***] Field, (ii) a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the [***] Licensed IP to research and Develop (only up to and including [***]) a CAR-T Cell Therapy *provided* that (A) [***], and (B) [***]; *provided further* that [***] and (iii) a non-exclusive license under the [***] Licensed IP to Exploit [***] in conjunction with one or more [***] Licensed Products in the [***] Field (the "[***] **Option**"),

(b) (i) an exclusive, payment-bearing, license under the [***] Licensed IP (1) to Develop the [***] Licensed Binder in connection with a [***] Licensed Product, and (2) to Exploit [***] Licensed Products in the Field, and (ii) a non-exclusive, non-transferable, limited, non-sublicensable (other than to Third Party Evaluators) license under the [***] Licensed IP to research and Develop (only up to and including [***]) a CAR-T Cell Therapy *provided* that (A) [***], and (B) [***]; *provided further* that [***] (the "[***] **Option**"),

(c) a non-exclusive, payment-bearing, license under the Safety Switch Licensed IP to Exploit Safety Switch Licensed Products directed to such specified Target, in the Safety Switch Field (the "**Safety Switch Option**"), and

(d) a Co-Exclusive, payment-bearing license under the Activity Enhancement Licensed IP to Exploit Activity Enhancement Licensed Products that express In Vivo any Activity Enhancement Licensed Technology ("**In Vivo AE Licensed Products**") and are directed to such specified Target in the Field, and

(e) a non-exclusive, payment-bearing license under the Activity Enhancement Licensed IP to Exploit Activity Enhancement Licensed Products that do not express In Vivo any Activity Enhancement Licensed Technology ("**Other AE Licensed Products**") and are directed to such specified Target in the Field, *provided* that such non-exclusive license in relation to a given Target is not effective unless and until such Target has been deemed Available pursuant to the gatekeeping procedure in Section 6.4. For clarity, if a specified Target is not Available then BioNTech may still exercise the Activity Enhancement Option on such Target to practice the Co-Exclusive license granted in relation to In Vivo AE Licensed Products.

The licenses for which BioNTech has an option under this Section 6.3 and that will be granted under the applicable Technologies License Agreement following BioNTech's exercise of a Technologies

Option, if any, may be sublicensed on the terms set forth in Section 2.2 of the applicable Technologies License Agreement.

If BioNTech, its Affiliates or Sublicensees wishes to Exploit any [***] Licensed Product in combination with a CAR-T Cell Therapy that [***] (the "**Autolus [***] CAR-T**"), then prior to [***], BioNTech shall provide Autolus with prior written notice and grants, and shall procure the grant of, to Autolus, for a period of [***] after receipt of such notice, a right of first negotiation to, [***], negotiate and enter into an agreement with BioNTech, its Affiliate or Sublicensee (as applicable) for Autolus or its Affiliate to be BioNTech's partner for such combination therapy, whereby such [***] Licensed Product would be used in combination with such Autolus [***] CAR-T. Prior to or during such [***] period, BioNTech, its Affiliates and Sublicensees shall [***].

If BioNTech, its Affiliates or Sublicensees wishes to Exploit any [***] Licensed Product in combination with a CAR-T Cell Therapy that [***] (the "**Autolus [***] CAR-T**"), then prior to [***], BioNTech shall provide Autolus with prior written notice and grants, and shall procure the grant of, to Autolus, for a period of [***] after receipt of such notice, a right of first negotiation to, [***], negotiate and enter into an agreement with BioNTech, its Affiliate or Sublicensee (as applicable) for Autolus or its Affiliate to be BioNTech's partner for such combination therapy, whereby such [***] Licensed Product would be used in combination with such Autolus [***] CAR-T. Prior to or during such [***] period, BioNTech, its Affiliates and Sublicensees shall [***].

6.4 **Gatekeeping for Other AE Licensed Products**.

(a) **Appointment**. The Parties shall, within [***], appoint a Gatekeeper. The fees and expenses of the Gatekeeper's responsibilities under this Agreement shall be borne by [***]. For the avoidance of doubt, no gatekeeping procedure is required in relation to any Activity Enhancement Licensed Product other than Other AE Licensed Products.

(b) **Nomination of Targets**. If BioNTech wishes to conduct the Evaluation or exercise its Activity Enhancement Option, in each case, for Other AE Licensed Products in relation to a given Target, BioNTech must first clear such Target pursuant to the remainder of this Section 6.4(b). [***], BioNTech may provide Autolus with a written request that Autolus provide the Gatekeeper with a complete, accurate and then-current list of Targets that are not Available ("**Nomination Notice**"). Within [***] after BioNTech provides Autolus with such Nomination Notice, (i) Autolus shall provide the Gatekeeper with a complete, accurate and then-current list of Targets that are not Available and (ii) BioNTech shall provide the Gatekeeper with a list of [***] Targets that BioNTech wishes to nominate as a Target for which BioNTech may commence its Evaluation or exercise its Activity Enhancement Option, in each case, for Other AE Licensed Products directed to such specified Target (each a "**Nominated Target**"). To identify a Target as a Nominated Target, BioNTech shall provide the Gatekeeper with a confidential written description of each Nominated Target, including the name, aliases, and UniProt/SwissProt database identifier for such Nominated Target. Within [***] following Gatekeeper's receipt of both Autolus's list of Targets that are not Available and BioNTech's list of Nominated Targets, the Gatekeeper shall notify BioNTech in writing whether or not each Nominated Target is Available (as defined below) (an "**Availability Notice**"). The Parties hereby acknowledge and agree that a Nominated Target shall be "**Available**" unless [***]. Within [***] after BioNTech's receipt of an Availability Notice, BioNTech may (A) [***], (B) [***], or (C) [***]. The Gatekeeper shall not disclose the identity of a Nominated Target to Autolus unless it is designated as a Reserved Target or the identity of any Targets that Autolus has provided to the Gatekeeper unless it is a Nominated Target. For clarity, [***].

(c) **Reserved Targets**. If BioNTech desires to reserve an Available Nominated Target, then BioNTech shall notify both Autolus and the Gatekeeper in writing of the identity of such

Nominated Target within [***] after BioNTech's receipt of an Availability Notice, including the name, aliases, and UniProt/SwissProt database identifier for such Nominated Target (a "**Reserved Target**"). Autolus shall not enter into an agreement with a Third Party for Other AE Licensed Products directed to such Reserved Target if such agreement would prejudice BioNTech's option rights to such Reserved Target until the end of the Module Option Period. For clarity, [***]. During the Module Option Period, BioNTech may designate [***], and may [***]. For clarity, [***].

(d) **Restricted Targets**. Autolus may notify the Gatekeeper in writing of the identity of [***] Targets within [***] following the appointment of the Gatekeeper, including the name, aliases, and UniProt/SwissProt database identifier for such Target (each a "**Restricted Target**"). [***] during the Module Option Period, Autolus may provide the Gatekeeper with a confidential written description of any Targets that it wishes to substitute for any existing Restricted Targets, including the name, aliases, and UniProt/SwissProt database identifier for such Target (each a "**Nominated Restricted Target**"), and identify which of the existing Restricted Targets that it wishes to substitute for each Nominated Restricted Target (a "**Substitutability Notice**"). Within [***] following the Gatekeeper's receipt of Autolus's list of Nominated Restricted Targets, the Gatekeeper shall notify Autolus in writing whether or not each Nominated Restricted Target is Substitutable (as defined below). The Parties hereby acknowledge and agree that a Nominated Restricted Target shall be "**Substitutable**" unless such Target (i) [***], or (ii) [***]. On notification to Autolus that a Nominated Restricted Target is Substitutable, the Gatekeeper shall replace the previously Restricted Target indicated in the applicable Substitutability Notice.

6.5 **Option Exercise**. BioNTech may notify Autolus in writing that it wishes to exercise any of the Technologies Options, identifying (a) precisely which Technologies Option Technology such Technologies Option will be exercised in relation to, including, where applicable, the relevant regulatable control module of the Safety Switch Licensed Technology, and module of the Activity Enhancement Licensed Technology, and (b) the identity of the applicable Target (which with respect to the [***] Option will be [***], and with respect to the [***] Option, will be [***]) ("**Technologies Option Exercise Notice**"). For clarity, with respect to any Activity Enhancement Option, with respect to an Other AE Licensed Product, such Target must either have been identified as being Available under Section 6.4(b) within the [***] prior to the date of delivery of such Technologies Option Exercise Notice or be a Reserved Target under Section 6.4(c). On receipt of such Technologies Option Exercise Notice, [***] shall, within [***], prepare the license agreement reflecting the details set out in such Technologies Option Exercise Notice, which shall be in the form set out in Schedule 6.5 ("**Technologies License Agreement**"). The Parties shall [***] execute the Technologies License Agreement after it has been finalized, and the Technologies Option Exercise Fee for the applicable Technology Option shall be paid in accordance with Section 6.6. BioNTech may exercise any Technologies Option on one or more occasions during the applicable Technologies Option Period. For the avoidance of doubt, [***] only one Technologies Option Exercise Fee will have to be paid for each such [***].

6.6 **Option Exercise Fee**. [***], Autolus shall submit to BioNTech an invoice for the applicable Technologies Option exercise fee (if any) set out in the below table ("**Technologies Option Exercise Fee**"), *provided* that, if a particular Technologies Option is exercised in respect of [***] of the [***] Option, [***] Option, any Safety Switch Licensed Technology module, and any Activity Enhancement Licensed Technology module in respect of the same Target, then the applicable Technologies Option Exercise Fee shall be [***]: (a) [***], and (b) [***] (the "**Technologies Option Exercise Fee Cap**").

	Activity Enhancement Option (per module)	Safety Switch Option (per regulatable control module)	[***] Option	[***] Option
Technologies Option Exercise Fee	[***]	[***]	[***]	[***]

[***].

6.7 **Failure to Exercise Technologies Option**.

(a) **[***]**. On expiry of the [***] Option Period, the [***] Option shall expire without any further action required on the part of either Party, and Autolus will have no further obligations to BioNTech under this Article 6 with respect to [***] and, except to the extent it would conflict with the terms of any Technologies License Agreement, Autolus, at its sole discretion, may negotiate with any Third Party a transaction, including an exclusive license, in respect of the [***] Licensed IP, and all rights relating thereto, without reference to BioNTech. BioNTech shall [***] destroy any data, results, and information generated by it pursuant to the Evaluation with respect to the expired [***] Option, other than data, results, and information pertaining to [***].

(b) **[***]**. On expiry of the [***] Option Period, the [***] Option shall expire without any further action required on the part of either Party, and Autolus will have no further obligations to BioNTech under this Article 6 with respect to [***] and, except to the extent it would conflict with the terms of any Technologies License Agreement, Autolus, at its sole discretion, may negotiate with any Third Party a transaction, including an exclusive license, in respect of the [***] Licensed IP, and all rights relating thereto, without reference to BioNTech. BioNTech shall [***] destroy any data, results, and information generated by it pursuant to the Evaluation with respect to the expired [***] Option, other than data, results, and information pertaining to [***].

(c) **Module**. On expiry of the Module Option Period, each Module Option shall expire without any further action required on the part of either Party, and Autolus will have no further obligations to BioNTech under this Article 6 with respect to the Activity Enhancement Licensed Technology and the Safety Switch Licensed Technology and, except to the extent it would conflict with the terms of any Technologies License Agreement, Autolus, at its sole discretion, may negotiate with any Third Party a transaction, including an exclusive license, in respect of the Activity Enhancement Licensed IP and Safety Switch Licensed IP, and all rights relating thereto, without reference to BioNTech. BioNTech shall [***] destroy any data, results, and information generated by it pursuant to the Evaluation with respect to the expired Module Option, other than data, results, and information pertaining to [***].

7. OBE-CEL PRODUCT

7.1 **Reporting Obligations**.

