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

FORM 10-K

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

For the fiscal year ended December 31, 2024

OR

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

for the transition period from _____ to

Commission file number: 001-38547

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, 2024, the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $613,667,644 based on the closing sale price on that date of $3.48 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 19, 2025, there were 266,128,900 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, current reports and registration statements on U.S. domestic issuer forms, the Company intends to 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, AUCATZYL® and our other trademarks or service marks appearing in this Annual Report are our property. Solely for convenience, the trademarks and trade names in this Annual Report we referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. Products or service names of other companies mentioned in this Annual Report may be trademarks, trade names or service marks 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 therapeutic potential and expected clinical benefits of AUCATZYL/obe-cel (obecabtagene autoleucel) for adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia ("r/r B-ALL");
- our ability to generate revenues from AUCATZYL, which is dependent upon maintaining significant market acceptance among physicians, patients and healthcare payors;
- our ability to maintain regulatory approval of AUCATZYL in the United States ("US"), to obtain and maintain regulatory approval for obe-cel for adult r/r B-ALL in additional territories and the timing thereof, and to obtain and maintain regulatory approval of our other 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;
- our expectations regarding the commercialization and marketing of AUCATZYL for adult r/r B-ALL, including expanding into additional territories and the related timing of reaching patients in such territories;
- the development of our commercial product and 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 commercialization, marketing and manufacturing capabilities and strategy for AUCATZYL, including our ability to successfully recruit and retain sales and marketing personnel and to successfully build the market for AUCATZYL;
- our expectations about the willingness of healthcare providers to recommend AUCATZYL to people with adult r/r B-ALL;
- 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 expectations regarding our ability to obtain and maintain intellectual property protection and our ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements;
- our plans to research, develop, manufacture and commercialize our product candidates;
- the potential benefits of our commercial product and product candidates;
- the timing or likelihood of regulatory filings and approvals for our product candidates, along with regulatory developments in the US, European Union ("EU"), the United Kingdom ("U.K.") and other foreign countries;

- the size and growth potential of the markets for our commercial product and product candidates, if approved, and the rate and degree of market acceptance of our commercial product and 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,
- 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 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 macroeconomic events, including inflation, changes in interest rates, changes in trade policies, political changes, unfavorable general market conditions and the impacts of the war in Ukraine, the conflicts involving 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 are an early commercial stage biopharmaceutical company and have incurred significant losses since our inception. We expect to continue to incur losses for the foreseeable future.
- AUCATZYL and any other product candidates, if approved, 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, thereby limiting our potential to generate revenue.
- If we are unable to fully develop our sales, marketing and distribution capability on our own , or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing AUCATZYL, or our other product candidates, if and when approved.
- 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 successfully commercialize AUCATZYL and to complete the development of and commercialize our other product candidates, which may not be available on acceptable terms, if at all.
- 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.
- 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, fluctuations in foreign currency exchange rates, political changes, and changes in trade policies, 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 an early commercial-stage biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer and autoimmune diseases. On November 8, 2024, the U.S. Food and Drug Administration, or FDA, granted marketing approval for our first approved commercial product, AUCATZYL/obe-cel (obecabtagene autoleucel) for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia, or r/r B-ALL. We commercially launched AUCATZYL in the United States in January 2025, and we plan to initiate sales of AUCATZYL/obe-cel in the European Union, or EU, and the United Kingdom, or UK, once regulatory approval is received. Marketing authorization submissions for AUCATZYL/obe-cel were accepted by the European Medicines Agency, or EMA, in April 2024 and the U.K. Medicines and Healthcare products Regulatory Agency, or MHRA, in August 2024, and we expect to receive notification of approval status from these authorities in the second half of 2025.

AUCATZYL 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 chimeric antigen receptor T cell, or CAR T, therapies. Adult r/r/ B- ALL is an extremely aggressive type of blood cancer with a high unmet medical need in the treatment of patients once they relapse, where historically patients suffer from poor outcomes. AUCATZYL is manufactured at our dedicated commercial manufacturing site, the Nucleus, in Stevenage, UK. If we receive approval to commercialize AUCATZYL outside of the United States, we intend for the Nucleus to meet the global supply demands of AUCATZYL, with Cardinal Health serving as our commercial distribution partner in the United States.

In addition to AUCATZYL/obe-cel for the treatment of adult r/r B-ALL, we are advancing obe-cel in other oncology indications including pediatric B-ALL and B-NHL, for which we have initiated Phase 1 studies. Obe-cel is also being developed for the treatment of autoimmune indications and we have initiated a Phase 1 study in patients with severe, refractory systemic lupus erythematosus (“SLE”).

Using our broad suite of proprietary and modular T cell programming technologies, we are also developing five programs in seven hematological and solid tumor indications and one autoimmune indication. 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 into 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 sufficient tolerability profile to enable use in outpatient settings.

Our Pipeline

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

Our pipeline

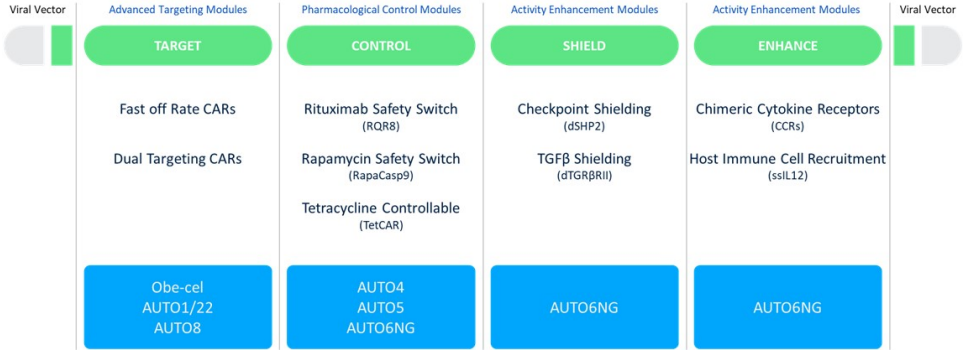
PRODUCT	INDICATION	TARGET	STUDY NAME	PHASE
obe-cel	B-NHL & CLL	CD19	ALLCAR19*	Phase 1
obe-cel	Primary CNS Lymphoma	CD19	CAROUSEL*	Phase 1
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL*	Phase 1
obe-cel	SLE	CD19	CARLYSLE	Phase 1
AUTO4	TRBC1+ Peripheral TCL	TRBC1	LibrA T1	Phase 1
AUTO5	TRBC2+ Peripheral TCL	TRBC2		Preclinical
AUTO6NG	Neuroblastoma; Other tumor types	GD2	MAGNETO†	Phase 1
AUTO8	Multiple Myeloma	BCMA & CD19	MCARTY*	Phase 1

B Cell Malignancies · T-Cell Lymphoma · Solid Tumors · Multiple Myeloma · Autoimmune Disease

* Collaboration with UCL
† BioNTech holds an option to co-fund and co-commercialize

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.

Our Strategy

Our strategic priorities include:

- Execute on the U.S. launch and commercialization of AUCATZYL/obe-cel for adult r/r B-ALL
- Subject to receiving regulatory approval, launch AUCATZYL/obe-cel for adult r/r B-ALL in the U.K. and European Union
- Develop obe-cel for treatment of potential additional indications, including Lupus
- Build our research and development pipeline

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.

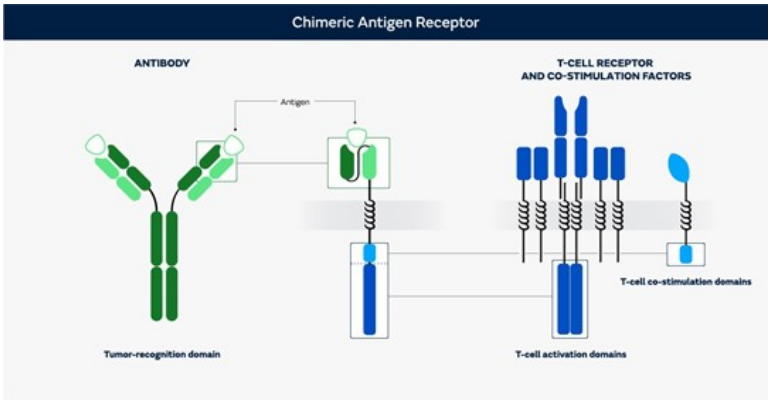
More recently, redirected T cell therapies that are designed to give the patient's T cells a new specificity to recognize cancer cells have been developed. The first approved product of this class is a bi-specific T cell engager called blinatumomab (Blincyto®) from Amgen Inc. Blinatumomab targets the 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®, 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 commercial product and our clinical-stage product candidates and our approach to T cell programming have the potential to address these limitations.

Programmed T Cell Therapies

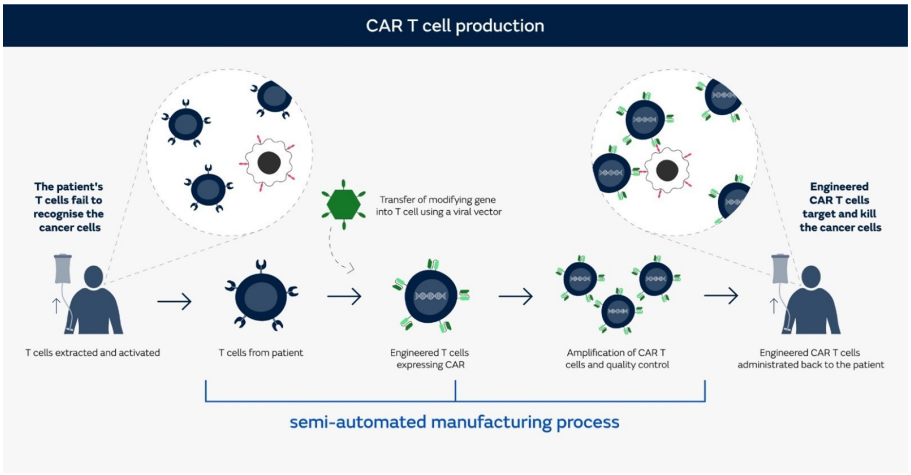
Chimeric Antigen Receptors ("CARs")

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 be life threatening in some cases. 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 cannot 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.

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 heterodimerize 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 Commercial Product: AUCATZYL for Adult r/r B-ALL

AUCATZYL/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 autologous 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.

AUCATZYL/obe-cel recognizes and interacts with the CD19 target with a fast off-rate enabled by the novel CAT scFv binding domain. This property allows the AUCATZYL/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.

The US FDA granted marketing approval for obe-cel for the treatment of adult patients with r/r B-ALL on November 8, 2024 under the brand name AUCATZYL. Marketing authorization applications ("MAA") for AUCATZYL/obe-cel in adult r/r ALL are being reviewed by the regulators in both EU and the U.K., with a submission to the EMA accepted in March 2024, and a submission accepted by the U.K. MHRA in August 2024. We expect to receive notification of approval status from these authorities in the second half of 2025.

Clinical Development of Obe-cel in Adult ALL

Background of Adult ALL

Obe-cel was 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.

On November 8, 2024 the FDA approved the use of obe-cel for the treatment of adults with r/r B-ALL.

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

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, in 2020. Most recently the data were published in the New England Journal of Medicine in December 2024.

The published data were from a pooled analysis of data from all patients across all cohorts in the FELIX Phase 1b/2 study. Of the 153 r/r B-ALL patients enrolled patients in the FELIX study, 127 (83.0%) received at least one obe-cel infusion and were evaluable. Eligible patients underwent leukapheresis, and bridging therapy, except blinatumomab, was permitted at the investigator's discretion. Obe-cel was administered in a bone marrow ("BM") burden adjusted split dose following lymphodepletion, with a BM mandated prior to lymphodepletion to guide dosing. The second obe-cel dose was given in the absence of severe/unresolved toxicity.

The primary end point was overall remission ("CR/Cri"). In the pivotal cohort of patients, (cohort IIA (n=94)), the CR/CRi for patients who received at least one infusion of obe-cel was 76.6%. Across all infused patients (n=127), of the 91/127 with ≥5% BM blasts pre-lymphodepletion, the CR/CRi was 74.7%. Median response duration for all infused patients was 21.2 months. Median event-free survival (EFS) was 11.9 months and the estimated 6- and 12-month event-free survival rates were 65.4% and 49.5%, respectively. BM burden pre-lymphodepletion correlated with median event-free survival; patients with low (<5% BM blasts), intermediate (≥5–≤75% blasts), and high (>75% blasts) BM burden had event-free survival rates at 12 months of 68.0%, 54.9% and 25.0%, respectively.

Median overall survival ("OS") was 15.6 months and estimated 6- and 12-month overall survival rates were 80.3% and 61.1%, respectively. BM burden pre-lymphodepletion correlated with overall survival; patients with low, intermediate, and high BM burden had an overall survival rate at 12 months of 71.5%, 58.7% and 55.0%, respectively. BM burden before enrollment also influenced event-free and overall survival.

Of the 127 patients infused (pooled across all study cohorts), 99 patients responded. Of the responders, 18 patients (18.2%) proceeded to allo-Stem Cell Transplant ("allo-SCT") while in remission at a median of 101 days post-obe-cel infusion. In 6/18 (33.3%), this was a second allo-SCT. Of 11 patients who had persisting CAR T cells before allo-SCT, and who had samples available post, none had CAR T cells detected following allo-SCT. There was no difference in event-free and overall survival observed between patients who received allo-SCT and those who did not.

Median duration of CAR T persistence by droplet digital PCR (ddPCR) in peripheral blood was 17.8 months.

Obe-cel was associated with minimal immunotoxicity. CRS and Immune effector cell-associated neurotoxicity syndrome ("ICANS") rates (Grade ≥3) were 2.4% and 7.1%, respectively. Overall, 87 (68.5%) patients developed CRS, and 29 (22.8) developed ICANS. Severe ICANS post-obe-cel were seen as largely limited to patients with high BM burden pre-lymphodepletion. Intensive care unit (ICU) admissions occurred in 20 (15.7%) patients for a median of 5.5 days (range,1−37) of which 7/20 were admitted due to immunotoxicity management (5 ICANS, 2 CRS).

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

In the first quarter of 2018, our academic partner University College London ("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 B-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.

Regulatory Status and Plans

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). The US FDA granted marketing approval for obe-cel on November 8, 2024 under the brand name AUCATZYL for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (r/r B-ALL) without the need for a Risk Evaluation and Mitigation Strategy (REMS). The approval is based on data from the Phase 2 cohort of FELIX study. MAAs for obe-cel in r/r B-ALL are being reviewed by the regulators in both the EU and the UK, with a submission to the EMA accepted in March 2024, and a submission accepted by the U.K. MHRA in August 2024. Based on prior regulatory timelines, we expect to hear from the MHRA and EMA regarding potential marketing approvals in the second half of 2025.

Commercialization Strategy for AUCATZYL

The U.S. FDA has granted marketing approval for AUCATZYL for the treatment of patients with r/r B-ALL. We are now in the process of launching the product in the US. In addition to the standard sales & marketing elements and medical affairs activities required to successfully commercialize an oncology/hematology product, there are several additional requirements needed for commercializing CAR-T cell therapies. This required several bespoke elements, including the processes for distribution, patient scheduling, center engagement and service hub to be established. It is a requirement that the product is administered only by authorized centers that are specialized in hematology and have the necessary infrastructure and capabilities for administering CAR-T therapies. We achieved our target 33 centers fully authorized to deliver AUCATZYL by end of January 2025, covering 60% of the accessible patient population, and this number of centers will steadily increase with the expectation it will be over 50 centers by mid-2025. We expect to complete authorization of 60 treatment centers, covering approximately 90% of the target patient population, by the end of 2025.

In December 2024, the National Comprehensive Cancer Network®, or NCCN, added AUCATZYL to its Clinical Practice Guidelines in Oncology, or NCCN Guidelines®, for the treatment of adult r/r B-ALL. The NCCN is a not-for-profit alliance of 30 leading cancer centers devoted to patient care, research, and education. The NCCN Guidelines are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97% of cancers affecting patients in the U.S and are intended to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that reflect the latest evidence in oncological patient care.

We have retained worldwide commercial rights for AUCATZYL. We plan to expand our global commercialization capabilities over time such that we are able to commercialize any product candidate in a broader number of countries over time, but with a focus on achieving an early presence in the U.S., U.K. and parts of Europe, i.e. countries where we expect to obtain a regulatory approval. We may pursue strategic collaborations with third parties in order to maximize the commercial potential of AUCATZYL. 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 U.K., EU and subsequently in other major markets. The product option for AUTO1/22 was not exercised and has expired as of February 8, 2025. 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.”

Our Manufacturing and Logistics Capabilities

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

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 AUCATZYL will allow us to focus on expanding manufacturing capacity during our 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, the Nucleus, is located in Stevenage, U.K.. 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.

The licensure and commercial supply of our cell products will be from our 70,000 square foot facility called the Nucleus, in Stevenage, United Kingdom. We believe 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. 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. 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.

Our 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 106 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.

Manufacturing Agreements with Third Parties

We obtain viral vector for commercial supply of AUCATZYL and for late stage clinical trials from our partner AGC Biologics. We also have manufacturing agreements with King's College London for early phase vector manufacturing, and some internal capability to produce vector for early and late-stage trials. 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.

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, including for commercial production of AUCATZYL as well as for preclinical and clinical 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.

Competition

There are two direct in class competitors to AUCATZYL approved for the treatment of adult patients with r/r B-ALL: the autologous CAR therapies Tecartus and Kymriah. Tecartus is approved for use in adult B-ALL and Kymriah is approved for use in adolescents and young adults, (i.e., patients up to the age of 25). We believe obe-cel has a differentiated safety profile and shows potential for longer term outcomes when compared to these current approved therapies.

In addition, 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 in indications other than B-ALL, 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.

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 for the Treatment of Pediatric ALL, B-NHL and other B-cell malignancies

In addition to AUCATZYL/obe-cel for the treatment of adult r/r B-ALL, we are advancing obe-cel in other oncology indications including pediatric B-ALL and B-NHL, for which we have initiated Phase 1 studies.

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.

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 ASH 2023 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.

We continue to evaluate obe-cel's potential to address current unmet medical needs in these indications.

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.

Obe-cel for Lupus and Other Autoimmune Diseases

In addition to advancing AUCATZYL/obe-cel for oncology indications, we are advancing obe-cel for the treatment of Lupus and other autoimmune diseases. We have initiated the Phase 1 CARLYSLE trial to determine the safety, tolerability, and preliminary efficacy of obe-cel in patients with severe, refractory systemic lupus erythematosus.

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 estimated 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 published in 2023 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, we have 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. We believe obe-cel's potential advantages over other autoimmune therapies that are approved or in development include its differentiated mechanism of action via its fast-off rate CD19 binder, the existing clinical data and approval in r/r B-ALL and our established manufacturing and commercial capabilities. In particular, the favorable safety profile, with low rates of high-grade CRS and ICANS in the cancer setting, have the potential to drive acceptability of a cell therapy approach in the rheumatology setting. Additionally, the fast-off rate kinetics observed with obe-cel in the cancer setting show increased T-cell engraftment and profound B-cell depletion. These properties have the potential to drive a deeper cut into CD19+ B cells and plasma blasts in SLE-affected tissues, and could potentially trigger an immune reset in patients. Obe-cel is the only autologous CD19 CAR T-cell therapy being developed for lupus with an approval in another indication. We expect that data supporting the safety and manufacture of obe-cel in r/r B-ALL could potentially be useful to support the development of obe-cel in autoimmune indications. Finally, our established commercial systems and manufacturing infrastructure for AUCATZYL/obe-cel could be leveraged to support an autoimmune indication.

Clinical Development in SLE, LN and other Autoimmune Diseases

The CARLYSLE trial is a single-arm, open-label, Phase 1 trial to determine the safety, tolerability, and preliminary efficacy of obe-cel in patients with severe, refractory SLE. The primary goal of this trial is to confirm the fixed dose of obe-cel in adult SLE patients. Six patients received a target dose of 50 x 106 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 and we completed patient doing in early 2025. We expect to provide initial data at our R&D Investor Event in April 2025 and follow up presentation of full data at a medical conference in the second half of 2025.

Depending on the outcome of the dose confirmation 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 confirmation 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. This study is no longer enrolling patients.

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 U.K. 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. This study is no longer enrolling patients.

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 U.K.. 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 American Association for Cancer Research ("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. This study is currently enrolling patients

Commercialization and Manufacturing Plans for our Clinical-Stage Programs

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 are also planning to advance obe-cel in autoimmune indications, and plan to leverage our established clinical and commercial manufacturing infrastructure, including our purpose-built manufacturing facility, the Nucleus.

We have retained worldwide commercial rights for our product candidates. We plan to expand our global commercialization capabilities over time such that we are able to commercialize any product candidate in a broader number of countries over time, but with a focus on achieving an early presence in the U.S., U.K. and parts of Europe, i.e. countries where we expect to obtain a 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 U.K., EU and subsequently in other major markets. The product option for AUTO1/22 was not exercised as of February 8, 2025 and has expired. 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."