(a) Autolus shall, within [***], and on [***] thereafter, until [***], provide BioNTech with a written report [***], Development activities conducted during [***] in respect of the Obe-cel Product for all Indications other than [***]. All information and reports provided to BioNTech pursuant to this Section 7.1 shall be treated as Confidential Information of Autolus hereunder.

(b) Autolus shall, at the end of [***] following [***], provide BioNTech with [***] of the Commercialization of Obe-cel Product in [***] in such [***], including [***]; *provided*, that upon [***], the reports provided under this Section 7.1(b) will be provided [***] and will be limited to [***]; *provided*, further, [***].

(c) At BioNTech's request, within [***] following BioNTech's receipt of the reports detailed in Section 7.1(a) or Section 7.1(b), the Parties shall meet to discuss the reports and the progress of the activities detailed in such reports, as well as the anticipated activities to be undertaken by Autolus during the forthcoming [***] period.

7.2 **Potential Support** . The Parties may discuss potential commercial support which could be provided by BioNTech in support of the Commercialization of Obe-cel Product. For clarity, unless BioNTech and Autolus subsequently enter into an exclusivity agreement in relation to the Commercialization of Obe-cel Product (which for clarity, neither Party is under an obligation to enter into), Autolus may discuss and conclude agreements with Third Parties for the Commercialization of Obe-cel Product without any obligation to notify BioNTech.

7.3 **Upfront Payment**. As partial consideration for the Obe-cel Revenue Interest, within [***] after the receipt of an invoice issued by Autolus on or after the Effective Date BioNTech shall pay to Autolus the non-refundable, non-creditable sum of Forty Million Dollars ($40,000,000) (the "**Upfront Payment**").

7.4 **Obe-cel Milestones**.

(a) As partial consideration for the rights granted under this Agreement, BioNTech may, at its sole discretion, elect to pay to Autolus the non-refundable, non-creditable milestone payments upon the achievement of each of the following milestone events by the Obe-cel Product (whether by or on behalf of Autolus, its Affiliates or Autolus Licensees). Each milestone will be payable a maximum of once. For clarity, [***]:

Milestone Event	Milestone Payment
[***] ("**Obe-cel Milestone 1**")	[***]
[***] ("**Obe-cel Milestone 2**")	[***]
[***] ("**Obe-cel Milestone 3**")	[***]
Total	**$100,000,000**

(b) **Notice and Payment**. Autolus shall notify BioNTech in writing within [***] after the first achievement of any milestone event set forth in this Section 7.4 by or on behalf of Autolus, its Affiliates or Autolus Licensees. If BioNTech elects to make a milestone payment in respect of the achievement of such milestone event, BioNTech shall notify Autolus within [***] following receipt of Autolus's notification of the first achievement of such milestone event, and Autolus shall send to BioNTech the invoice for the appropriate milestone payment, which shall be paid by BioNTech within [***] of receipt of such invoice. For clarity, [***].

7.5 **Obe-cel Revenue Interest Payments**. As partial consideration for the receipt by Autolus of the Upfront Payment, on a country-by-country basis in the Territory during the Obe-cel Revenue Interest Term in such country, Autolus shall pay to BioNTech an amount equal to [***] of annual Net Sales of Obe-cel Products (the "**Initial Obe-cel Revenue Interest Percentage**"). As consideration for the receipt by Autolus of milestone payments under Section 7.4, the Initial Obe-cel Revenue Interest

Percentage shall be increased as set forth in the table below upon Autolus's receipt of the applicable milestone payment under Section 7.4 (the Initial Obe-cel Revenue Interest Percentage and any Additional Revenue Interest Percentage, collectively the "**Obe-cel Revenue Interest**").

Milestone Event	Additional Revenue Interest Percentage
[***]	[***]
[***]	[***]
[***]	[***]

By way of example, [***].

7.6 **Obe-cel Product Diligence**. Autolus shall use Commercially Reasonable Efforts: to (a) [***], and (b) [***].

8. [***]

8.1 [***] hereby grants [***] a [***] with [***] granting [***] and [***] if [***] intends (a) to [***], or to [***], or (b) to [***] related to [***] ((a) and (b) constituting an **"**[***]**"**) for a period of [***] commencing on the Effective Date (the **"**[***]**"**), subject to and as further set out in Section 8.3. Notwithstanding the foregoing, the rights in this Section 8.1 do not apply to [***]. For clarity, this Section 8.1 remains in full force and effect following [***]. For further clarity, [***].

8.2 [***] shall, within [***] after the Effective Date, deliver to [***], all information and data [***] in relation to the [***]. Upon [***] request, [***] shall deliver to [***] (to the extent such [***]) in the formats such information and data are held by [***] at the time of such request. [***] will provide the JSC with updates on the progress of [***] in relation to [***], every [***] during the [***]. During [***] shall on [***] reasonable request (a) request from [***] in relation to [***] which has not been provided to [***], (b) [***] facilitate access for [***] to the [***], and (c) [***] provide [***]. To the extent that any data to be provided under this Section 8.2 constitutes Personal Data, [***] shall only be obliged to deliver such Personal Data to [***] to the extent to which it can be delivered in compliance with Applicable Data Protection Law. If the current formats are not compatible with the transfer of such information and data to [***] in compliance with Applicable Data Protection Law, then [***] shall use [***] (i) to obtain such information and data in an anonymized or other format that (1) can be transferred to [***] and (2) results in the applicable information and data no longer constituting Personal Data under Applicable Data Protection Law, or (ii) to facilitate an appropriate data transfer agreement under which such data can be provided to [***] in compliance with Applicable Data Protection Law, *provided* that if [***].

8.3 If, during the [***] is contemplating [***], then, prior to [***] (an "[***]"), [***] shall provide [***] with prior written notice and all material information and data relating to [***] then in its possession (to the extent not previously provided pursuant to Section 8.2) and for a period of [***] after receipt of such notice and information, [***] has a [***], and during such [***] would not [***].

8.4 If the Parties [***] may engage [***] with a [***] or enter into [***] with a [***].

9. FINANCIAL PROVISIONS

9.1 **License Payment**. As partial consideration for the rights granted under this Agreement with respect to the [***] Licensed IP and the Technologies Option Technology, within [***] after the receipt of an invoice issued by Autolus on or after the Effective Date BioNTech shall pay to Autolus the non-refundable, non-creditable sum of Ten Million Dollars ($10,000,000).

9.2 **[***] Royalty Payments**.

(a) **Royalty Rate**. In partial consideration of the license granted to BioNTech pursuant to Section 5.1, on a [***] Licensed Product-by-[***] Licensed Product and country-by-country basis, during the applicable [***] Royalty Term for such [***] Licensed Product and such country, BioNTech shall pay to Autolus royalties on Net Sales of such [***] Licensed Product in such country at a rate of [***], as may be increased pursuant to Section 9.2(c) and as may be decreased pursuant to Section 9.2(b) ("[***] **Royalties**").

(b) **Royalty Rate Reductions**.

(i) [***]. For any period during the [***] Royalty Term in which [***] (A) [***], the royalty rate with respect to Net Sales of such [***] Licensed Product for the remainder of the applicable [***] Royalty Term shall be reduced by [***], and (B) [***], the royalty rate with respect to Net Sales of such [***] Licensed Product for the remainder of the applicable [***] Royalty Term shall be reduced by [***]. The Parties [***].

(ii) **Biosimilar Reduction**. On a country-by-country and [***] Licensed Product-by-[***] Licensed Product basis, during the [***] Royalty Term for such [***] Licensed Product in such country, if [***], the [***] of such [***] Licensed Product in such country [***], then, thereafter, the [***] Royalties payable with respect to [***] of such [***] Licensed Product in such country will be reduced by percentage set forth in the following table.

[***]	Royalty Reduction
[***]	[***]
[***]	[***]

(iii) **Third Party Intellectual Property**. If BioNTech or one of its Affiliates obtains a license to [***] owned or otherwise controlled by a Third Party that [***], and [***], then, thereafter, BioNTech may deduct [***] of the [***] paid by BioNTech to the applicable Third Party ([***]) as an offset to the royalties payable by BioNTech to Autolus for the applicable [***] Licensed Product with respect to [***].

(iv) **IRA Reduction**. If a [***] Licensed Product is designated as a "selected drug" by the Secretary of the U.S. Department of Health and Human Services, and BioNTech is required to negotiate a maximum fair price that shall apply to sales of such [***] Licensed Product during the price applicability period as specified in the Inflation Reduction Act, then the royalties payable with respect to all sales of such [***] Licensed Product in the United States shall be reduced by [***].

(v) **Royalty Floor**. Save as provided in [***], when royalties may be reduced to [***], on a [***] Licensed Product-by-[***] Licensed Product and country-by-country basis, in no event

will the aggregate amount of [***] Royalties due to Autolus for such [***] Licensed Product in such country in a Calendar Quarter during the applicable [***] Royalty Term be reduced pursuant to this Section 9.2(b) by more than [***] of the amount that would otherwise be due to Autolus in the absence of such reductions *provided* that BioNTech may carry over and apply any such royalty reductions that are incurred or accrued in a Calendar Quarter and are not deducted in such Calendar Quarter, to any subsequent Calendar Quarters (subject to the floor in this Section 9.2(b)).

(c) **Royalty Rate Increase**. Notwithstanding Section 9.2(a), but subject to Section 9.2(b) if BioNTech, its Affiliates or Sublicensee Commercializes a [***] Licensed Product and, during the applicable [***] Royalty Term for such [***] Licensed Product, Autolus, its Affiliates or Autolus Licensees has obtained or does obtain Regulatory Approval for a product containing a [***] Licensed Binder and/or a [***] Licensed Binder in both the same Indication and in the same country as such [***] Licensed Product ("[***] **Competing Product**"), then, on a [***] Licensed Product-by-[***] Licensed Product basis and country-by-country basis, the royalty rate in respect of such [***] Licensed Product in such Indication in such countries shall be increased to [***] from First Commercial Sale of the [***] Competing Product during any Calendar Quarter in which sales of the [***] Competing Product in such Indication and country are made.

9.3 **[***] Milestone Payments**.

(a) In partial consideration of the rights granted by Autolus to BioNTech hereunder and subject to the terms and conditions set forth in this Agreement, BioNTech shall pay to Autolus on a [***] Licensed Product-by-[***] Licensed Product basis, the non-refundable, non-creditable milestone payments upon the first achievement of each of the following milestone events for each [***] Licensed Product to achieve such milestone event (whether by or on behalf of BioNTech, its Affiliates or Sublicensees). Each milestone will be payable a maximum of once for a given [***] Licensed Product. For clarity, [***]:

Milestone Number	Milestone Event	Milestone Payment
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]
5	[***]	[***]
Total Per [***] Licensed Product		**$32,000,000**

(b) **Notice and Payment**. BioNTech shall notify Autolus in writing within [***] after the first achievement of any milestone event set forth in this Section 9.3 by or on behalf of BioNTech, its Affiliates or Sublicensees. Based on this notice, Autolus shall then issue and send to BioNTech the invoice for the appropriate milestone payment, which shall be paid by BioNTech within [***] of receipt of such invoice.

(c) **Skipped Milestone Event**. If any of the [***] milestones set out in Section 9.3(a) is skipped for any reason, then such skipped milestone shall become payable on the achievement of the next milestone to be achieved, as if both the following milestone and the skipped milestone had been achieved simultaneously, but the [***] milestones are payable only as and when achieved. By way of example, if

[***] is achieved, and then [***] is achieved without [***] having been achieved, then the milestone payments in respect of both [***] and [***] would become payable upon the achievement of [***]. If [***] is achieved before [***] have been achieved, then upon the achievement of [***] each of [***] will be payable to the extent not already paid. However, if [***].

9.4 **Cap on Option Exercise and Milestone Payments**. Notwithstanding the terms of this Article 9 or the terms of any Technologies License Agreement, the total amount payable by BioNTech to Autolus for all milestone payments and Technologies Option Exercise Fees under this Agreement and all Technologies License Agreements shall not exceed [***]. For the avoidance of doubt, this cap does not apply to royalty payments.