In addition to the Nucleus, we maintain separate manufacturing capabilities for clinical-stage programs separate to The Nucleus (which is used exclusively for commercial manufacturing of AUCATZYL) to support further clinical trials of obe-cel in autoimmune conditions and potentially future hematological indications. For clinical trial supply, we have established our internal cell and vector manufacturing capacity at the Cell and Gene Therapy Catapult in Stevenage, United Kingdom. We have a cell manufacturing suite capable of supporting clinical supply operations.

Our early-stage programs such as AUTO1/22 and AUTO6NG are manufactured in collaboration with the UCL study teams. However, phase-appropriate Process Development activities have been initiated within our laboratories in order to leverage our existing manufacturing capabilities for progression to a late-stage clinical program.

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, 2024, our patent portfolio is comprised of 83 patent families, of which 17 patent families originated from UCLB, the technology-transfer company of UCL and 63 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.

We also protect our brand via the use of trademarks. As of December 31, 2024, our trademark portfolio consists of 5 trademark families covering our core brand and product. These families include protection in commercially relevant jurisdictions, including the U.S. and Europe. We have established internal guidelines for the use of our brands and monitor for the registration of similar marks by third parties.

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. The product option for AUTO1/22 was not exercised and has expired as of February 8, 2025;
- 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 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, including revenues from sales of AUCATZYL, 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. We expect to make initial payments of the revenue interest to BioNTech in 2025.

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. On November 8, 2024 we were notified by the FDA that our obe-cel BLA was approved, allowing for the marketing of AUCATZYL in the US for the treatment of adult patients (18 years and older) with r/r B-ALL. Consequently, we paid a regulatory milestone payment of £10.0 million to UCLB. 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 2024, $0.1 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 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 with Kymriah also being an option for adolescents and young adults, (i.e., patients up to the age of 25 years old). 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).

Company, trial	
Fate Therapeutics FT819 (CD19 allo)	Atara Bio ATA3219 (allo' CD19-1XX CAR+EBV CAR-T)
iCell (BCMA-CD19 cCAR-T)	BMS CC97540 (auto' CD19 CAR-T)
ImmPACT Bio IMPT-514 (CD19/CD20 CAR-T)	Cabaletta Bio CABA-201 (auto' CD19 CAR-T)
Guangdong Ruishun Biotech/Renji Hospital RJMty19 (CD19-CAR-DNT)	Cartesian Therapeutics/Selecta Biosciences DESCARTES-08 (BCMA mRNA CAR-T)
Juventas Cell Therapy CNCT19 (CD19 CAR-T)	Century Therapeutics CNTY-101 (allo' CD19 CAR-iNK)
Kyverna KYV-101 (auto' CD19 CAR-T)	CRISPR Therapeutics CTX112 (allo' CD19 CAR-T)
Miltenyi MB-CART 2219.1 (auto CD19 CAR-T)	Gracell/AstraZeneca AZD0120 (GC012F, BCMA/CD19 dual CAR-T)
Nkarta NKX019 (allo' CD19 CAR-NK)	Genentech/Roche REGENCY3
Sana Biotechnology SC291 (allo' CD19 hypoimmune CAR-T)	

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 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 payors include federal and state healthcare programs, private managed care organizations, health insurers and other organizations. The process for determining whether a third-party payor 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 U.K. 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 that we expect will have a significant impact on the pharmaceutical industry. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA"), was signed 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 biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation ("CMMI") to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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 exempts value-based or outcomes-based payment arrangements from the definition of "best price" which provides manufacturers more flexibility to work with commercial payors 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 U.K. Bribery Act 2010 and Other Anti-corruption and Trade Control 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. In addition to the FCPA, other U.S. laws such as the U.S. domestic bribery statute and U.S. Travel Act prohibit the provision of improper payments and benefits to government and private-sector recipients within the United States.

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 U.K. 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 and the third parties with whom we work 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 U.K. law by virtue of section 3 of the EU (Withdrawal) Act 2018 ("UK GDPR"), and the ePrivacy Directive and local implementations thereof, including the U.K.'s Privacy and Electronic Communications Regulations 2003. In the past few years, several states within the United States 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, and may become in the future, 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 U.K. and/or the EU in certain circumstances.

See the risk factor captioned "We and the third parties with whom we work 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 (or the third parties with whom we work) 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 are or 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 an 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 CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

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 competent authorities of EU Member States 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 the EU, medicinal products can only be commercialized after a related marketing authorization ("MA"), has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application ("MAA"), either under a centralized procedure administered by the European Medicines Agency ("EMA"), or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). A MA may be granted only to an applicant established in the EU. The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs"), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, 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 a MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP.

A 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.

A MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles.

Like a conditional MA, a 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

Advanced Therapy Medicinal Products, or 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, commonly known as the Community code on medicinal products. 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 European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA. 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.

Products made from substances of human origin must also comply with Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human application. This Regulation describes the conditions and quality requirements which must be applied when sourcing the substances of human origin intended for manufacturing of such medicinal products and removed divergences between EU Member States that were present under the (now repealed) Directive (EC) No. 2004/23.

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, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP"), agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. 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. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

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 a 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 a MAA. A 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 designation, 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, a 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 a 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 a 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 a MA. The SmPC is the document that provides information to physicians and other healthcare professionals 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. Some EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

In addition, some EU Member States may require the completion of additional studies 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. The HTA Regulation has applied from January 12, 2025 although it will enter into force iteratively and initially apply to new active substances to treat cancer and to all advanced therapy medicinal products (ATMPs), it will then be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Selected high-risk medical devices will also be assessed under the HTA Regulation as of 2026. The HTA Regulation is intended to harmonize the clinical benefit assessment of HTA across the EU. In light of the fact that the U.K. has left the EU, Regulation No 2021/2282 on HTA does not apply in the U.K.. However, the U.K. Medicines and Healthcare products Regulation Agency ("MHRA") is working with U.K. 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, including, effective as of 31 March 2025, relaunching the Innovative Licensing and Access Pathway with more predictable timelines and closer involvement of the National Health Service.

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 authorized 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 authorization 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 United Kingdom's, or U.K., withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the U.K. and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the U.K.'s standalone regulator for medicinal products and medical devices. The United Kingdom is now a third country to the EU.

The U.K. 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 U.K. national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the U.K. 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 U.K. Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. The U.K. Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation and such changes were laid in parliament on December 12, 2024. These resulting legislative amendments will, if implemented in their current form, bring the U.K. into closer alignment 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 United Kingdom are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU's centralized procedure marketing authorization can no longer be established in the United Kingdom. As a result, since this date, companies established in the United Kingdom cannot use the EU's centralized procedure. In order to obtain a United Kingdom MA to commercialize products in the United Kingdom, an applicant must be established in the United Kingdom and must follow one of the United Kingdom national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP"), when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the United Kingdom. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasn't been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

All existing marketing authorizations of the EU for centrally authorized products were automatically converted or grandfathered into the United Kingdom's 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 remained within the scope of authorizations of the EU in relation to centrally authorized medicinal products until January 1, 2025. However, on January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduces a U.K.-wide licensing process for medicines.

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 the United Kingdom, 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 the United Kingdom.

Post-Approval Controls

Where a MA is granted in relation to a medicinal product in the U.K., 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 and the EU, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the MHRA. The holder of a 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 U.K., the advertising and promotion of medicinal products are subject to U.K. 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 U.K. law. The U.K. SPC 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 U.K. SPC is considered off-label and is prohibited in the U.K.

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, 2024, we had 647 full-time employees, 65 of whom hold Ph.D. or M.D. degrees, as shown in the table below:

	At December 31,	
	2024	**2023**
Function:		
Sales and general administration	173	8
Research and development including manufacturing	474	38
Total	**647**	**46**
Geography:		
U.K.	495	39
Switzerland and Germany	18	1
United States	134	5

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.

As of December 31, 2024. the Company added the manufacturing function following the BLA approval granted by the FDA.

Item 1A. Risk Factors

Our business is subject to numerous risks. You should carefully consider and evaluate each of the following factors as well as the other information in this Annual Report on Form 10-K, including our financial statements and related notes, in evaluating our business and prospects. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations. If any of the following risks actually occur, our business and financial results could be harmed. In that case, the trading price our ADSs could decline.

Risks Related to Our Financial Position and Need For Capital

We are an early commercial-stage biopharmaceutical company and have incurred significant losses since our inception. We expect to continue to incur losses for the foreseeable future.

We are an early commercial-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 $220.7 million and $208.4 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $1,099.2 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 one product, AUCATZYL (obe-cel), approved for commercial sale, and while we have generated revenue from licensing, we are devoting substantially all of our financial resources and efforts to manufacturing and commercializing AUCATZYL and for the research and development of our other programmed T cell product candidates and T cell programming technologies. 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.

Should we be unsuccessful in our commercialization efforts for AUCATZYL or if the rates of market acceptance do not meet our expectations, we may not generate sufficient 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 other product candidates, including obe-cel in additional indications or territories. 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:

- expand our sales, marketing and distribution infrastructure to commercialize AUCATZYL/obe-cel and any other product candidate for which we may obtain regulatory approval;
- make required milestone, royalty and revenue sharing payments to third parties under license and collaboration agreements;
- continue to scale up internal and external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for commercialization of AUCATZYL and clinical trials of our other product candidates;
- 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;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- 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 regulatory approvals for any product candidates that successfully complete clinical trials;
- 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 the commercial development of AUCATZYL, as well as our other product development and 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 commercializing AUCATZYL and developing and eventually commercializing other products that generate significant revenue. This will require us to be successful in a range of challenging activities, including marketing and selling AUCATZYL and any future products for which we may obtain regulatory approval, 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.

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

Unless and until we are able to successfully commercialize AUCATZYL and achieve significant revenue from sales, 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 AUCATZYL and our other product candidates. Even once we begin to generate revenue from sales of AUCATZYL, 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:

- our ability to execute our commercialization strategies for and generate revenue from sales of AUCATZYL and, if approved, our other product candidates;
- 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, royalty payments or revenue sharing 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 commercialization activities, including product manufacturing, marketing, sales and distribution, for any future 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, AUCATZYL, or our other product candidates, if approved, may not achieve commercial success. Our product revenues in the near term will be derived primarily from sales of AUCATZYL in the US, as we that we do not expect to generate material revenues from obe-cel in other jurisdictions or from 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 agreed to pay us up to $150 million to support the continued development and commercialization of AUCATZYL/obe-cel and next-generation product candidates (collectively, the "Collaboration Products") in exchange for our agreement to make substantial payments to Blackstone following approval of such Collaboration 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, 2024, Blackstone has paid us the full $150 million under the terms of the Blackstone Collaboration Agreement, including the final payment of $30 million in the fourth quarter of 2024 following regulatory approval of AUCATZYL.

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.

Under the BioNTech License Agreement with BioNTech entered into in February 2024, we also agreed to pay BioNTech a low single-digit percentage of annual net revenue of AUCATZYL/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.

Risks Related to the Commercialization of AUCATZYL and Our Other Product Candidates

AUCATZYL and any other product candidates, if approved, 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, thereby limiting our potential to generate revenue.

AUCATZYL and any other product candidates, if approved, 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 AUCATZYL and those product candidates that are approved, and a decrease in demand for AUCATZYL or any such product candidates. The degree of market acceptance of AUCATZYL, and any other product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the timing of market introduction of those products compared to competitive products;
- the continued safety and efficacy of those products;
- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product and 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 and 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 cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product and product candidates;
- the availability of coverage, adequate reimbursement, and pricing by third-party payors and government authorities;
- the willingness and ability 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 scheduling and 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 AUCATZYL and our other product candidates, 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 AUCATZYL and any future products, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of those products 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.

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.

If we are unable to fully develop our sales, marketing and distribution capability on our own , or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing AUCATZYL, or our other product candidates, if and when approved.

We have spent significant resources to build our global commercialization capabilities in anticipation of the commercial launch of AUCATZYL. To achieve commercial success for AUCATZYL or any other product candidate for which we may obtain marketing approval, we will need to maintain 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 has required and will continue to require substantial resources, will be time-consuming and could delay any product launch. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our medicines and any additional medicines we may acquire will be expensive and time-consuming. In addition, not all members of our sales force have promoted medicines for treatment of adult r/r B-ALL prior to the launch of AUCATZYL. We have spent and will continue to expend significant time and resources to train our sales force to be able to educate physicians on the benefits of prescribing and pharmacists dispensing AUCATZYL. Furthermore, we must train our sales force to ensure that a consistent and appropriate message about AUCATZYL is being delivered to our potential customers. We may experience turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate physicians about the benefits of AUCATZYL and its proper administration and label indication, as well as our patient assistance programs, our efforts to successfully commercialize AUCATZYL could jeopardize, which could have a material adverse effect on our financial condition, share price and operations.

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 AUCATZYL/obe-cel or our other 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 be lower than if we were to sell, market and distribute AUCATZYL/obe-cel and any other 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 AUCATZYL/obe-cel and any of our other product candidates effectively.

The incidence and prevalence for target patient populations for AUCATZYL and our other product candidates have not been established with precision. If the market opportunities for AUCATZYL and our other product candidates are smaller than we estimate, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The total addressable market opportunity for AUCATZYL and our other product candidates will ultimately depend upon, among other things, acceptance by the medical community and patient access, product pricing and reimbursement as well as expansion into additional markets. The number of patients who may benefit from AUCATZYL or our other future products may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business.

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”), and Janssen Biotech 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 have received marketing approval from the FDA for AUCATZYL for the treatment of adult r/r B-ALL. Novartis, Gilead and BMS have also received marketing approval for anti-CD19 CAR T cell therapies. Gilead's therapy was approved for the treatment of adult ALL in October 2021. AUCATZYL is expected to compete directly with these companies and therapies. In addition, some companies, such as Cellectis, Inc., Les Laboratoires Servier SAS, Allogene Therapeutics Inc., Lyell Immunopharma, Cargo Therapeutics and Crispr Therapeutics AG 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.

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.

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 trial 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.

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

Market acceptance and sales of our product and 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 our product or any product candidates that we develop, once approved, 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, and product candidates, once approved, in addition to the costs required to obtain FDA approvals. Our product and product candidates, once approved, may not be considered medically necessary or cost-effective by third-party payors.

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 our product or any product candidates and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for our product or any 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 our product and 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 products and 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 and product candidates, if approved.

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

We face an inherent risk of product liability exposure related to the testing of our product and 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 million in product liability insurance coverage in the aggregate, with a per incident limit of £10 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 the Development of Our Product Candidates

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.

Other than AUCATZYL, the rest of our product pipeline is in clinical or preclinical development. We have established clinical proof-of-concept for only one of our products, AUCATZYL, which recently received FDA approval in r/r B-ALL. 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. Although we received marketing approval from the FDA for AUCATZYL in the US, and have submitted MAAs to the MHRA and EMA, we may not be successful in receiving marketing approval from these regulatory agencies, including the European Commission, for obe-cel or for any of our other 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 U.K. and EU. We are sponsoring active, recruiting clinical trials for obe-cel in additional indications and AUTO4. We are also collaborating with our academic partner UCL to support clinical trials sponsored by them of obe-cel in additional indications, 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 for our product candidates 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 other 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. 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 other clinical-stage programmed T cell product candidates and our preclinical programs. Our product candidates will require significant clinical or preclinical testing before we can seek regulatory approval for and launch a product commercially.

Although we have received FDA approval for AUCATZYL in r/r B-ALL, our business remains substantially dependent on our ability to successfully obtain regulatory approval for, and, if approved, to successfully commercialize our other 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 U.K. 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 U.K., 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 U.K. ILAP designation in r/r B-ALL was granted in June 2021 and we submitted an MAA to the MHRA at the end of July 2024. Additionally, EMA PRIME designation in r/r B-ALL was obtained in March 2021 and we submitted an MAA to the EMA, which was accepted in April 2024. Moreover, Orphan Designation in B-ALL was granted by the FDA in November 2019 and by the European Commission in March 2022. Prior to seeking approval for any of our other 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 other 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.

Even though we have received FDA approval for AUCATZYL in r/r B-ALL, and even if any of our other product candidates 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, the regulatory approval of AUCATZYL, or of any of our other 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 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 trial 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 trial 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 r/r B-ALL, or pediatric or adult ALL, and r/r DLBCL, r/r 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 trial 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 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.

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.

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 to four weeks, but several patients died in clinical trials involving CAR T cells developed by other companies and academic institutions. For example, the FDA-approved label for AUCATZYL carries a boxed warning for, among other adverse side effects, the risk of developing secondary T-cell malignancies.

There can be no assurance that patients in ongoing or future trials of obe-cel in additional indications, 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. Although we have received FDA approval for AUCATZYL in r/r B-ALL, it is impossible to predict accurately when or if any of our other 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-delivery cycle. We have constructed and use a new facility (which we call "The Nucleus") in Stevenage, U.K. which we believe will support our commercial manufacturing needs for AUCATZYL and any future products. 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 have limited experience as a company in designing and operating a commercial cell therapy or vector manufacturing facility and may not be successful in sustaining our own manufacturing 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. 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 sustained manufacturing capacity at commercial scale and may underestimate the cost and time required to do so, and may 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. Further, as we scale up our commercial production, we expect our margin will be lower as we will not initially be utilizing our full manufacturing capacity, which may cause our cost of goods to be higher until we reach economies of scale.

Our products and product candidates are biologics and the manufacture of such biologics 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 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 products or 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 products or 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 products or 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 products and 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. Any product that is out of specification, even if supplied to a treatment center for administration to a patient, must be provided free of charge. 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 as published in the New England Journal of Medicine in December 2024, 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 supply chain, the manufacturing process for that patient will need to be restarted, if sufficient starting materials are still available; the resulting delay may adversely affect that patient's outcome due to the risk of disease progression.

In addition, because our products and 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, changes may be considered in an effort to optimize processes or clinical approach. Any changes to a process or clinical approach must serve the needs of the patient and delivery must be economically viable. 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 candidates, impair commercialization efforts of our products, 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. For example, patients with autoimmune diseases receive multiple types of treatment including toxic lympho-depleting chemotherapies, which may have an impact on 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 U.K. 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 U.S. and 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 U.K.'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.

For example, the U.S. government has threatened to impose new tariffs on imported products from various foreign countries. As we produce our clinical and commercial supply of drug in the United Kingdom, the import of clinical and commercial supply of our products into the United States could be impacted to the extent any such tariffs are imposed and applicable to pharmaceutical products. The impact of such tariffs would be subject to a number of factors, including the effective date and duration of such tariffs, changes in the amount, scope and nature of the tariffs in the future, any retaliatory responses to such actions that the target countries may take and any mitigating actions that may become available. Tariffs on our products would increase our cost of importing clinical and commercial product into the United States, which would increase the cost of revenue from sale of therapies and reduce our margins on the sale of our products.

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 U.K. 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. The TCA primarily focuses on ensuring free trade between the EU and the U.K. 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 certain limited EU regulatory rules, including in relation to trade in medical devices, but not in relation to medicinal products. As part of the TCA, the EU and the U.K. 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 U.K. 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 U.K. must be retested and re-released when entering the EU market for commercial use.

On February 27, 2023, the U.K. 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. Under the Windsor Framework, effective from January 1, 2025, medicinal products to be placed on the market in the U.K. (including in Northern Ireland) will be authorized solely in accordance with U.K. laws. Northern Ireland is reintegrated back into a U.K.-only regulatory environment under the authority of the MHRA with respect to all medicinal products.

A significant proportion of the regulatory framework in the U.K. applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for U.K. 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 U.K. 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 U.K. 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 U.K. 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 U.K. 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 U.K., 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 expect to continue to expand our development, commercial and regulatory capabilities and have recently developed sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2024, we had 650 employees, 647 of whom are full-time. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly 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 with whom we work, 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 with whom we work, 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 with whom we work 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 with whom we work. 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 with whom we work, 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 with whom we work 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 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 the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work 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 that of the third parties with whom we work 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 with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities, including on a timely basis. Further, we have (and may in the future) experienced 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.

Certain of the previously identified or similar threats have in the past and may in the future 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 with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. For example, several of Snowflake's customer accounts were targeted as part of Snowflake's security incident in June 2024, and the Autolus customer account was among those targeted. While Autolus did not experience any data loss or other material impact as a result of Snowflake incident, a security incident or other interruption could disrupt our ability (and that of third parties with whom we work) 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 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 with whom we work) 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 £10,000,000 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 and the third parties with whom we work 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 (or the third parties with whom we work) 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 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.

Outside of the U.S., an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the EU GDPR and the U.K. 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 U.K. 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 U.K. 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 U.K., 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 U.K. 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 U.K., 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 or have already adopted similarly stringent 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 U.K.'s International Data Transfer Agreement/Addendum, the Swiss-U.S. Data Privacy Framework, and the EU-U.S. Data Privacy Framework and the U.K. 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 U.K., 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 U.K. 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 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 and allows private litigants affected by certain data breaches to recover significant statutory damages.