9.5 **Existing Third Party Payments**. Autolus is solely responsible for any payments owed to any Third Parties under the Upstream License Agreements and for any payments owed under the Intra-Group License.

10. REPORTS AND PAYMENT TERMS

10.1 **Reports; Timing of Payment and Royalty Statements**.

(a) The Obe-cel Revenue Interest and [***] Royalties shall accrue at the time the payment for the sale of the applicable product is [***]. For each [***] during the Obe-cel Revenue Interest Term and [***] Royalty Term the Paying Party shall send to the Receiving Party within [***] a statement of [***]. Where there are Net Sales of Obe-cel Product or [***] Licensed Product other than [***], the Paying Party shall also provide details of [***]. The Selling Party shall procure that the foregoing information is obtained from any Autolus Licensee with respect to Obe-cel Product or Sublicensee with respect to [***] Product, as applicable. Each Party shall [***] require any Autolus Licensee (in the case of Autolus) and Sublicensee (in the case of BioNTech) to provide such statement within [***] after the end of such [***]. Royalty and revenue interest obligations that have accrued during a particular [***] shall be paid by the applicable Paying Party, on a [***] basis, within [***] after the end of such [***].

(b) BioNTech has no payment obligations to [***], but to enable Autolus to comply with its reporting obligations under [***], with effect on a [***] Licensed Product-by-[***] Licensed Product basis from the First Commercial Sale of such [***] Licensed Product and throughout the remainder of the [***] Royalty Term for such [***] Licensed Product, within [***] following [***], BioNTech shall provide Autolus with a written report showing [***].

10.2 **Mode of Payment and Currency**. All payments hereunder shall be made by deposit of Dollars in the requisite amount to such bank account as the recipient may from time to time designate by written notice to the Paying Party, *provided* that such bank account is located in the European Union, the United Kingdom, or the United States. With respect to sales not denominated in Dollars, the Paying Party shall convert applicable sales in foreign currency into Dollars by using the then-current and reasonable standard exchange rate methodology applied to its external reporting. Based on the resulting sales in Dollars, the Paying Party shall calculate the applicable Obe-cel Revenue Interest or [***] Royalties.

10.3 **Late Payments**. If either Party fails to pay any undisputed payment under this Agreement by the date when such payment is due, then, without limiting any other right or remedy of the other Party, such late payment shall be paid together with interest thereon at an annual rate [***], from the date on which such payment was originally due until the date of payment (*provided*, that, such rate shall not exceed the rate permissible under Applicable Law).

10.4 **Financial Records**. (a) Autolus shall, and shall cause its Affiliates and Autolus Licensees to, keep complete and accurate financial books and records pertaining to the Exploitation of Obe-cel Products, and (b) BioNTech shall, and shall cause its Affiliates and Sublicensees to, keep complete and accurate financial books and records pertaining to the Exploitation of [***] Licensed Products, in each case ((a) and (b)) in sufficient detail to calculate all amounts payable hereunder with respect thereto and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by the Parties and their Affiliates and, Autolus Licensees and Sublicensees (as applicable), until [***] after the end of the Calendar Year to which such books and records pertain.

10.5 **Audit Rights**.

(a) Either Party (the "**Auditing Party**") may, upon written request to the other Party (the "**Audited Party**"), cause an internationally recognized independent accounting firm (which is reasonably acceptable to the Audited Party) (the "**Auditor**") to inspect the relevant records of the Audited Party or its Affiliates to verify the royalties or revenue interest payable by such Audited Party under this Agreement, and the related reports, statements and books of accounts, as applicable; *provided* that, the Auditor may only inspect the relevant books and records of the Audited Party to verify sums payable under this Agreement by the Audited Party with respect to the [***] prior to the [***] in which such inspection request is made. Before beginning its audit, the Auditor will execute an undertaking acceptable to the Audited Party by which the Auditor shall agree to keep confidential all Confidential Information reviewed during such audit. The Auditor will disclose to the Auditing Party only its conclusions regarding any payments owed under this Agreement. On written request by Autolus, following a written request to Autolus by [***] to audit Autolus in accordance with [***], BioNTech shall, [***], provide to Autolus [***], *provided* that the foregoing obligations shall expire [***].

(b) The Audited Party shall make its relevant records available for inspection by such Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from the Auditing Party. The records shall be reviewed solely to verify the accuracy of the Audited Party's payments under this Agreement. The Auditing Party shall not exercise such inspection right more than once in any [***] and not more frequently than once with respect to records covering any specific period of time. The Auditing Party shall hold in strict confidence all Confidential Information received and all Confidential Information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any law, regulation or judicial order.

(c) If the final result of the inspection reveals an undisputed underpayment or overpayment by the Audited Party, then the underpaid or overpaid amount shall be settled [***].

(d) The Auditing Party shall pay for the fees and expenses of the Auditor, except that (i) BioNTech shall pay for such fees with respect to audits initiated by Autolus if BioNTech is found to have underpaid Autolus by more than [***] of the amount that should have been paid for the audited period and (ii) Autolus shall pay for such fees with respect to audits initiated by BioNTech if Autolus is found to have underpaid BioNTech by more than [***] of the amount that should have been paid for the audited period.

10.6 **Taxes**.

(a) **Sales Tax**.

(i) All payments and other consideration under this Agreement are stated exclusive of Sales Tax. If any Sales Tax is chargeable in respect of any supply made by Autolus to

BioNTech pursuant to this Agreement and Autolus, or any Affiliate of it, is required to account for such Sales Tax to a tax authority, BioNTech shall pay to Autolus an amount equal to such Sales Tax in addition to the payment or other consideration in respect of that supply. Such Sales Tax shall be payable at the same time as such payment or other consideration is due or otherwise required to be provided and Autolus, where applicable, shall provide BioNTech with a valid Sales Tax invoice. If any Sales Tax is chargeable in respect of any supply made by BioNTech to Autolus pursuant to this Agreement and BioNTech, or any Affiliate of it, is required to account for such Sales Tax to a tax authority, Autolus shall pay to BioNTech an amount equal to such Sales Tax in addition to the payment or other consideration in respect of that supply. Such Sales Tax shall be payable at the same time as such payment or other consideration is due or otherwise required to be provided and BioNTech, where applicable, shall provide Autolus with a valid Sales Tax invoice.

(ii) Where a Party is required under this Agreement to indemnify, pay or otherwise reimburse an amount in respect of any liability, cost, charge or expense incurred by another Party, the payor shall not be required to indemnify, pay or reimburse any amount in respect of Sales Tax which is recoverable (whether by way or repayment, credit or set off) by the payee (or any Affiliate of it), subject to the payee (or such Affiliate) using [***] to recover such Sales Tax.

(b) **Withholding Tax**.

(i) All sums payable and other consideration provided under this Agreement shall be paid or provided by the Party making the payment or providing the consideration (the "**Paying Party**") without any withholding or deduction for, or on account of, any Taxes, except for taxes that are required to be withheld or deducted by Applicable Law.

(ii) If any deductions or withholdings for or on account of Tax are required to made by Applicable Law in respect of any amounts payable or other consideration provided under this Agreement, the Paying Party shall withhold or deduct an amount equal to any such Tax, account for such Tax to the relevant tax authority within the time required by Applicable Law and provide to the party entitled to receive such amount or other consideration (the "**Receiving Party**") reasonable evidence of the payment of such Tax, including official receipts (where available), and such withheld or deducted Taxes shall be treated for all purposes of this Agreement as having been paid to the Receiving Party.

(iii) The Parties shall, in respect of the payment or other consideration in question (other than any payment of interest), cooperate and take all steps reasonably and lawfully available to them, including completing such procedural formalities as are necessary, to establish the Receiving Party's entitlement to any exemption from, or diminution in the amount of, any relevant deduction or withholding for or on account of Tax and to enable the Paying Party to obtain any necessary authorization to make payment or provide consideration without, or subject to a reduced amount of, deduction or withholding for or on account of Tax (including, in each case and for the avoidance of doubt, in relation to any applicable exemption certificate) and to provide the Receiving Party with such assistance as is reasonably required to obtain a refund of, or credit with respect to, any such Tax required to be deducted or withheld.

(iv) If a Party takes any action (not required by the terms of this Agreement), including any assignment, transfer, sublicense, change of place of incorporation or tax residence, or a change of the place of business or other permanent establishment through which it receives the supplies made under this Agreement or with which the performance of its obligations under this Agreement is effectively connected, which results in an obligation, or increased obligation, to withhold or deduct tax with respect to payments to be made or other consideration to be provided to the other Party pursuant to this Agreement, then [***].

(v) In the event that (i) a withholding tax deduction was omitted, (ii) an exemption certificate of the Receiving Party as required under the German anti-treaty-shopping rules for the Paying Party to abstain from a withholding obligation has become invalid, and (iii) it is detected after a payment to the Receiving Party that a withholding tax deduction should have been made under such rules in respect of such payment, the Paying Party may withhold such amount as ought to have been so withheld from subsequent payments under this Agreement, or the Receiving Party shall reimburse the Paying Party for such amounts [***]. In respect of any such subsequent deduction or reimbursement, any effect resulting from currency conversion is benefit or burden of Receiving Party as taxpayer and not borne by Paying Party. Each of the Paying Party and the Receiving Party shall notify the other Party [***] after becoming aware that an exemption certificate (that has reduced or eliminated any obligation to deduct or withhold an amount of, or in respect of, Tax, from any payment under this Agreement) has become invalid.

(vi) The Parties' assessment of currently Applicable Law is that [***].

(c) **Information and Assistance**. Each Party shall, [***] following a request in writing by the other Party [***], provide to that other Party (or any of its Affiliates) such information within its possession and assistance concerning the matters contemplated by this Agreement (including any matters contemplated by any MCSA and any Research and Development Collaboration Agreement referred to in Section 3.2) as the relevant Party may reasonably request in connection with its (or any Affiliate's) tax affairs (including in connection with any claim for research and development tax credits that such Party (or any of its Affiliates) may wish to make).

(d) **Customs**. Autolus shall provide to BioNTech any documents necessary for tax and customs clearance for the Transferred Materials in a format as required and specified by BioNTech. Any shipment of Transferred Materials by Autolus to BioNTech or its Affiliates must be announced [***] in advance at [***]. An invoice for customs purposes showing exact costs per shipped good must be provided. Shipments of Transferred Materials to BioNTech will be made [***] designated by BioNTech. Deviation must be discussed in advance with [***].

11. INTELLECTUAL PROPERTY RIGHTS.

11.1 **Background Intellectual Property**. Except as expressly set forth herein, as between the Parties, each Party is and shall remain the owner of all intellectual property that it owned or otherwise controlled as of the Effective Date or that it develops, licenses, or otherwise acquires thereafter pursuant to activities independent of this Agreement (with respect to each Party, "**Background IP**").

11.2 **Inventions**.

(a) Save as provided in [***], as between the Parties, [***]. Save as provided in Section 11.2(b), [***].

(b) Notwithstanding Section 11.2(a), or any other provision to the contrary set forth in this Agreement, the terms of the MCSA, the Research and Development Collaboration Agreement and any [***], and any [***] shall govern ownership of inventions generated under such agreement.

11.3 **Patent Prosecution and Maintenance of [***] Licensed Patents**.

(a) [***] has the [***] right, but not the obligation, to prepare, file, prosecute and maintain the [***] Licensed Patents, at [***] sole cost and expense. [***] shall keep [***] reasonably informed of all steps with regard to the preparation, filing, prosecution, and maintenance of the [***] Licensed Patents. [***] shall provide [***] with a copy of [***] communications to and from the patent

authorities regarding the [***] Licensed Patents, including drafts of [***] shall consider [***] reasonable comments with respect to such drafts. Without limitation to the generality of the foregoing, [***] shall during the Term:

(i) on a [***] basis, keep [***] informed of [***] with respect to those [***] Licensed Patents that [***] (the "[***] **Licensed Product-Specific Patents**"), and the status of, filing, prosecution and maintenance activities therefor, including providing [***];

(ii) [***], give [***] (1) an opportunity to review and comment (for not less than [***]) on the proposed text of any papers related to the filing of [***] Licensed Product-Specific Patents, and (2) an opportunity to review and comment (for not less than [***]) on the proposed text of any papers related to prosecution of [***] Licensed Product-Specific Patents;

(iii) supply [***] with a copy of each such [***] Licensed Product-Specific Patent application as filed, together with notice of its filing date and serial number; and

(iv) provide copies of any papers, office actions and other [***] correspondence received related to the prosecution of such [***] Licensed Product-Specific Patents within [***] prior to the deadline for taking action with respect thereto.

(b) [***] agrees that, in consultation with [***] and at [***] request, [***] shall (i) prepare, file, prosecute, and maintain the [***] Licensed Patents in a manner that will generate one or more [***] Licensed Product-Specific Patents, and (ii) include any reasonable comments of [***] on all such potential filings of [***] pursuant to clause (i) of this sentence so as to generate a mutually agreeable filing; *provided*, *however*, that [***].

11.4 **Enforcement of [***] Licensed Patents**.

(a) **Notice**. If either Party knows or believes that an infringement, unauthorized use, misappropriation, ownership claim, threatened infringement or other similar activity by a Third Party exists or has occurred with respect to any [***] Licensed Patent, or if a Third Party claims that any [***] Licensed Patent is invalid or unenforceable, then such Party shall notify the other Party and provide it with all details that are known by such Party.

(b) **Right to Bring an Action**. As between the Parties, [***] has the [***] right, but not the obligation, to enforce and defend under its control, at its own expense, the [***] Licensed Patents (including the [***] Licensed Product-Specific Patents) where the putative infringing activity [***] (collectively a "**Competitive Infringement**"). Notwithstanding the foregoing, [***] shall not take any action in respect of any Competitive Infringement that [***], without the express written consent of [***]. [***] has the [***] right, but not the obligation, at its own expense, to enforce any other infringements of the [***] Licensed Patents. [***] also has the right to defend the [***] Licensed Patents where such defense arises outside the context of a Competitive Infringement. If the validity or enforceability of a [***] Licensed Patent is challenged in the course of a Competitive Infringement or any action that [***] is controlling, then [***] shall have the [***] right to control such challenge in accordance with Section 11.6.

(c) **Reasonable Assistance**. Upon request from the other Party, each Party shall provide reasonable assistance to the other Party to prosecute and to settle any enforcement or defense action under the control of the prosecuting Party in accordance with Section 11.4(b), including joining as a party to such action, providing access to relevant documents and other evidence and making its employees available, subject to [***]. If either Party is unable to initiate or prosecute an action without joinder of the other Party, then such Party will join such action voluntarily and will execute and cause its Affiliates to

execute all documents necessary for such Party to initiate litigation under Section 11.4(b). Notwithstanding the foregoing, [***] shall not settle any Competitive Infringement in a manner that [***], without the express written consent of [***].

(d) **Recovery**. Any recovery realized as a result of such litigation described in this Section 11.4 (whether by way of settlement or otherwise) shall [***]. Any remainder after such reimbursement is made shall [***].

11.5 **Infringement Claims by Third Parties**. If the Exploitation of a [***] Licensed Product in the Territory pursuant to this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging patent infringement by [***], then [***] has the [***] right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense, using counsel of its own choice; *provided*, *however*, that the provisions of Section 11.4 shall govern the right of [***] to assert a counterclaim of infringement of any [***] Licensed Patent, and where the validity or enforceability of a [***] Licensed Patent is challenged in the course of such litigation, the provisions of Section 11.6 shall govern the right of [***] to defend such [***] Licensed Patent. [***] shall [***] notify [***] of any such claim, suit, or proceeding where the alleged patent infringement relates to [***], and keep [***] reasonably informed of all material developments in connection with any such claim, suit, or proceeding.

11.6 **Defense of [***] Licensed Patents**. Each Party shall [***] notify the other Party in writing of any alleged or threatened assertion by a Third Party of invalidity or unenforceability of any of the [***] Licensed Patents, in each case in the Territory and of which such Party becomes aware. As between the Parties, [***] shall have the [***] right, but not the obligation, to defend and control the defense of the validity and enforceability of the [***] Licensed Patents, at its sole cost and expense. [***] shall assist and cooperate with [***] as [***] may reasonably request from time to time, at [***] sole cost and expense, in connection with its activities set forth in this Section 11.6, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. Where [***] exercises its right to control the defense of a challenge to the validity or enforceability of a [***] Licensed Patent in the course of a Competitive Infringement action or proceeding pursuant to Section 11.4, or a Third Party infringement action or proceeding pursuant to Section 11.5, the Parties shall fully consult and cooperate as regards the conduct of such action or proceeding. Notwithstanding the foregoing, [***] shall not settle the defense of a challenge to the validity or enforceability of a [***] Licensed Patent in the course of any Competitive Infringement action or proceeding pursuant to Section 11.4, or any Third Party infringement action or proceeding pursuant to Section 11.5, [***] without the express written consent of [***].

11.7 **UPC**. [***] has the [***] right to determine whether to opt in or opt out (and to opt in again) of the Unified Patent Court system with respect to the [***] Licensed Patents, and if requested by [***] shall [***], *provided* that [***].

11.8 **Patent Linkage**. As between the Parties, [***] shall have the [***] right, at its sole cost and expense, to obtain patent term extensions, supplementary protection certificates, and equivalents thereof with respect to any [***] Licensed Patent in any country in the Territory, *provided* that [***] shall [***].

12. CONFIDENTIALITY

12.1 **Duty of Confidence**. Subject to the other provisions of this Article 12, all Confidential Information disclosed by or on behalf of a Party or any of its Affiliates (the "**Disclosing Party**") under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party and its

Affiliates ("**Recipient Party**") during the Term and for a period of [***] thereafter. Notwithstanding the foregoing, (a) [***] and any statement in respect of the Obe-cel Revenue Interest provided under Section 10.1 is the Confidential Information of Autolus, (b) any information and reports delivered under Section 5.11, any notice delivered under Section 9.3(b), any statement in respect of the [***] Royalties provided under Section 10.1, and any [***] is the Confidential Information of BioNTech, and (c) the terms of this Agreement are the Confidential Information of both Parties. The Recipient Party may only use the Confidential Information of the Disclosing Party for the purposes set forth in this Agreement. Subject to the other provisions of this Article 12, each Recipient Party shall hold as confidential such Confidential Information of the Disclosing Party or its Affiliates [***].

12.2 **Exceptions**. The obligations under this Article 12 shall not apply to any information to the extent that [***] such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Recipient Party;

(b) was known to, or was otherwise in the possession of, the Recipient Party prior to the time of disclosure by the Disclosing Party;

(c) is disclosed to the Recipient Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party or a Third Party; or

(d) is independently developed by or on behalf of the Recipient Party, [***], without reference to the Confidential Information disclosed by the Disclosing Party under this Agreement.

Any combination of Confidential Information shall not be considered in the public domain or in the possession of the Recipient Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Recipient Party unless the combination and its principles are in the public domain or in the possession of the Recipient Party.

12.3 **Authorized Disclosures**. Each Recipient Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement (including under Section 12.10), or if and to the extent such disclosure is necessary in the following instances:

(a) filing or prosecuting Know-How or Patents without breaching this Agreement;

(b) complying with applicable court orders, Applicable Laws, Applicable Data Protection Law, or the listing rules of any exchange on which such Recipient Party's securities (or the securities of its parent entity) are traded (subject to Section 12.5 with respect to any disclosure of the terms of this Agreement);

(c) in the case of BioNTech as the Recipient Party only, disclosure of such of Autolus's Confidential Information in Regulatory Filings that the Recipient Party has the right to file, or holds;

(d) in the case of BioNTech as the Recipient Party only, disclosure of such of Autolus's Confidential Information to BioNTech's Affiliates, licensees, sublicensees/Sublicensees (through multiple tiers), subcontractors, and other Third Party collaboration partners, and potential licensees, sublicensees/Sublicensees, subcontractors, and other Third Party collaboration partners, *provided*, that [***];

(e) disclosure to a Tax authority in connection with the Tax affairs or a reporting obligation of the Recipient Party;

(f) disclosure to such Recipient Party's directors, employees, [***] who have a need to know such information in order for the Recipient Party to exercise its rights or fulfill its obligations under this Agreement and [***];

(g) disclosure to (i) [***], and (ii) [***], *provided*, in each case, that [***], and *provided*, *further*, that [***]; and

(h) in the case of Autolus as the Recipient Party only, disclosure of (i) [***], and (ii) [***], in each case (i) and (ii) as reasonably required to enable Autolus and its Affiliates to comply with the terms of each Upstream License Agreement.

Notwithstanding the foregoing, and subject to Section 12.5 with respect to any disclosure of the terms of this Agreement, if the Recipient Party is required to disclose Confidential Information of the Disclosing Party in connection with Section 12.3(b), then the Recipient Party shall (i) [***]; (ii) [***]; (iii) [***]; and (iv) [***], *provided* always that nothing in this Section 12.3 shall require the Recipient Party to breach or otherwise violate any applicable court order, Applicable Law, or the listing rules of any exchange on which such Party's securities (or the securities of its parent entity) are traded.

12.4 [***]**.** Nothing in this Agreement shall prevent a Party from [***]. A Party shall [***].

12.5 **Disclosure of Agreement**. Notwithstanding the foregoing, either Party may disclose the relevant terms of this Agreement to the extent required, in the reasonable opinion of such Party's counsel, to comply with the listing rules of any exchange on which such Party's securities (or the securities of its parent entity) are traded, *provided* that such Party shall: (a) [***]; (b) [***]; (c) [***]; and (d) [***], *provided* that [***].

12.6 **Ongoing Obligation for Confidentiality**. Following the expiration or early termination of this Agreement, each Party and its Affiliates shall [***], upon request of the Disclosing Party, return to the other Party or destroy, at [***] election, any Confidential Information of the other Party or any of its Affiliates, *provided* that the other Party may retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations under this Agreement, as required by Applicable Law, or for legal archival purposes, and, *provided further* that upon expiry of the [***] Royalty Term with respect to a given [***] Licensed Product, such [***] Licensed Product and all related [***] Licensed IP shall not be returned or destroyed. Notwithstanding the foregoing, such other Party also may retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose. All such copies of Confidential Information retained or archived as permitted under this Agreement remain subject to the obligations of confidentiality and non-use set out in this Agreement.

12.7 **Use of Name**. Except as expressly permitted in this Agreement, (including in connection with any authorized disclosure under Section 12.3, Section 12.5, Section 12.8 or Section 12.9) neither Party shall use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance, [***]. The restrictions imposed by this Section 12.7 shall not prohibit either Party from making any disclosure identifying the

other Party that, in the reasonable opinion of the disclosing Party's counsel, is required by Applicable Law.

12.8 **Publicity**. Except as expressly permitted under Section 12.3, Section 12.5, Section 12.7, this Section 12.8, or Section 12.9, neither Party shall make any public announcement regarding this Agreement without the prior written consent of the other Party ([***]), except for those disclosures reiterating information for which consent has already been obtained for the relevant purpose, *provided* that [***].

12.9 **Press Release**. Promptly following the Effective Date, the Parties shall issue a mutually agreed joint press release announcing the execution of this Agreement.

12.10 **Publication**.