Although the CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increases compliance costs and potential liability for us and the third parties with whom we work. 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.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and we are, and may become in the future, subject to such obligations. 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 concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, 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 with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work 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.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

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 conflicts in the Middle East. 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 political instability and tensions in the Middle East. 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 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 rapidly. For example, the EU adopted an ESG reporting rule, EU Directive No 2464/2022 on Corporate Sustainability Reporting (“CSRD”) that entered into force on January 5, 2023. The CSRD introduces new mandatory reporting obligations for in-scope companies that require the publication of fulsome audited ESG disclosures, including disclosures under the EU Taxonomy Regulation 2020/852.

The CSRD currently 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 being published during 2025 for the 2024 financial year, predominantly by entities with securities admitted to trading on an EU regulated market. In February 2025, the EU proposed to delay the application of the CSRD and amend the thresholds and reporting requirements going forward. The outcome of this proposal is currently uncertain, but it may impact Autolus Therapeutics plc’s ESG disclosure obligations in the EU.

In response to new ESG initiatives and regulations we may be required to adopt strategies, policies, or procedures related to ESG matters and report on these. Reporting could involve capital and human resources and could lead to the disclosure of information that 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 products and 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.

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 and 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 and 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 clinical cell manufacturing. In addition, we purchase equipment and reagents critical for the manufacture of our product and 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 AUCATZYL and our 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 commercial success of AUCATZYL and our product candidates, if approved. 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, or commercial materials for our commercial product in accordance with applicable specifications on a timely basis, our research and development efforts, including clinical trials, and the commercial success of our CAR T product, and product candidates, if approved, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

We, and the third parties on whom we rely in part for sales, marketing and distribution capabilities, may not be able to effectively market, sell and distribute AUCATZYL or our other product candidates, if approved.

We have invested, and expect to continue to invest, significant financial and management resources to develop internal our sales, distribution and marketing capabilities, particularly in anticipation of the commercial launch of AUCATZYL. With respect to jurisdictions outside the US, we will need to commit resources to buildings these capabilities prior to any confirmation that obe-cel or our other product candidates will be approved in a territory.

We utilize a hybrid model that includes in-house and contracted resources in the United States and Europe, and we have engaged third parties and may engage additional third parties to provide these services. We may enter into agreements with third parties to develop our commercial infrastructure for the commercial launch and continued sale of AUCATZYL and any product candidates that receive approval, including to potentially retain, train and deploy a direct sales force, but we have limited experience operating or managing a third-party sales force as a company. There can be no assurance that the capabilities of the third parties will be more effective than an internally developed sales organization. If third parties fail to hire, train, and retain qualified sales personnel, market our product successfully or on a cost-effective basis or otherwise terminates our relationship, our ability to generate revenue will be limited and we will need to identify and retain an alternative organization or develop our own sales and marketing capability. This could involve significant delays and costs, including the diversion of our management's attention from other activities. We may also need to retain additional consultants or external service providers to assist us in sales, marketing and distribution functions, and may be unsuccessful in retaining such services on acceptable financial terms or at all.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a commercial organization is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- the inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future product that we may develop;
- the lack of complementary treatments to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability to us from these revenue streams is likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little 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 and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates.

We collaborate with third parties in the research, development and commercialization of certain of our product and 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 others. 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 we face relating to product development, regulatory approval and commercialization 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 or product candidates, we or our partners may be unable to develop or commercialize these products or 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 collaborators. 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 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 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 AUCATZYL or our other 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 though the FDA granted marketing approval for AUCATZYL in the U.S. for the treatment of r/r B-ALL, comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion of AUCATZYL/obe-cel 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 or product candidates will be harmed.

Even though we have obtained marketing approval by the FDA for AUCATZYL, the terms of approvals and ongoing regulation of AUCATZYL may limit how we manufacture and market AUCATZYL and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even though we have been granted marketing approval by the FDA for AUCATZYL, 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 AUCATZYL/obe-cel and for any of our other 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, and product candidates, if approved, and significantly harm our business, financial condition, results of operations and prospects.

Accordingly, 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.

AUCATZYL, and any other 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.

Changes in funding for the FDA or comparable foreign regulatory authorities, the SEC, and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies or authorities from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA and other government agencies on which our operations may rely are subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations due to insufficient funding of the SEC and other government agencies or due to a government shutdown that affects the SEC. Similar considerations are applicable in relation to foreign regulatory authorities.

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 U.K., 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 products or 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 products or product candidates for which we obtain marketing approval, and foreign equivalents. In addition, we will 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 U.K. GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU and U.K. (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 products and product candidates are subject to government price controls in certain jurisdictions that may affect our revenue.

There has been heightened governmental scrutiny in the U.K., 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 on August 16, 2022, the Inflation Reduction Act was signed into law, which among other things (i) directed HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and (ii) imposed rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation ("CMMI") to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad, particularly in light of the recent U.S. presidential and Congressional elections. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our development candidates or additional pricing pressures, or otherwise adversely impact our operations.

Outside of the United States, particularly in the U.K. 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 products and future 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 and amendments to certain aspects of the ACA. For example, 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.

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.

In December 2021, Regulation No 2021/2282 on HTA, was adopted in the EU. This Regulation, which entered into application on January 12, 2025 and has a phased implementation, 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 permits 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 continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. 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.

Legislators, policymakers and healthcare insurance funds in the EU and the United Kingdom may continue to propose and implement cost-containing measures to keep healthcare costs down, particularly due to the financial strain that the COVID-19 pandemic placed on national healthcare systems of European countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. 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. 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 ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive ("CTD"), became applicable on January 31, 2022. The CTR allows 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 by all EU Member States concerned, 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. Once the clinical trial approved, clinical study development may proceed. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In light of the entry into application of the CTR on January 31, 2022, we may be required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR. Transition of clinical trials governed by the CTD to the CTR was required for clinical trials which had at least one site active in the EU on January 30, 2025. A transitioning application had to be submitted to the competent authorities of EU Member States through the Clinical Trials Information Systems and related regulatory approval obtained to continue the clinical trial past January 30, 2025. This required financial, technical and human resources.

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for 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 and such changes were laid in parliament on December 12, 2024. These resulting legislative amendments will, if implemented in their current form, bring the UK into closer alignment with the CTR. Failure of the UK to closely align its regulations with the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization for the Company's product candidates on the basis of clinical trials conducted in the United Kingdom.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on April 10, 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. 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 number of changes to the regulatory framework governing medicinal products, including 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. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, our development plans may be impacted.

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 U.K. 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 U.K. 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 U.K. 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 U.K. 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 U.K. 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 U.K. 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 U.K., 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 U.K. Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the U.K. 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, U.K. 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 previously identified material weaknesses in our internal control over financial reporting. If we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.

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 identified a material weakness in our internal control over financial reporting in connection with the historic misinterpretation and application of ASC 740, resulting in our U.K. 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 our Annual Report for additional information. We have taken steps to remediate the material weakness by (i) enhancing the training provided to the individuals operating the income taxation controls and related financial reporting controls and (ii) improving the design of our controls related to the use of taxation subject matter experts in the determination of our U.K. SME tax credits balances. This material weakness was remediated at June 30, 2024, but there can be no assurance that we will not identify further control deficiencies in this area.

In addition, in connection with our review procedures for the three months ended March 31, 2024, we identified an additional material weakness due to an insufficiency of controls over complex accounting transactions. The lack of controls did not allow us to identify, understand and evaluate the impact of certain key judgments that arose during the three months ended March 31, 2024 related to the BioNTech Agreements. Our process, as designed, was inadequate to deal with the complexity of the accounting for the transaction and did not allow for an effective and timely evaluation of these matters and their impact on our financial statements. We have taken steps to remediate the material weakness by (i) implementing structured project plans and project monitoring techniques; (ii) the use of summary outputs allowing for earlier review of key judgements, estimates and other factors which impact the financial statements; and (iii) enhancing our review process, and controls including building in more time to allow for its effective operation and iv) assessing resourcing needs and capabilities. This material weakness was remediated at December 31, 2024, but there can be no assurance that we will not identify further control deficiencies in this area.

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 our most Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 21, 2024.

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 weaknesses described above, 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 identified. 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 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 U.K. 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 may claim technology related to obe-cel. These U.S. patents will expire between 2025 and 2038. 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 in those jurisdictions. 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 AUCATZYL 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, 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, 2024, our patent portfolio was comprised of 83 patent families, of which 17 patent families originated from UCLB, the technology-transfer company of UCL, and 63 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.

Our existing trademarks and 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 AUCATZYL from the products of competitors, and also expect to rely in the future trademarks to protect any of our other product candidates that are approved for marketing. We have a U.S. trademark for AUCATZYL but we have not yet selected trademarks for our other product candidates, including obe-cel for r/r B-ALL in other jurisdictions. 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 has been 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 report, the trading price for our ADSs may be influenced by the following:

- our failure to successfully execute our commercialization strategy with respect to AUCATZYL;
- actions or announcements by third-party or government payors with respect to coverage and reimbursement of AUCATZYL;
- the commencement, enrollment or results of our planned or future clinical trials our 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 US, U.K. 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 programs;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of AUCATZYL or 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 U.K.;
- price and volume fluctuations of the listed securities of 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.

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 filed a resale registration statement on Form S-3 to register the ADSs we sold to BioNTech in February 2024. 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 directly received 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, 2024. 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, 2024, 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.

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 U.K. tax legislation.

As a U.K. resident trading entity, we are subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since inception. As of December 31, 2024, we had cumulative carryforward tax losses of $545.6 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, or R&D, expenditure is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government. As a company that carries out extensive R&D activities, we benefit from the U.K. R&D tax credit regime.

In respect of our accounting period commencing January 1, 2024, we expect to qualify as a Small and Medium-sized Enterprise, or SME, that is not "R&D-intensive" for the purposes of the U.K. R&D tax credit regime. We may therefore surrender trading losses that arise from our R&D activities during the accounting period for a cash rebate of up to 18.6% of qualifying R&D expenditure. We do not expect to qualify as a SME for R&D purposes for subsequent accounting periods due to exceeding the relevant headcount limits, and will therefore be entitled to make claims solely under the R&D expenditure credit, or RDEC, scheme, under which we will be able to receive cash payments or other tax relief at a lower rate (up to 16.2%). The U.K. R&D tax credit regime's rules are complex, and if a tax authority were to challenge or seek to disallow our claims (in whole or in part, whether under RDEC or otherwise), for example by asserting that we do not (or the relevant expenditure does not) meet the technical conditions to be granted tax credits (or cash rebates), then a successful challenge or disallowance could have a material impact on our cash-flow and financial performance. In addition, future changes to the U.K. R&D tax credit regime (including changes in HMRC practice in respect of such regime) may mean that we no longer qualify or have a material impact on the extent to which we can make claims (or benefit from them). We may also benefit in the future, when we generate profits subject to U.K. corporate taxation, from the U.K.'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 U.K. 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.