(a) If BioNTech proposes to make any scientific or other publication or presentation that [***], BioNTech shall provide Autolus with an advance copy of each proposed publication or presentation at least [***] prior to its proposed date of publication or presentation. Autolus will have [***] to review and provide any comments on the proposed publication or presentation and BioNTech shall [***]. BioNTech shall comply with any written request of Autolus (i) to delete Autolus's Confidential Information from such publication or presentation and (ii) withhold publication or presentation for an additional [***] in order to permit Autolus to obtain Patent protection in accordance with the terms of this Agreement. BioNTech shall acknowledge Autolus's contribution and authorship according to customary standards.

(b) Save as permitted under the relevant Technologies License Agreement, BioNTech shall not have the right to make any scientific or other publication or presentation regarding any information BioNTech may generate during the performance of the Evaluation, *provided* that [***].

(c) Autolus may make any scientific or other publication or presentation; *provided* that, such publications or presentations shall not contain any Confidential Information of BioNTech and if Autolus proposes to make any scientific or other publication or presentation that (i) [***], or (ii) [***], Autolus shall provide BioNTech with an advance copy of each proposed publication or presentation at least [***] prior to its proposed date of publication or presentation. BioNTech will have [***] to review and provide any comments on the proposed publication or presentation and Autolus shall [***]. Autolus shall comply with any written request of BioNTech (1) to delete BioNTech's Confidential Information from such publication or presentation and (2) withhold publication or presentation for an additional [***] in order to permit BioNTech to obtain Patent protection in accordance with the terms of this Agreement. Autolus shall acknowledge BioNTech's contribution and authorship according to customary standards.

13. TERM AND TERMINATION

13.1 **Term; Effect of Expiration**.

(a) Notwithstanding any provision to the contrary set forth in this Agreement, (i) this Section 13.1(a), Section 14.3 (Survival), Article 17 (Governing Law and Dispute Resolution), Article 18 (General Provisions), and Article 1 (solely with respect to defined terms used in the foregoing Sections or Articles) will be effective as of the Execution Date, and (ii) all other terms of this Agreement will be automatically effective as of the Effective Date. If the Initial Closing has not occurred within [***] following the Execution Date, [***].

(b) The term of this Agreement will commence upon the Effective Date and expire: (i) with respect to the [***] License, on a [***] Licensed Product-by-[***] Licensed Product and country-

by-country basis until the expiration of the last to expire [***] Royalty Term with respect to such [***] Licensed Product in such country, and finally in its entirety with respect to all [***] Licensed Products in all countries upon expiration of the [***] Royalty Term with respect to the last [***] Licensed Product in the last country in the Territory; (ii) with respect to the Obe-Cel Revenue Interest, upon the expiration of the Obe-cel Revenue Interest Term; and (iii) in its entirety upon the later of clause (i) and (ii) above, in each case, unless earlier terminated as permitted by this Agreement (the "**Term**").

(c) Following the expiration of the [***] Royalty Term with respect to a given [***] Licensed Product and country, the license grant in Section 5.1 for such [***] Licensed Product and country shall automatically become fully paid-up, perpetual, irrevocable and royalty-free.

13.2 **Termination for Material Breach; Insolvency**.

(a) If either Autolus or BioNTech is in material breach of any material obligation hereunder, then the non-breaching Party may give written notice to the breaching Party specifying the claimed particulars of such material breach, and if such material breach is not cured within [***] after the breaching Party's receipt of such notice, or, if such breach (other than with respect to undisputed payments under this Agreement) is not capable of being cured within [***] after the breaching Party's receipt of such notice, the non-breaching Party may terminate this Agreement immediately by giving written notice to the breaching Party to such effect *provided* that if the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party, and such alleged breaching Party provides the other Party notice of such dispute within [***], then the other Party shall not have the right to terminate this Agreement under this Section 13.2(a) unless and until the dispute resolution process in accordance with Section 17.2, has determined that the alleged breaching Party has materially breached a material obligation under the Agreement and such Party has failed to cure such breach within [***] following such decision.

(b) Autolus may terminate this Agreement on [***] written notice if BioNTech fails to pay Autolus the Upfront Payment when due and such failure to pay is not cured within such [***] period.

(c) Either Autolus or BioNTech may terminate this Agreement on written notice if an Insolvency Event occurs in relation to the other Party.

13.3 **Termination by BioNTech Without Cause**. BioNTech may terminate this Agreement on a [***] Licensed Product-by-[***] Licensed Product basis or in its entirety (a) on [***] prior written notice to Autolus if the First Commercial Sale of a [***] Product has not occurred or (b) on [***] prior written notice to Autolus if the First Commercial Sale of a [***] Product has occurred.

14. EFFECTS OF TERMINATION.

14.1 **Upon Termination**. Upon termination, but not expiry, of this Agreement:

(a) All licenses granted to BioNTech in respect of the [***] Licensed IP under Section 5.1 terminate; *provided* that upon termination of this Agreement for any reason, upon the request of any Sublicensee of BioNTech who is not then in breach of its sublicense agreement or the terms and conditions of this Agreement applicable to such Sublicensee, Autolus will enter into a direct license to such Sublicensee on the same terms as the relevant terms of this Agreement, taking into account any difference in license scope, territory and duration of sublicense grant;

(b) To the extent not prohibited by Applicable Law, BioNTech shall wind down any ongoing Clinical Trials with respect to any [***] Licensed Product in a manner and on a timeline reasonably determined by BioNTech and, in each case, consistent with BioNTech's ethical obligations;

(c) If applicable, BioNTech and its Affiliates and Sublicensees shall be entitled, during the [***] period following such termination, to sell any commercial inventory of such [***] Licensed Product which remains on hand as of the date of the termination, including any further Commercialization activities in connection with the same, and to continue the Manufacture of in-progress [***] Licensed Product, so long as BioNTech pays to Autolus the royalties applicable to such subsequent sales in accordance with the terms and conditions set forth in this Agreement;

(d) Each Receiving Party shall return or destroy all Confidential Information of the Disclosing Party to the extent requested pursuant to Section 12.6; and

(e) Solely if such termination was by Autolus pursuant to Section 13.2(b), the Obe-cel Revenue Interest payments set out in Section 7.5 shall terminate as of the effective date of termination.

14.2 **BioNTech's Options**. Upon termination of this Agreement, to the extent that any MCSA Negotiation Period, Product Option Period, or Technologies Option Period have not expired, such periods shall expire with effect from the effective date of termination.

14.3 **Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of [***].

15. WARRANTIES AND COVENANTS

15.1 **Warranties by Each Party**. Each Party warrants to the other Party, as of the Effective Date that:

(a) it is an entity duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

(d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained other than any such consents, approvals and authorizations that may be required under Antitrust Laws, including the HSR Act, with respect to any Technologies Option, other option exercise or any other collaboration contemplated by this Agreement (including the MCSA and the Research and Development Collaboration Agreement); and

(e) the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby do not: (i) conflict with or result in a breach of any provision of its

organizational documents; (ii) result in a breach of any other agreement to which it is a party; or (iii) violate any Applicable Law.

15.2 **Warranties by Autolus**

Except as disclosed in Schedule 15.2, Autolus warrants to BioNTech, as of the Effective Date that:

(a) Except for those rights licensed to Autolus under the Upstream License Agreements, Autolus is the sole and exclusive owner of all of the Autolus IP and the Autolus IP is free from encumbrances;

(b) Autolus has the right to grant to BioNTech the rights that Autolus purports to grant BioNTech hereunder, including the right to grant: the Product Options; exclusive licenses under the [***] Licensed IP, [***] Licensed IP and [***] Licensed IP; co-exclusive and non-exclusive licenses under the Activity Enhancement Licensed IP; non-exclusive licenses under the Safety Switch Licensed IP and non-exclusive internal research license under the Technologies Option IP to conduct the Evaluation, in each case subject to, and as further set out in, the terms of this Agreement;

(c) Autolus has, prior to the Effective Date, obtained and provided BioNTech with true, accurate and complete copies of, all relevant consents and waivers from Third Parties, including [***] that enable Autolus to grant, as of the Effective Date (with regards to the [***] License and Obe-cel Revenue Interest and the non-exclusive internal research license under the Technologies Option IP to conduct the Evaluation) or anytime immediately after the Effective Date (with regards to each of the options within the Product Option and Technologies Option), the rights to BioNTech that are contemplated under this Agreement without any further action required to be taken;

(d) to Autolus's Knowledge, the Development, Manufacture and Commercialization of the [***], the Obe-cel Products, the Autolus Products, and the Option Products does not violate any license and does not infringe or misappropriate any intellectual property rights of any Third Party;

(e) Autolus and its Affiliates have conducted, and to Autolus's Knowledge, their respective consultants and subcontractors have conducted, all research, Development, Manufacture, and other Exploitation of the [***], the Obe-cel Products, the Autolus Products, and the Option Products in material compliance with all Applicable Law;

(f) other than the Upstream License Agreements, there are no agreements or other arrangements to which Autolus or any of its Affiliates is a party relating to the Autolus IP that materially restrict (i) BioNTech's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize [***] Licensed Products or (ii) Autolus's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize the Autolus Products, the Obe-Cel Products or the Option Products;

(g) neither Autolus nor any of its Affiliates are delinquent in any payment obligations to any Third Party, or engaged in any dispute with any Third Party, in each case, that, to Autolus's Knowledge, would limit (i) BioNTech's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize [***] Licensed Products or (ii) Autolus's ability to research, Develop, Manufacture, use, import, offer for sale, sell, have sold and otherwise Commercialize the Obe-cel Product, the Autolus Products, or the Option Products;

(h) no claims, challenges, oppositions, nullity actions, interferences, inter-partes reexaminations, inter-partes reviews, post-grant reviews, derivation proceedings or other proceedings are

pending or, to Autolus's Knowledge, have been threatened: (i) as to the Autolus Patents, including any seeking to invalidate or otherwise challenge the Autolus Patents; or (ii) asserting that Autolus is infringing or has misappropriated or otherwise is violating any Patent right, trade secret, or other proprietary right of any Third Party as would reasonably be expected to impair the ability of Autolus to fulfil any of its obligations or BioNTech to exercise any of its rights under this Agreement;

(i) to Autolus's Knowledge, no Third Party is infringing, misappropriating, or otherwise violating, or threatening to infringe, misappropriate or otherwise violate, the Autolus IP;

(j) the inventions claimed, covered or encompassed by the Autolus IP (i) were not conceived, discovered, developed, invented, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States (or any agency thereof) or the government of any other country, (ii) are not a "subject invention" as that term is described in 35 U.S.C. § 201(e), (iii) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, codified at 35 U.S.C. §§ 200-212, or any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401, (iv) in the case of clauses (ii) or (iii), are not subject to similar obligations or restrictions under the Applicable Law of any other country, and (v) are not the subject of any licenses, options or other rights of any Governmental Authority, within or outside the United States;

(k) Schedule 15.2(k) contains all Autolus Patents that are Controlled by Autolus as of the Effective Date;

(l) all issued Autolus Patents are subsisting, and to Autolus's Knowledge, are not invalid or unenforceable, in whole or in part;

(m) to Autolus's Knowledge, (i) the Autolus Patents are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law, (ii) Autolus has not taken any action that would render any invention claimed in the Autolus Patents unpatentable, and (iii) the Autolus Patents have been filed and maintained properly and correctly, and all necessary ownership and priority right assignments from named inventors to Autolus have been procured and timely filed and recorded with appropriate patent offices;

(n) all required application, registration, maintenance, other related fees and renewal fees in respect of the Autolus Patents have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of obtaining or maintaining the Autolus Patents;

(o) all current and former officers, employees, agents, advisors, consultants, contractors or other representatives of Autolus or any of its Affiliates who are inventors of or have otherwise contributed in a material manner to the creation or development of any Autolus IP have, where Applicable Law does not automatically vest such individual's rights in Autolus, executed and delivered to Autolus or any such Affiliate a valid and enforceable written assignment or other agreement regarding the protection of proprietary information and the assignment to Autolus of any Autolus IP;

(p) to Autolus's Knowledge, no Person who claims to be an inventor of an invention claimed in an Autolus Patent is not identified as an inventor of such invention in the filed patent documents for such Autolus Patent;

(q) to Autolus's Knowledge, no dispute regarding inventorship, authorship, or ownership has been alleged or threatened with respect to any Autolus IP;

(r) Autolus and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Autolus Know-How that constitutes trade secrets under Applicable Law, including by requiring all employees, consultants and subcontractors to execute binding and enforceable agreements requiring all such employees, consultants and subcontractors to maintain the confidentiality of all such Know-How;

(s) there are no claims, judgements, settlements, litigations, suits, actions, disputes, arbitration, judicial or legal, administrative or other proceedings, or governmental investigations pending or, to Autolus's Knowledge, threatened against Autolus or any of its Affiliates that could reasonably be expected to adversely affect or restrict the ability of Autolus to consummate or perform the transactions and obligations contemplated under this Agreement, or that would affect the Autolus IP, Autolus's Control thereof, or the [***] Licensed Products, the Autolus Products, the Obe-Cel Products, or the Option Products;

(t) Autolus is not in material breach of or material default under the Upstream License Agreements and has not taken or failed to take any action that with or without notice, lapse of time or both would constitute a material breach of or material default under the Upstream License Agreements;

(u) the Upstream License Agreements, to Autolus's Knowledge, are valid, binding, enforceable, and in full force and effect, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity);

(v) Autolus has received no written notice regarding any material violation, breach, or default under the any Upstream License Agreements;

(w) Autolus has not waived any rights under any Upstream License Agreements in a manner that would adversely affect in any material respect BioNTech's rights hereunder;

(x) the Upstream License Agreements are the only agreements under which Autolus receives rights under the Autolus IP, and Autolus has provided BioNTech with true, complete, and correct copies of each such Upstream License Agreement; and

(y) [***] has, as required by [***], consented to [***] under this Agreement.

15.3 **Warranties by BioNTech**. BioNTech warrants to Autolus, as of the Effective Date that neither it, nor its Affiliates, develops, sells or manufactures tobacco products or makes the majority of its profits from the importation, marketing, sale or disposal of tobacco products.

15.4 **Covenants**.

(a) Each Party hereby covenants that it shall not employ or use the services of any Person who is debarred under the United States Federal Food, Drug and Cosmetic Act or comparable laws in any other country or jurisdiction, in connection with the Exploitation of [***] Licensed Products (in the case of BioNTech) or the Exploitation of Obe-cel Products and Option Products (in the case of Autolus). If a Party becomes aware of the debarment or threatened debarment of any Person providing services to such Party (including the Party itself and its Affiliates, and any Autolus Licensees and Sublicensees (as applicable)) that directly or indirectly relate to activities under this Agreement, such Party shall [***] notify the other Party in writing.

(b) Autolus hereby covenants it shall not (1) [***], and (2) [***], unless [***]:

(i) breach its obligations under any Upstream License Agreement in any way that results in, or would reasonably be expected to result in, the termination of such Upstream License Agreement;

(ii) modify or amend any Upstream License Agreement in any way that would adversely affect BioNTech's rights hereunder in any material respect, without BioNTech's prior written consent, [***]. Following any modification or amendment to an Upstream License Agreement, Autolus shall provide BioNTech with a copy of the applicable modification to or amendment of the applicable Upstream License Agreement, [***];

(iii) terminate any Upstream License Agreement in whole or in part without BioNTech's prior written consent, [***]; and

(iv) within [***] after Autolus's knowledge thereof, provide BioNTech with notice of and information relating to any alleged or suspected breach or default by Autolus or the other party(s) to the Upstream License Agreements that would adversely affect in any material respect Autolus or BioNTech or its rights hereunder and, following BioNTech's request, reasonably consult with BioNTech before taking any action in relation to such alleged or suspected breach or default.

(c) Each Party hereby covenants that it shall not, and shall not permit its Affiliates, Autolus Licensees (in the case of Autolus) or Sublicensees (in the case of BioNTech) or anyone acting on its or their behalf under this Agreement to grant or otherwise convey to any Third Party any rights that would be inconsistent with the other Party's rights hereunder.

(d) Neither Autolus nor its Affiliates shall grant any option, right or license to any Third Party under the Autolus IP in a manner that conflicts with any of the rights or licenses granted to BioNTech, or any obligations of Autolus, hereunder.

(e) If Autolus receives notice of an alleged payment default by Autolus or its Affiliates under any Upstream License Agreement that Autolus does not cure within [***], Autolus hereby grants to BioNTech the right (but not the obligation) to: (i) [***]; and (ii) [***]. The foregoing shall not preclude any other right or action that BioNTech may have against Autolus for such breach of Section 15.4(b)(iv).

(f) If Autolus has not obtained and provided to BioNTech prior to the Effective Date: (i) [***]; and (ii) [***], in each case ((i) and (ii)), then Autolus will [***]. In each case, [***].

15.5 **No Other Warranties**. Except as expressly stated in this Article 15: (a) no representation, condition or warranty whatsoever is made or given by or on behalf of BioNTech or Autolus; and (b) all other conditions and warranties, whether arising by operation of law or otherwise, are hereby expressly excluded, including any conditions and warranties of merchantability, fitness for a particular purpose or non-infringement.

15.6 **Upstream Obligations**. Notwithstanding anything to the contrary in this Agreement, the licenses and rights granted hereunder are subject to those terms of the Upstream License Agreements that are set out in Schedule 15.6, and BioNTech will, and will procure that its Affiliates, Subcontractors and Sublicensees will, comply with such terms set forth in Schedule 15.6 to the extent applicable. Subject to the foregoing, and without limitation to any remedy that may be available to Autolus, if [***], then [***].

15.7 **Compliance**.

(a) **Compliance with Anti-Corruption Laws**. In connection with this Agreement, the Parties shall comply with all applicable local, national, and international laws, regulations, and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977, as amended ("**FCPA**"), the UK Bribery Act 2010, as amended, any laws enacted to implement the Organisation of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and any other applicable equivalent laws. Without limiting the foregoing, in performing its obligations under this Agreement, neither Party shall, directly or indirectly, pay any money to, or offer or give anything of value to, any Government Official, in order to obtain or retain business or to secure any commercial or financial advantage for any Party, including the other Party or for itself or any of their respective Affiliates or Autolus Licensees or Sublicensees (as applicable).

(b) **Prohibited Conduct**. Without limiting the other obligations of the Parties set forth in this Section 15.7, each Party covenants to the other that, as of the Effective Date and in the performance of its obligations under this Agreement through the expiration or termination of this Agreement, such Party and, to its knowledge, its Affiliates and its and its Affiliates' employees and contractors, in connection with the performance of their respective obligations under this Agreement, have not made, offered, given, promised to give, or authorized, and shall not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly through Third Parties, to any Government Official for the purpose of (i) improperly influencing any act or decision of the Government Official, (ii) inducing the Government Official to do or omit to do an act in violation of a lawful or otherwise required duty, (iii) securing any improper advantage, or (iv) inducing the Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist any Party in obtaining or retaining business. If, during the Term of this Agreement, either Party becomes aware that any Person acting on that Party's behalf has engaged in any prohibited conduct pursuant to this Section 15.7(b) related to the performance of such Party's obligations under this Agreement, then such Party will [***]; *provided* that, [***].

(c) **Compliance with Export Control and Sanctions Laws**. In connection with this Agreement, (i) the Parties shall comply with all applicable local, national, and international laws, and regulations regarding export controls, economic sanctions, trade embargoes, and anti-boycott matters including sanctions regulations administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"), and the Office of Financial Sanctions Implementation in the United Kingdom, and (ii) except as permitted by applicable government license or authorization, each Party shall not engage in any direct or indirect transactions or dealings with (including export, reexport, or transfer of any items to) (1) any country or territory that is subject to an embargo by the U.S. government, European Union or the United Kingdom, or (2) any Person identified on, or fifty percent (50%) or more owned (individually or in the aggregate) by Persons identified on, any list of designated or prohibited parties maintained by the United States, the European Union or the United Kingdom or other applicable jurisdictions (including the List of Specially Designated Nationals and Blocked Persons, the Foreign Sanctions Evaders List, and the Sectoral Sanctions Identifications List, which are maintained by OFAC, and the Entity List, Denied Persons List, and Unverified List, which are maintained by the Bureau of Industry and Security of the U.S. Commerce Department).

(d) **Compliance with Data Protection Laws**. In connection with this Agreement the Parties are independent Data Controllers (as defined in the EU GDPR and UK GDPR) in respect of the Personal Data provided by Autolus to BioNTech (the "**Shared Personal Data**") and shall disclose, make available, transfer, store, use and process the Shared Personal Data in accordance with Applicable Data Protection Law. Without limiting the obligations of the Parties set forth in Applicable Data Protection Law, each Party covenants to the other that it shall: (i) provide such assistance to the other Party as is reasonably required to enable the other Party to comply with requests by patients to exercise their rights under, and

within the time limits imposed by, Applicable Data Protection Law; (ii) have in place throughout the term of this Agreement appropriate technical and organizational security measures to prevent the unauthorized or unlawful processing of the Shared Personal Data and the accidental loss or destruction of, or damage to, the Shared Personal Data, and to ensure a level of security appropriate to the harm that might result from such unauthorized or unlawful processing or accidental loss, destruction or damage and the nature of the Shared Personal Data to be protected; (iii) ensure that any transfer of the Shared Personal Data other than to the United Kingdom or within the European Economic Area is either to a country approved under the EU GDPR or UK GDPR as providing adequate protection, or that there are appropriate safeguards or binding corporate rules in place pursuant to the EU GDPR or UK GDPR, or one of the derogations for specific situations in the EU GDPR or UK GDPR applies to the transfer; and (iv) inform the other Party of any Personal Data Breach (as defined in the EU GDPR and UK GDPR) irrespective of whether there is a requirement to notify any applicable data protection authority or patients.

15.8 **Compliance with Applicable Laws**. (a) Autolus and BioNTech shall coordinate and cooperate fully with each other in mutually determining whether any filings or submissions pursuant to Antitrust Laws or Foreign Investment Laws in connection with the transactions contemplated hereby would be necessary, (b) if BioNTech determines that any such filings or submissions, including HSR Filings, are required with respect to BioNTech's exercise of any Technologies Option, other option exercise, or any other collaboration contemplated by this Agreement (including but not limited to the MCSA and Research and Development Collaboration Agreement), then the Parties shall cooperate to make an HSR Filing within [***] (unless otherwise agreed to in writing by counsel for the Parties), and any other filings or submissions under other Antitrust Laws or Foreign Investment Laws [***], and (c) any information required to be provided under this Agreement by one Party to the other or to the JSC shall be subject to applicable Antitrust Laws relating to the exchange of competitively sensitive information. The Parties shall cooperate with one another to the extent necessary in the preparation of any such filings or submissions, shall consult and cooperate with each other in connection with obtaining HSR Clearance (if required) and all other required clearances under other Antitrust Laws or Foreign Investment Laws and shall [***] resolve [***] any objections that may be asserted by any applicable Governmental Authority with respect to the transactions notified in any such filings or submissions, including HSR Filings. Each Party shall be responsible for its own costs and expenses associated with any such filings. [***] shall be responsible for the filing fees associated with any such filings or submissions under Antitrust Laws or Foreign Investment Laws, including any HSR Filing. Notwithstanding any other terms of this Agreement, (i) if BioNTech, after coordinating and consulting with Autolus, determines that an HSR Filing is required with respect to BioNTech's exercise of any Technologies Option, including the [***] Option or the [***] Option, no option exercise fee shall be payable until after the date of HSR Clearance with respect to the applicable disclosure and (ii) any such option exercise will not be effective prior to receipt of any approvals, non-disapprovals, or expirations or terminations of any applicable waiting period in jurisdictions (if any) where necessary filings or submissions pursuant to Antitrust Laws or Foreign Investment Laws are to be made.