We have been advised by HMRC that the sale of our obe-cel CAR T therapy to U.K. customers in the future will be considered an exempt supply from a U.K. VAT perspective. Consequently, Autolus Limited has reassessed and commenced restricting the amount of U.K. VAT it reclaims. The restriction is based on an estimate of our U.K. market turnover as a percentage of global turnover. We currently expect revenue from U.K. customers to only represent a small proportion of our overall activity. If the proportion of revenue from U.K. customers increases this would further restrict the amount of U.K. input VAT which we are able to recover.

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. 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, 2025. 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 U.K. 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 U.K. (or the Channel Islands or the Isle of Man). This is known as the "residency test." The test for central management and control under the Takeover Code is different from that used by the U.K. tax authorities.

Under the Takeover Code, the Takeover Panel will determine whether we have our place of central management and control in the U.K. 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 U.K..

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 U.K. 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 U.K.. In addition, uncertainty exists as to whether English courts would entertain original actions brought in the U.K. 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, 2024 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, 2024, 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, 2024 to disapply preemptive rights for a period of five years from June 28, 2024 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 Chief Information Officer, 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. In February 2025, we obtained ISO 27001 certification for our information security management systems.

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 with whom we work, 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 has charged our Audit Committee with oversight of our cybersecurity risk management program. The board and Audit Committee are 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.

Since September 2017, the Company has had an arrangement with Cell Therapy Catapult Limited to lease manufacturing suites at the Cell and Gene Therapy Catapult manufacturing center in Stevenage, United Kingdom. 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. 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 August 2024, one of the manufacturing suite leases ended and the Company exited the suite. In September 2024, the Company extended the lease term from August 2024 to March 2025 for the remaining manufacturing suite.

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 terminated at the end of February 2025.

In February 2019, we entered into a lease for a manufacturing facility, consisting of approximately 39,558 square feet, in Enfield, U.K.. 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 September 2021, we entered into an arrangement for lease with Forge Life Sciences Nominee ("Landlord"), an affiliate of the Reef Group, for the design, construction and lease of a new 70,000 square foot commercial manufacturing facility in Stevenage, U.K.. 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. On September 10, 2024, we and Landlord completed a variation of the lease for the manufacturing facility, related to additional works at the site. The Landlord will provide funding for certain specified improvements to the facility (the “Works”), which we committed to undertake on a mutually agreed schedule. Funding received for the Works done are deemed lease incentives in accordance to ASC 842. Once the Works are complete, the rental payments under the lease will be increased according to a specified formula for the remainder of the lease term. The deed of variation does not affect the lease term, which continues to run for 20 years from September 19, 2023. The Nucleus will have a GMP cell manufacturing capacity of approximately 2,000 batches a year. We anticipate that the size and layout of the Nucleus 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, U.K. 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 October 2025.

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 19, 2025, we had approximately 33 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, 2024.

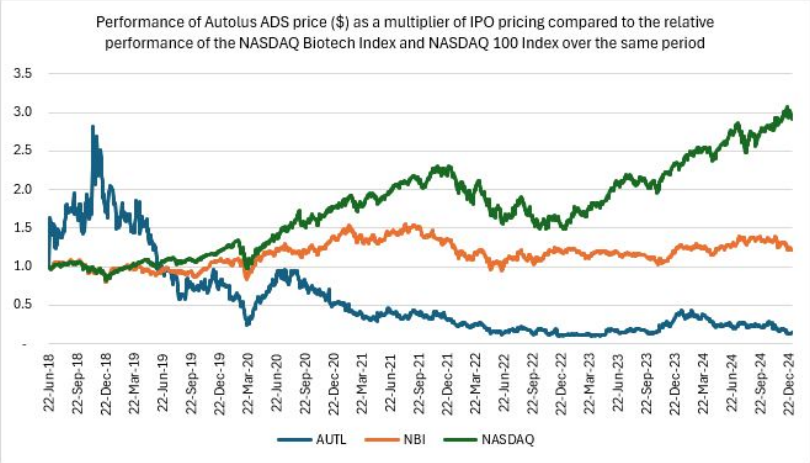
Issuer Purchases of Equity Securities

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

Stock Performance Graph

Notwithstanding any statement to the contrary in any of our previous or future filings with the 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, 2024. 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, 2024 and 2023 have been translated from pounds sterling into U.S. dollars at the rate of £1.00 to $1.2535 and £1.00 to $1.2730, respectively. Our consolidated statements of operations and comprehensive loss and consolidated statements of cash flows for the years ended December 31, 2024 and 2023 have been translated from pounds sterling to U.S. dollars at the rate of £1.00 to $1.2779, £1.00 to $1.2433, 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 an early commercial-stage 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 kill 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.

Since our inception, we have incurred significant operating losses. For the years ended December 31, 2024 and 2023, we incurred net losses of $220.7 million and $208.4 million, respectively. As of December 31, 2024, we had an accumulated deficit of $1,099.2 million.

Based on our current commercial and development plans, we believe our existing cash and cash equivalents of $227.4 million and marketable securities of $360.6 million at December 31, 2024, will be sufficient 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 revenues and 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

- **AUCATZYL U.S. launch**
  - AUCATZYL was approved by the FDA for the treatment of adult patients with relapsed and refractory B-cell acute lymphoblastic leukemia on November 8, 2024.
  - In December 2024, the National Comprehensive Cancer Network® (NCCN) added AUCATZYL to its Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for the treatment of adult patients with r/r B-ALL.
  - The U.S. commercial launch progresses on track, with 33 centers authorized as of March 19, 2025 (versus the Company's initial target of 30 by the end of Q1 2025), covering approximately 60% of the target U.S. patient population
  - Autolus continues to expect to complete authorization of 60 treatment centers by the end of 2025, covering approximately 90% of the target patient population

Obe-cel updates:

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

- Obe-cel is under regulatory review in both the EU and the U.K., and the Company expects to receive notification of approval status from the MHRA and EMA in second half of 2025
- Post period, Autolus submitted obe-cel for appraisal by the U.K. National Institute for Health and Care Excellence ("NICE"), and a decision is expected at the time of a potential MHRA approval
- Autolus has presented updated data on obe-cel in adult ALL at the Society of Hematologic Oncology ("SOHO") meeting in August 2024, the Lymphoma, Leukemia & Myeloma Congress in October 2024, the American Society of Hematology ("ASH") Meeting in December 2024, and post-period at TANDEM 2025. The data presented at these conferences builds on previously published obe-cel data, highlighting its tolerability and long-term responses. In addition, a health economic cost model has been presented, directly comparing the cost of serious adverse events across various comparable CAR-T cell therapies.

Obe-cel in B-cell mediated autoimmune diseases

- The Phase 1 dose confirmation study ("CARLYSLE") in refractory SLE patients is ongoing, with all six patients dosed. Autolus will present the initial data from this trial and development plans at its R&D event being held on April 23, 2025, and its are targeting the second half of 2025 for the presentation of full data with longer term follow-up.

Early stage pipeline programs and collaborations:

- Clinical programs AUTO8 and AUTO6NG are progressing, and the Company is planning updates for programs at its R&D event which will be held on April 23, 2025.
- BioNTech's product option for AUTO1/22 was not exercised as a result of BioNTech's pipeline prioritization, and has expired as of February 8, 2025.

Strategic Financing Agreements

BioNTech

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 $32.0 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. The product option for AUTO1/22 was not exercised and has expired as of February 8, 2025;
- 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 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, including revenues from sales of AUCATZYL, 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. We expect to make initial payments of the revenue interest to BioNTech in 2025.

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 $20.0 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.

Blackstone

Pursuant to the Blackstone Collaboration Agreement, Blackstone agreed to pay the Company up to $150.0 million to support the continued development of obe-cel, as well as next generation product therapies of obe-cel in B-cell malignancies. These payments include (i) an upfront payment of $50.0 million and (ii) up to $100.0 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 $50.0 million was paid by Blackstone upon execution of the Blackstone Collaboration Agreement. In December 2022, two Blackstone Development Payments were paid by Blackstone of $35.0 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 ("B-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. In December 2024, the remaining $30.0 million Blackstone Development Payment was paid to the Company on the approval of AUCATZYL by the FDA. The Company considers the achievement of the specified regulatory milestone as probable when actually achieved (i.e., when the contingency resolves).

Financial Operations Overview

License Revenue

We account for our revenue pursuant to the provisions of ASC Topic 606. We have one product approved for commercial sale but have not generated any revenue from commercial product sales through the period covered by this Annual Report. Rather, our total revenue to date has been generated principally from license agreements. During the year ended December 31, 2024, 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).

Cost of Sales

Cost of sales represents production costs including raw materials, employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in commercial manufacturing functions, external manufacturing costs including outsourced professional expenses services, allocated facilities costs, depreciation and other expenses, and other costs incurred in bringing inventories to their location and condition prior to sale. Cost of sales may also include costs related to excess or obsolete inventory adjustment charges and amortization expense of intangible assets.

Research and Development Expenses, net

Research and development expenses, net ("R&D") 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 U.K. small and medium enterprise ("SME") regime and research and development expenditure credit ("RDEC") regime provided by His Majesty's Revenue and Customs ("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.

After consultation, we have been advised by HMRC that any sale of our obe-cel CAR T therapy to U.K. customers in the future will be considered an exempt supply from a U.K. VAT perspective. Consequently, we have assessed and restricted the amount of U.K. VAT we have historically reclaimed and will continue to do so in the future. The restriction will be based on the estimated U.K. market turnover as a percentage of global turnover. We currently expect revenue from U.K. customers to only represent a small proportion of our overall activity. If the proportion of revenue from U.K. customers increases this would further restrict the amount of U.K. input VAT recovered. Included in research and development expenses is historical irrecoverable input VAT previously claimed on research and development expenses and subsequently reversed.

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 other than AUCATZYL. 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 European Medicines Agency ("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.

U.K. Research and Development Tax Credits

Research and development expenditure is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government. As a company that carries out extensive research and development activities, we benefit from the SME regime and, to the extent that our projects are grant funded, the RDEC regime.

The benefits from U.K. 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 U.K.

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. The U.K. Government also enacted further changes to the SME regime effective from April 1, 2023 (with some amendments effective for accounting periods commencing after April 1, 2024) which included the introduction of a new rate for R&D intensive companies of 27%. 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 contained in the Finance Act 2024 (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 U.K. or such workers are not subject to U.K. 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. These changes take effect from periods commencing after April 1, 2024.