15.9 **Regulatory Efforts.**

(a) **Cooperation for Antitrust/Foreign Investment approvals**. Without limiting the foregoing, neither Autolus nor BioNTech, and none of their Affiliates, without the consent of the other Party, shall enter into any agreement with any Governmental Authority pursuant to which Autolus, BioNTech or any of their respective Affiliates, as applicable, agree not to consummate the transactions contemplated hereunder, withdraw any filing, or authorize the extension of any investigation, for any period of time. Each Party shall (i) notify the other [***] upon the receipt by it or any Affiliates of any communication from any Governmental Authority in connection with the transactions contemplated by this Agreement, (ii) permit the other to review in advance any proposed communication by either Party to any Governmental Authority, (iii) provide copies of all communications received from or provided to any

Governmental Authority in connection with the transactions contemplated by this Agreement; and (iv) provide advance notice of any meeting, whether in person or by telephone or video conference, with any Governmental Authority in connection with the transactions contemplated by this Agreement and, [***], allow the other to attend unless prohibited by such Governmental Authority. Each Party shall, and shall cause their Affiliates to, [***] collaborate in reviewing and commenting on in advance, provide information and providing such assistance as the other may reasonably request in connection with, and to consult the other on, any (proposed) filing, notification or submission made with, or (proposed) communication with, any Governmental Authority in connection with any filing, submission, investigation or inquiry in connection with the transactions contemplated by this Agreement; *provided*, *however*, that (1) a party may designate any competitively sensitive materials provided to the other as "outside counsel only," and such materials and information shall be given only to outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient without the advance written consent of the party providing such materials, and (2) a party may redact such materials to comply with contractual arrangements, and address reasonable attorney-client or other established legal privilege concerns, to the extent they are not governed by a common interest privilege or doctrine.

(b) **Other Conduct Prior to Antitrust/Foreign Investment approvals**. Notwithstanding anything to the contrary in this Agreement, this Section 15.9 and [***] does not require that either Party: (i) offer, negotiate, commit to, or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or businesses of it or any of its Affiliates; (ii) agree to any restrictions on its or its affiliates' business(es); or (iii) pay any amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying the transactions contemplated by this Agreement (collectively, an "**Antitrust Remedy**" or "**Foreign Investment Remedy**"), where such Antitrust Remedy or Foreign Investment Remedy would have a material effect on its ability to operate, exercise control or otherwise enjoy any part of its business(es), including any part of its business transferred or contemplated to be transferred by the transactions contemplated in this Agreement.

(c) **Outside Date for Any Antitrust/Foreign Investment Approvals**. If any filings or submissions, including HSR Filings, are required under Antitrust Laws or Foreign Investment Laws with respect to BioNTech's exercise of any Technologies Option, other option exercise, or any other collaboration contemplated by this Agreement (including but not limited to the MCSA and Research and Development Collaboration Agreement), for each such option or collaboration, the option exercise shall be deemed withdrawn or the collaboration abandoned if such option or collaboration has not become effective on the date that is [***] following the applicable option exercise date or execution of an agreement contemplated hereunder for failure to obtain the necessary approvals, non-disapprovals, or expirations or terminations of any applicable waiting period in jurisdictions where necessary filings or submissions pursuant to Antitrust Laws or Foreign Investment Laws are to be made (the "**Option End Date**"), unless agreed otherwise by the parties; *provided, however*, the rights under this Section 15.9(c) shall not be available to any Party whose breach of this Agreement has been a principal cause of or resulted in the failure of the effectiveness of the option or collaboration to occur on or before the Option End Date.

16. INDEMNIFICATION; LIABILITY

16.1 **Indemnification by Autolus**. Autolus shall indemnify BioNTech, its Affiliates, and their respective officers, directors, and employees (the "**BioNTech Indemnitees**") from and against any and all liabilities, damages, losses, costs, fees, or expenses of any nature (including reasonable attorneys' fees and litigation expenses) ("**Losses**") incurred by or imposed upon the BioNTech Indemnitees or any of them in connection with any Claim to the extent arising or resulting from: (a) Autolus's or any of its Affiliates', (sub)licensees' or contractors' Exploitation of Obe-cel Product (including, for clarity, actual

or alleged infringement of any Third Party's intellectual property); (b) the gross negligence or willful misconduct of Autolus or any Autolus Indemnitee; and (c) the material breach of any provision (including any representation or warranty) of this Agreement by Autolus; *provided*, that Autolus shall not be obliged to so indemnify the BioNTech Indemnitees for any Claims to the extent that BioNTech has an indemnification obligation to an Autolus Indemnitee under Section 16.2.

16.2 **Indemnification by BioNTech**. BioNTech shall indemnify Autolus, its Affiliates, their respective officers, directors, and employees (the "**Autolus Indemnitees**") from and against any and all Losses incurred by or imposed upon the Autolus Indemnitees or any of them in connection with any Claim, in each case, to the extent arising or resulting from: (a) BioNTech's, or any of its Affiliates', Sublicensees' or Subcontractors' Development of a [***] Licensed Binder or a [***] Licensed Binder or Exploitation of [***] Licensed Products; (b) the gross negligence or willful misconduct of BioNTech or any BioNTech Indemnitee; or (c) the material breach of any provision of this Agreement by BioNTech; *provided*, that BioNTech shall not be obliged to so indemnify the Autolus Indemnitees for any Claims to the extent that Autolus has an indemnification obligation to a BioNTech Indemnitee under Section 16.1.

16.3 **Indemnification Procedure; Settlement; Quantification**.

(a) If any of the BioNTech Indemnitees or Autolus Indemnitees (the "**Indemnified Parties**") receives written notice of the commencement of any Claim, and such Indemnified Party intends to seek indemnification pursuant to this Article 16, then the Indemnified Party shall [***] provide BioNTech (if such Indemnified Party is a BioNTech Indemnitee) or Autolus (if such Indemnified Party is a Autolus Indemnitee) written notice of such Claim, and such Party shall provide the other Party (the "**Indemnifying Party**") with written notice of such Claim within [***] of its receipt of notice from the Indemnified Party, stating the nature, basis and the amount thereof, to the extent known, along with copies of the relevant documents evidencing such Claim and the basis for indemnification sought. Failure of the Indemnified Party to give such notice within the time frame specified will not relieve the Indemnifying Party from its indemnification obligations hereunder, except to the extent that the Indemnifying Party is actually and materially prejudiced thereby.

(b) The Indemnifying Party may assume the defense, appeal or settlement proceedings of the Indemnified Party against the Claim with counsel of its choice. The Indemnified Party may retain separate co-counsel at its sole cost and expense and participate in the defense, appeal or settlement proceedings of the Claim, and cooperate, and cause the individual indemnitees to cooperate, with the Indemnifying Party in the defense, settlement or compromise of such Claim.

(c) In no event shall the Indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the Indemnified Parties without the prior written consent of the Indemnified Party. The Indemnified Party and the Indemnifying Party will act in good faith in responding to, defending against, settling or otherwise dealing with Claims. The Indemnified Party and the Indemnifying Party will also cooperate in any such defense, appeal or settlement proceedings, and give each other reasonable access to all information relevant thereto. Whether or not the Indemnifying Party has assumed the defense, appeal or settlement proceedings with respect to a Claim, such Indemnifying Party will not be obligated to indemnify the Indemnified Party for any settlement entered into or any judgment that was consented to without the Indemnifying Party's prior written consent ([***]).

16.4 **Insurance**. Each Party shall maintain, at its own cost, insurance with respect to its activities and obligations under this Agreement in such amounts as are commercially reasonable in the industry for companies conducting similar business and shall require any of its Affiliates undertaking activities under this Agreement to do the same. BioNTech may fulfill the foregoing insurance obligations through self-insurance.

16.5 **Special, Indirect and other Losses**. Except for [***], neither Party nor any of its Affiliates shall be liable in contract, tort, negligence breach of statutory duty or otherwise for any special, indirect, incidental, punitive or consequential damages or for any economic loss or loss of profits suffered by the other Party, regardless of any notice of the possibility of such damages.

16.6 **After-Tax Basis**. All payments made under Section 16.1 and Section 16.2 shall be on an after-tax basis. "After-tax basis" shall mean that the amount payable pursuant to the indemnities given by the Parties under Section 16.1 and Section 16.2 will be calculated in such a manner as will ensure that, after taking into account: (a) the amount of any Tax payable by the Indemnified Party as a result of the payment being subject to Tax in the hands of the Indemnified Party (or would be subject to Tax but for a relief (save for any relief described in (b))); and (b) all reliefs that arise to the Indemnified Party in respect of either that Tax or a matter giving rise to the payment, the Indemnified Party is in the same position as it would have been in if the matter giving rise to the payment had not occurred.

17. GOVERNING LAW AND DISPUTE RESOLUTION

17.1 **Governing Law**. This Agreement is governed by, and will be interpreted in accordance with, the substantive laws of [***] without giving effect to 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 provisions of the United Nations Convention on Contracts for the International Sale of Goods are expressly excluded.

17.2 **Dispute Resolution**. In the event of any disputes, controversies or differences between the Parties, arising out of, in relation to, or in connection with this Agreement, including any alleged breach of this Agreement or any issue relating to the formation, scope, validity, construction, interpretation, enforceability, breach, performance, application, or termination of this Agreement a ("**Dispute**"), then upon the written request of either Party, the Parties agree to a meeting of the appropriate subject matter expert at each Party, and discuss in good faith an amicable resolution thereof. If the Dispute is not resolved within [***] following the written request for amicable resolution, then either Party may then escalate the matter to the [***]. If [***] cannot resolve the Dispute within [***] following escalation thereto for amicable resolution, and a Party wishes to pursue the matter, it may commence litigation. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the courts in [***] for the resolution of all Disputes.

17.3 **Patent Disputes**. As between the Parties, notwithstanding anything herein to the contrary, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent shall [***]. With respect to any Patent issues related to the enforceability or validity of a Patent, [***].

17.4 **Specific Performance**. The Parties agree that irreparable damage may occur if [***] this Agreement was not performed in accordance with the terms thereof and that each Party may seek specific performance of the terms thereof, in addition to any other remedy to which it is entitled at law or in equity. It is therefore agreed that each Party may seek a temporary, preliminary, or permanent injunction or injunctions to prevent breaches of [***] this Agreement, without posting any bond or other undertaking, in addition to any other remedy to which they are entitled at law or in equity, and if any action should be brought in equity to enforce any of the provisions of [***] this Agreement, the other Party shall not raise the defense that there is an adequate remedy at law.

18. GENERAL PROVISIONS

18.1 **Assignment.**

(a) Neither Party may assign or transfer this Agreement or its rights and obligations under this Agreement without [***], except that, and without prejudice to Section 18.1(b) (a) [***] this Agreement or its rights and obligations under this Agreement [***] without [***]; and (b) [***] this Agreement [***] without [***]; *provided* that [***] this Agreement [***] and this Agreement [***]. The assigning Party shall provide the other Party with [***] written notice of any such assignment. Any permitted assignee shall assume all obligations of its assignor under this Agreement ([***]). Any attempted assignment in contravention of the foregoing is void. This Agreement is binding upon and inures to the benefit of the Parties hereto and their respective successors and permitted assigns.

(b) Autolus may:

(i) enter into an Obe-cel Product Transaction at any time, *provided* that [***] in accordance with the terms of the foregoing Section 18.1(a), Autolus shall [***] pursuant to which [***];

(ii) subject to [***], enter into an Option Product or Next Gen Option Product Transaction at any time, *provided* that, [***] in accordance with the terms of the foregoing Section 18.1(a), Autolus shall [***] pursuant to which [***];

(iii) enter into a [***] Transaction at any time, *provided* that, [***] in accordance with the terms of the foregoing Section 18.1(a), Autolus shall [***]; and

(iv) enter into a Technologies Option Transaction at any time, *provided* that, [***] in accordance with the terms of the foregoing Section 18.1(a) [***], Autolus shall [***].