In the accounting period ended December 31, 2024, we met the conditions of the SME regime, but we could also make claims under the RDEC regime to the extent that our projects are grant funded. In addition, based on the relevant tax legislation, we may meet the conditions of the R&D intensive scheme. From January 2025, we will not qualify as a small or medium-sized enterprise under the SME program, based on size criteria concerning employee headcount, turnover and gross assets. However, we may make a claim under the merged RDEC regime for periods 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).

Selling, General and Administrative Expenses

Selling, 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. Selling, 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. Included in general and administrative expenses is historical irrecoverable input VAT previously claimed on general and administrative expenses and subsequently reversed.

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. We 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 AUCATZYL and our other product candidates.

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, net

Other income (expense), net consists primarily of sublease income and gains or losses arising from the termination of leases.

Foreign exchange (losses) gains, net

Foreign exchange (losses) gains, net consist of foreign currency transaction gains and losses arising from transactions denominated in foreign currencies.

Interest Income

Interest income primarily relates to interest on cash, cash equivalents and available-for-sale debt securities and is presented net of amortization or accretion of the premium or discount on purchase and sales of the debt securities.

Interest Expense, Net

Interest expense, net consists primarily of interest expense arising from amortization of the liabilities related to future royalties and milestones, pursuant to our collaboration agreements with Blackstone and BioNTech, using the effective interest rate method. On a quarterly basis, we assess the expected present value of the future Blackstone and BioNTech payments under the Blackstone Collaboration Agreement and BioNTech Agreements which may be received by us and future royalties and sales milestone payments to Blackstone and BioNTech 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 liabilities related to future royalties and 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 (Expense) Benefit

We are subject to corporate taxation in the U.K., U.S., Germany and Switzerland. Due to the nature of our business, we have generated losses since inception. Our income tax (expense) benefit recognized represents the sum of income tax payable or receivable in the U.K. and in the U.S.

Un-surrendered U.K. 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 U.K. of $545.6 million at December 31, 2024 and $418.1 million at December 31, 2023. No deferred tax assets are recognized on our U.K. losses and tax credit carryforwards because there is currently no indication that we will make sufficient taxable profits to utilize these tax losses and tax credit carryforwards. We carry a $3.2 million deferred tax asset balance related to the U.S. entity at December 31, 2024. 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 U.K. 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 U.K. “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, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		Change (in thousands)	Change (in percentage)
	2024	2023		
Product revenue, net	$ —	$ —	$ —	— %
License revenue	10,120	1,698	8,422	496 %
Total revenue, net	**10,120**	**1,698**	**8,422**	**496 %**
Cost and operating expenses:				
Cost of sales	(11,387)	—	(11,387)	100 %
Research and development expenses, net	(138,436)	(130,481)	(7,955)	6 %
Selling, general and administrative expenses	(101,086)	(46,745)	(54,341)	116 %
Loss on disposal of leasehold improvements	(223)	(3,791)	3,568	(94)%
Impairment of operating lease right-of-use assets and related property and equipment	(414)	(382)	(32)	8 %
Loss from operations	**(241,426)**	**(179,701)**	**(61,725)**	**34 %**
Other income, net	220	222	(2)	(1)%
Foreign exchange (losses) gains, net	(989)	2,639	(3,628)	(137)%
Interest income	32,355	13,505	18,850	140 %
Interest expense, net	(9,294)	(45,067)	35,773	(79)%
Total other income (expense), net	**22,292**	**(28,701)**	**50,993**	**(178)%**
Net loss before income tax	**(219,134)**	**(208,402)**	**(10,732)**	**5 %**
Income tax (expense) benefit	(1,528)	19	(1,547)	(8142)%
Net loss	**$ (220,662)**	**$ (208,383)**	**$ (12,279)**	**6 %**

License Revenue

License revenue amounting to $10.1 million for the year ended December 31, 2024 related to license revenue recognized pursuant to the License and Option Agreement with BioNTech. License revenue of $1.7 million for the year ended December 31, 2023 primarily related to the execution of the Cabaletta Bio Inc. (“Cabaletta”) Option and License Agreement, which included recognition of 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.

Cost of Sales

Cost of sales amounting to $11.4 million was recognized from November 8, 2024, the date of the FDA approval of AUCATZYL, to December 31, 2024, consisting primarily of salaries and other employment related costs, including share-based compensation expense, for employees engaged in manufacturing activities related to AUCATZYL, as well as outsourced professional services. It also consisted of direct production costs relating to commercial product manufactured, and allocated facility costs including maintenance, depreciation, utilities and rent.

Research and Development Expenses

The following tables provide additional detail on our R&D expenses (in thousands):

	Year Ended December 31,			
	2024	**2023**	**Change (in thousands)**	**Change (in percentage)**
Direct research and development expenses				
B cell malignancies (Obe-cel, AUTO1/22 & AUTO3)	$ 24,370	$ 22,855	$ 1,515	7 %
Other projects (AUTO4, AUTO5, AUTO6, AUTO7 & AUTO8)	2,003	3,098	(1,095)	(35) %
Total direct research and development expense	**26,373**	**25,953**	**420**	**2 %**
Research and development expense and unallocated costs:				
Personnel related (including share-based compensation)	74,329	63,542	10,787	17 %
Indirect research and development expense*	37,734	40,986	(3,252)	(8) %
Total research and development expenses	**$ 138,436**	**$ 130,481**	**$ 7,955**	**6 %**

** Indirect research and development expense includes U.K. research and development tax credits*

Research and development expenses increased by $7.9 million to $138.4 million for the year ended December 31, 2024 from $130.5 million for the year ended December 31, 2023 primarily due to:

- an increase of $12.0 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 $3.6 million in clinical trial costs, manufacturing costs and material transportation costs relating to research and development activities;
- a decrease of $5.2 million in legal fees and professional consulting fees in relation to our research and development activities;
- a decrease of $2.2 million related to our information technology infrastructure and support for information systems related to our research and development activities and facilities offset by an increase in depreciation and amortization related to property and equipment; and
- an increase of $0.3 million in U.K. R&D tax credits (decrease in R&D expense) due primarily to an increase in qualifying research and development expenditures related to the SME scheme.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $54.3 million to $101.0 million for the year ended December 31, 2024 from $46.7 million for the year ended December 31, 2023 primarily due to:

- an increase of $29.1 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 $22.1 million in commercial readiness costs including legal and professional fees due to increased commercial readiness activities being undertaken; and
- an increase of $3.1 million in information technology infrastructure and support for information systems and facility costs relating related to the conduct of corporate and commercial operations and the increase in space utilized for general and administrative activities and related to general office expenses.

Loss on Disposal of Property and Equipment

For the year ended December 31, 2024, a loss on disposal of $0.2 million was recognized related to a manufacturing facility in Stevenage, U.K that we exited. 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 the manufacturing facility exited in Stevenage, United Kingdom.

Foreign Exchange (Losses) Gains, Net

Foreign exchange (losses) gains, net decreased to a loss of $1.0 million for the year ended December 31, 2024 from a gain of $2.6 million for the year ended December 31, 2023. The (loss)/gain arises on a variety of items, including on U.S. dollar monetary assets and liabilities held by our main operating subsidiary in the U.K., including our cash and cash equivalents and liabilities related to future royalties and milestones.

Interest Income

Interest income increased to $32.4 million for the year ended December 31, 2024, as compared to $13.5 million for the year ended December 31, 2023. The increase in interest income of $18.9 million primarily relates to higher account balances associated with our cash, cash equivalents and marketable securities during the year ended December 31, 2024 as compared to the year ended December 31, 2023.

Interest Expense, Net

Interest expense, net decreased to $9.3 million for the year ended December 31, 2024 as compared to $45.1 million for the year ended December 31, 2023. Interest expense, net decreased by $35.8 million primarily due to changes in the assumptions used in the valuation of the Collaboration Agreement with Blackstone and the BioNTech License and Option Agreement for the year ended December 31, 2024 compared to the year ended December 31. 2023.

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 market AUCATZYL and advance our other product candidates through preclinical and clinical development and seek regulatory approval and pursue commercialization of any additional approved products. As a result, we will need significant additional capital to fund our operations until such time as we can generate significant revenue from sales of AUCATZYL or other products.

As of November 8, 2024, we have one product approved for commercial sale in the United States, AUCATZYL, of which the first commercial sale of AUCATZYL in the United States was made during January 2025. 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-equity market facility, through U.K. research and development tax credits and receipts from the SME and RDEC schemes, out-licensing arrangements and strategic collaboration and financing agreements. From our inception in 2014 through December 31, 2024, we have raised an aggregate of $1.7 billion from these capital sources.

As of December 31, 2024, we had cash and cash equivalents on hand of $227.4 million and available-for-sale debt securities of $360.6 million.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Year Ended December 31,	
	2024	**2023**
Net cash used in operating activities	$ (206,271)	$ (145,587)
Net cash used in investing activities	(394,552)	(10,986)
Net cash provided by (used in) financing activities	589,554	(883)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(261)	15,030
Net decrease in cash, cash equivalents and restricted cash	**$ (11,530)**	**$ (142,426)**

Net Cash Used in Operating Activities

During the year ended December 31, 2024, operating activities used $206.3 million of cash, resulting from our net loss of $220.7 million, and net cash used resulting from changes in our operating assets and liabilities of $23.6 million, partially offset by non-cash charges of $38.0 million. The non-cash charges related to interest expense accrued and cumulative catch-up adjustment of $8.9 million, share-based compensation of $15.5 million, depreciation and amortization of $7.6 million, non-cash operating lease expense of $4.7 million, foreign exchange differences of $1.9 million, impairment of operating lease right-of-use assets and related property and equipment of $0.4 million, loss on disposal of leasehold improvements of $0.2 million, and loss on termination of operating lease of $0.2 million which is partially offset by accretion of available-for-sale securities of $1.2 million and a deferred income tax movement of $0.2 million. Net cash used in operating activities resulting from changes in our operating assets and liabilities for the year ended December 31, 2024 consisted primarily of an increase in accrued expenses and other liabilities of $11.9 million, an increase in accounts payable of $1.6 million, offset by a $32.5 million increase in prepaid expenses and other current and non-current assets, an increase in inventories of $4.2 million, and a decrease in a $0.4 million in operating lease liabilities.

During the year ended December 31, 2023, operating activities used $145.6 million of cash, resulting from our net loss of $208.4 million, partially offset by net cash used resulting from changes in our operating assets and liabilities of $0.3 million and 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 partially 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 and a decrease in accounts payable of $0.5 million, offset by a $12.4 million decrease in prepaid expenses and other current and non-current assets, a decrease in long-term deposits of $0.9 million and an increase in accrued expenses and other liabilities of $1.0 million.