For clarity, [***].

18.2 **Force Majeure**. No Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to a cause beyond the reasonable control of a Party, including acts of God, fires, floods, earthquakes, acts of war, terrorism, or civil unrest, or hurricane or other inclement weather, explosions, embargoes, epidemics, pandemics, quarantines, or any other event similar to those enumerated above ("**Force Majeure**"); *provided*, that the affected Party [***] notifies the other Party, and *provided further* that the affected Party shall [***] avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. Such excuse from liability will be effective only to the extent and duration of the Force Majeure event causing the failure or delay in performance and *provided* that a Party has not caused such events to occur. When such circumstances arise, the Parties shall [***].

18.3 **Extension to Affiliates**. Without prejudice to the provisions of any Section in this Agreement that explicitly refers to a Party's Affiliates, the Parties agree that any Affiliates of a Party may exercise any of the rights granted to such Party in this Agreement or perform any of such Party's obligations in this Agreement *provided* that such Party shall be responsible for the performance of any of its obligations that are performed by its Affiliates.

18.4 **Severability**. Should one (1) or more of the provisions of this Agreement become invalid or unenforceable as a matter of law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will [***] substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.

18.5 **Waivers and Amendments**. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right

or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

18.6 **Relationship of the Parties**. It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party. The Parties (and any successor, assignee, transferee, or Affiliate of a Party) shall not treat or report the relationship between the Parties arising under this Agreement as a partnership for tax purposes, unless required by Applicable Law.

18.7 **Notices**. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); (b) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), or (c) delivered by electronic mail followed by delivery via either of the methods set forth in Section 18.7(a) or Section 18.7(b), in each case, to the appropriate addresses set forth below (or to such other addresses as a Party may designate by notice):

If to Autolus:

Autolus Limited and Autolus Holdings (UK) Limited
The Mediaworks
191 Wood Lane
London
England
W12 7FP
Attn: General Counsel
Email: [***]

with a copy to:

Cooley LLP
11951 Freedom Drive
One Freedom Square
Reston Town Center
Reston, VA 20190-5656
Attn: [***]
Telephone: [***]
Email: [***]

If to BioNTech:

BioNTech SE
An d. Goldgrube 12,
55131 Mainz,
Germany
Attn: [***]
Email: [***]

with a copy to:

[***]
Attn: [***]
Email: [***]

18.8 **Further Assurances**. BioNTech and Autolus each hereby covenant and agree, without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

18.9 **Compliance with Law**. Each Party shall perform its obligations under this Agreement in accordance with all Applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Law.

18.10 **No Third Party Beneficiary Rights**. Except for the rights of Sublicensees under Section 14.1(a), the provisions of this Agreement are for the sole benefit of the Parties and no other Person or entity shall have any right or claim against either Party by reason of these provisions or be entitled to enforce any of these provisions against either Party (including under the Contracts (Rights of Third Parties) Act 1999). The rights of the Parties to amend this Agreement are not subject to the consent of any other Person.

18.11 **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. All notices and other communications given under this Agreement shall be in the English language.

18.12 **Interpretation**. In this Agreement, unless otherwise specified: (a) "includes" and "including" shall mean respectively includes and including without limitation; (b) "hereof," "herein," and "herewith," and words of similar import, shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) "in writing" or "written" includes any mode of reproducing words in a legible and non-transitory form, including emails and faxes, unless another form is prescribed by Applicable Law; (d) "or" is disjunctive but not necessarily exclusive; (e) a Party includes its permitted assignees or the respective successors in title to substantially the whole of its undertaking; (f) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted in accordance with any requirements with respect to such amendment or re-enactment; (g) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders; (h) the Exhibits, Schedules and other attachments

form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits, Schedules and attachments; (i) the headings in this Agreement are for information only and shall not be considered in the interpretation of this Agreement; (j) general words shall not be given a restrictive interpretation by reason of their being preceded or followed by words indicating a particular class of acts, matters or things; (k) the word "any" shall mean "any and all" and (l) "shall" has the same meaning as "will" wherever referenced, and vice versa. The Parties agree that the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement shall not be construed in favor of or against any Party by reason of the extent to which any Party participated in the preparation of this Agreement.

18.13 **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.

18.14 **Entire Agreement**. This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, for clarity, the confidentiality agreement entered into by [***] dated [***]. Each Party acknowledges that in entering into this Agreement it does not rely on, and shall have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement. Each Party agrees that it shall not have any claim for innocent or negligent misrepresentation based on any statement in this Agreement. In the event of any inconsistency between the terms of this Agreement and the pharmacovigilance agreement entered into pursuant to Section 5.12(b) the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relate directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the pharmacovigilance agreement shall prevail and govern.

18.15 **Counterparts**. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures (including .pdf) and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

18.16 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

[***]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

BIONTECH SE

By: /s/ Ryan Richardson

Name: Ryan Richardson

Title: Management Board Member and Chief Strategy Officer

By: /s/ Sierk Poetting

Name: Sierk Poetting

Title: Management Board Member and Chief Operating Officer

AUTOLUS LIMITED

By: /s/ Christian Itin

Name: Christian Itin

Title: Chief Executive Officer

AUTOLUS HOLDINGS (UK) LIMITED

By: /s/ Christian Itin

Name: Christian Itin

Title: Chief Executive Officer

SCHEDULE 1.8

ACTIVITY ENHANCEMENT LICENSED TECHNOLOGY

[***]

SCHEDULE 1.27

AUTO1/22 PRODUCT

[***]

SCHEDULE 1.29

AUTO6NG PRODUCT

[***]

SCHEDULE 1.30

[***] PRODUCT

[***]

SCHEDULE 1.36

BASEBALL ARBITRATION

[***]

SCHEDULE 1.38

[***] LICENSED BINDER

[***]

SCHEDULE 1.60

[***] LICENSED BINDERS

[***]

SCHEDULE 1.61

[***] LICENSED BINDERS

[***]

SCHEDULE 1.152

OBE-CEL PRODUCT

[***]

SCHEDULE 1.191

SAFETY SWITCH

[***]

SCHEDULE 1.227

[***] LICENSED BINDER

[***]

SCHEDULE 1.228

[***] LICENSED BINDER

[***]

SCHEDULE 3.1

MANUFACTURING AND COMMERCIAL SERVICES AGREEMENT TERMS

[***]

SCHEDULE 3.1(B)

PROCESS TIMELINES

[***]

SCHEDULE 4.4(A)

PRODUCT AGREEMENT TERMS

[***]

SCHEDULE 6.2

TRANSFERRED MATERIALS

[***]

SCHEDULE 6.5

FORM TECHNOLOGIES LICENSE AGREEMENT

SCHEDULE 15.2

AUTOLUS DISCLOSURES

[***]

SCHEDULE 15.2(K)

AUTOLUS PATENTS

[***]

SCHEDULE 15.2(K)

AUTOLUS PATENTS

SCHEDULE 15.6

UPSTREAM OBLIGATIONS

[***]

Autolus Therapeutics plc
List of Subsidiaries

Subsidiary	Jurisdiction
Autolus Holdings (UK) Limited	England and Wales
Autolus Limited	England and Wales
Autolus Inc.	Delaware
Autolus GmbH	Germany
Autolus Switzerland AG	Switzerland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-276942) of Autolus Therapeutics plc,
(2) Registration Statement (Form S-8 No. 333-226457) pertaining to the Autolus Limited 2017 Share Option Plan and Autolus Therapeutics plc 2018 Equity Incentive Plan, and
(3) Registration statement (Form F-3 No. 333- 264304) of Autolus Therapeutics plc and in the related Prospectus,
(4) Registration statement (Form F-3 No. 333- 264650) of Autolus Therapeutics plc and in the related Prospectus,
(5) Registration Statement (Form S-8 Nos. 333-273776 and 333-275301) pertaining to the Autolus Therapeutics plc 2018 Equity Incentive Plan;

of our report dated March 21, 2024, with respect to the consolidated financial statements of Autolus Therapeutics plc included in this Annual Report (Form 10-K) of Autolus Therapeutics plc for the year ended December 31, 2023.

/s/ Ernst & Young LLP
Reading, United Kingdom
March 21, 2024

Exhibit 31.1

Certification by the Principal Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Christian Itin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Autolus Therapeutics plc (the "***Company***");

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 Company as of, and for, the periods presented in this report;

4 The Company's other certifying officer(s) 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 Company 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 Company, 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 Company'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 Company's internal control over financial reporting that occurred during the Company'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 Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company'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 Company'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 Company's internal control over financial reporting.

Date: March 21, 2024

/s/ Christian Itin, Ph.D.
Name: Christian Itin, Ph.D.
Title: Chief Executive Officer
(*Principal Executive Officer*)

Certification by the Principal Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert Dolski, certify that:

1. I have reviewed this Annual Report on Form 10-K of Autolus Therapeutics plc (the "***Company***");

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 Company as of, and for, the periods presented in this report;

4 The Company's other certifying officer(s) 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 Company 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 Company, 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 Company'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 Company's internal control over financial reporting that occurred during the Company'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 Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company'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 Company'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 Company's internal control over financial reporting.

Date: March 21, 2024

/s/ Robert Dolski
Name: Robert Dolski
Title: Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Certification by the Principal Executive Officer and Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Christian Itin, Chief Executive Officer of Autolus Therapeutics plc (the "Company"), and Robert Dolski, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

(1) The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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, as amended; and

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

Date: March 21, 2024

/s/ Christian Itin, Ph.D.
Name: Christian Itin, Ph.D.
Title: Chief Executive Officer
(*Principal Executive Officer*)

/s/ Robert Dolski
Name: Robert Dolski
Title: Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 97.1

AUTOLUS THERAPEUTICS PLC

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of Autolus Therapeutics plc, a public limited company incorporated under the laws of England and Wales (the "***Company***"), has determined that it is in the best interests of the Company and its shareholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's financial year in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the relevant securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

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

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company share price and total shareholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed financial years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's financial year) within or immediately following those three completed financial years (except that a transition period of at least nine months shall count as a completed financial year). Notwithstanding the foregoing, the Lookback Period shall not include financial years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax or social security withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on share price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the share price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. RECOUPMENT

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an

Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed. In no event shall the Company be required to award a Covered Officer an additional payment if the restated or accurate financial results would have resulted in a higher Incentive Compensation payment.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards;

(ii) recoupment of the applicable Recoverable Incentive Compensation would violate home country law where that law was adopted prior to November 28, 2022; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recoupment would result in such a violation, and shall provide such opinion to the Exchange in accordance with the Listing Standards; or

(iii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A (if applicable) or any equivalent local laws applicable to the Covered Officer; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation. Notwithstanding the foregoing, the Company makes no guarantee as to the compliance of the recoupment with Code Section 409A (if applicable) or any equivalent local laws applicable to the

Covered Officer) and shall have no liability with respect thereto.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's articles of association or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. ACKNOWLEDGEMENT

To the extent required by the Company under this Policy, each Covered Officer shall be required to sign and return to the Company the acknowledgement form attached hereto pursuant to which such Covered Officer will agree to be bound by the terms of, and comply with, this Policy. For the avoidance of doubt, each Covered Officer will be fully bound by, and must comply with, the Policy, whether or not such Covered Officer has executed and returned such acknowledgment form to the Company.

6. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

7. SEVERABILITY

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

8. NO IMPAIRMENT OF OTHER REMEDIES

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company or any subsidiary thereof from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company or any subsidiary thereof is a party or which the Company or any subsidiary thereof has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

9. AMENDMENT; TERMINATION

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

10. SUCCESSORS

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

11. REQUIRED FILINGS

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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