Net Cash Used In Investing Activities

During the year ended December 31, 2024, we used $394.5 million of cash in investing activities, including purchases of marketable securities of $359.7 million, purchases of property and equipment of $22.1 million, and acquisition of intangible assets of $12.7 million.

During the year ended December 31, 2023, we used $11.0 million of cash in investing activities which consisted primarily of purchases of property and equipment.

Net Cash Provided By (Used In) Financing Activities

During the year ended December 31, 2024, net cash provided financing activities was $589.6 million related to net aggregate proceeds raised from the BioNTech Agreements, our underwritten offering of ADSs and a Blackstone Development Payment paid by Blackstone to us upon the FDA approval of AUCATZYL.

During the year ended December 31, 2023, net cash used in financing activities was $0.9 million which pertains primarily to payments of equity issuance costs relating to a prior equity financing transaction..

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we begin to market and sell AUCATZYL, operate our new commercial manufacturing facility and advance the preclinical activities and clinical trials of our other product candidates. Our expenses will increase as we:

- establish and expand our sales, marketing and distribution infrastructure in connection with commercializing AUCATZYL and other product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- seek regulatory approvals for any other product candidates that successfully complete preclinical and clinical trials;
- hire additional manufacturing, 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 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 the development of our product candidates and commercialization of AUCATZYL. We also 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.

Based on our current clinical development and commercialization plans, we believe our existing cash and cash equivalents of $227.4 million and available-for-sale debt securities of $360.6 million at December 31, 2024, will enable us to fund our current and planned operating expenses and capital expenditure requirements for at least twelve months from the issuance of this 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:

- our ability to continue to execute our commercialization strategies for AUCATZYL and, if approved, our other product candidates;
- 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 AUCATZYL or any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sale of AUCATZYL or our other product candidates, should any 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 U.K. research and development tax credits and receipts from the SME and RDEC schemes, out-licensing agreements, or strategic collaboration agreements. To the extent that we raise additional capital through the sale of equity, the ownership interest of existing shareholders will be diluted. If we raise additional funds through other third-party funding, collaborations agreements, strategic alliances, out-licensing agreements 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, 2024, we had operating lease obligations of $52.6 million under non-cancellable leases for laboratory and office property in the United Kingdom and the United States. Further details of our operating leases are provided in Note 19 to our consolidated financial statements included in this Annual Report as well as Part I, Item 2 of this Annual Report.

Capital expenditures and 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, 2024, our unconditional purchase obligations for capital expenditures totaled $17.5 million and included signed orders for capital equipment and capital expenditure for construction and related expenditure relating to our properties in the U.K. and the United States. We expect to incur the full amount of these obligations within one year.

As of December 31, 2024, our unconditional purchase obligations for reagents and disposables totaled $0.6 million, which we expect to incur within one year.

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 ("B-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. In December 2024, the remaining $30 million Blackstone Development Payment was paid to the Company on the approval of AUCATZYL by the FDA. The Company considers the achievement of the specified regulatory milestone as probable when actually achieved (i.e., when the contingency resolves). 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 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.

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.

Allocation of transaction price using the relative standalone selling price

Upfront payments are allocated between performance obligations using our best estimate of the relative standalone selling price of the performance obligation. The relative standalone selling price is estimated by determining the market values of development and license obligations. As these inputs are not directly observable, the estimate is determined considering all reasonably available information including internal pricing objectives used in negotiating the contract, taking into account the different stage of development of each development program and consideration of adjusted-market data from comparable arrangements. Where performance obligations have been identified relating to material rights, the determination of the relative standalone selling price of these performance obligations also includes an assessment of the likelihood that the options will be exercised and any payments by the customer that are triggered upon exercising the right. This assessment involves significant judgment and could have a significant impact on the amount and timing of revenue recognition.

An assessment of the allocation of transaction price using the relative standalone selling price was required for the year ended December 31, 2024 and 2023 for the BioNTech License and Option Agreement, the Research, Option and License Agreement with Cabaletta and Research, Option and License Agreement with an investee of Syncona Portfolio Limited, respectively.

Liabilities related to future royalties and milestones, net and cumulative catch-up adjustments

We accounted for the Blackstone Collaboration Agreement ("Blackstone Collaboration Agreement Liability") and the BioNTech Obe-cel Product Revenue Interest, ("BioNTech Liability") as liabilities measured at amortized cost based on an effective interest rate determined at the outset of the arrangement. The Blackstone Collaboration Agreement Liability is measured based on our current estimates of the timing and amount of expected future royalty and milestone payments to be paid and the Blackstone Development Payments expected to be received over the estimated term of the agreement. Similarly, the BioNTech Liability is measured based on our current estimates of the timing and amount of expected future royalty expected to be paid over the estimated term of the agreement. Milestone payments ("BioNTech Milestone Payments") pursuant to the BioNTech License and Option Agreement are payable upon BioNTech's election, and therefore have not been included in the determination of the effective interest rate or in the measurement of the liability.

The liabilities are amortized using the effective interest rate, resulting in recognition of 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, milestone payments, 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 interest expense using the catch-up method.

Our estimate of the probability, timing and amount of expected future royalties and 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 interest expense over the estimated term of the agreements.

The carrying amount of the Blackstone Collaboration Agreement Liability and BioNTech Liability is based on our estimate of the future royalties, 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 or deficit of estimated present value of future royalty, milestone payments and the future Blackstone Development Payment received over the carrying amount is recognized as a cumulative catch-up adjustment within interest expense, net using the effective interest rate.

Recently Issued Accounting Pronouncements

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. We maintain significant amounts of cash 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 U.K. bank interest rates. As of December 31, 2024 and 2023, we had cash and cash equivalents of $227.4 million and $239.6 million, respectively. Our surplus cash has been invested in interest-bearing savings, money market funds and available for sale debt securities. An immediate hypothetical one percentage point change in interest rates would have resulted in a $2.3 million increase in interest income on our consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

As of December 31, 2024 and 2023, the Blackstone Collaboration Agreement Liability has a fixed effective interest rate and is not subject to any fluctuations due to interest rates. However, the effective interest rate for the BioNTech Liability may be subject to fluctuations due to the discretionary nature of certain contractual payments to us. We have no other debt outstanding that is subject to interest rate variability. The carrying amount of the Blackstone Collaboration Agreement Liability and BioNTech Liability is based on our estimate of the future royalties, 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 or deficit of estimated present value of future royalty, milestone payments and the future Blackstone Development Payment received over the carrying amount is recognized as a cumulative catch-up adjustment within interest expense, net using the effective interest rate.

Foreign Currency Exchange 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 and liabilities relating to future royalties and milestones 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, 2024, substantially all of our cash and cash equivalents were held by one of our U.K. subsidiaries, of which approximately 62% were denominated in pound sterling and approximately 38% were denominated in U.S. dollars, with immaterial amounts 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.

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 a foreign exchange loss of $1.0 million and a foreign exchange gain $2.6 million for the years ended December 31, 2024 and 2023 respectively 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 from available for sale debt securities and cash and cash equivalents. Our cash and cash equivalents and available for sale debt securities are held with multiple counterparties for varying periods according to our expected liquidity requirements. We monitor the credit rating of these counterparties on a regular basis. Our investment policy limits investments to certain types of instruments, such as available for sale debt securities, 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 consolidated financial statements required to be filed pursuant to this Item 8 begin on page F-1 of this Annual 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, 2024. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

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, 2024, 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, 2024 was effective.

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 review of our unaudited condensed consolidated financial statements for the quarter ended March 31, 2024, we identified a material weakness in relation to accounting for complex transactions. The material weakness did not allow us to identify, understand and evaluate the impact of certain key aspects of the accounting for the BioNTech Agreements. Our process as designed was inadequate to deal with the complexity of the accounting for the transaction and did not allow for an effective and timely evaluation of key aspects of the agreements and their impact on the consolidated financial statements.

We have taken steps to remediate the material weakness by (i) implementing structured project plans and project monitoring techniques; (ii) the use of summary outputs allowing for earlier review of key judgements, estimates and other factors which impact the financial statements; and (iii) enhancing our review process, and controls including building in more time to allow for its effective operation and iv) assessing resourcing needs and capabilities resulting additional resources being added to the finance team. We believe this material weakness was remediated at December 31, 2024.

Changes in Internal Control Over Financial Reporting

In connection with the review of our unaudited condensed consolidated financial statements for the quarter ended March 31, 2024, we identified a material weakness in relation to accounting for complex transactions. The material weakness did not allow us to identify, understand and evaluate the impact of certain key aspects of the accounting for the BioNTech Agreements. Our process as designed was inadequate to deal with the complexity of the accounting for the transaction and did not allow for an effective and timely evaluation of key aspects of the agreements and their impact on the financial statements.

We have taken steps to remediate the material weakness by (i) implementing structured project plans and project monitoring techniques; (ii) the use of summary outputs allowing for earlier review of key judgements, estimates and other factors which impact the financial statements; and (iii) enhancing our review process, and controls including building in more time to allow for its effective operation and (iv) assessing resourcing needs and capabilities. We believe this material weakness was remediated at December 31, 2024.

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, 2024 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, 2024, 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 20, 2025. There are no family relationships among any of our senior management or our directors.

NAME	AGE	POSITION(S)
Senior Management:		
Christian Itin, Ph.D.	60	Chief Executive Officer and Director
Robert Dolski	55	Senior Vice President, Chief Financial Officer
David Brochu	69	Senior Vice President, Chief Technical Officer
Alex Driggs	49	Senior Vice President, Legal Affairs and General Counsel
Miranda Neville	50	Senior Vice President, Chief Project Officer
Martin Pulé, MBBS	52	Senior Vice President, Founder, Chief Scientific Officer
Brent Rice	58	Senior Vice President, Chief Commercial Officer
Alexander Swan	60	Senior Vice President, Chief Human Resources Officer
Christopher Vann	60	Senior Vice President, Chief Operating Officer
Matthias Will, M.D.	52	Senior Vice President, Chief Development Officer
Christopher Williams, Ph.D.	45	Senior Vice President, Chief Business Development Officer
Non-Executive Directors:		
Michael Bonney	66	Chairman of the Board of Directors
Joseph Anderson, Ph.D.	65	Director
Robert Azelby	57	Director
Linda Bain	54	Director
John Berriman	76	Director
Cynthia Butitta	70	Director
Robert Iannone, M.D., M.S.C.E.	58	Director
Elisabeth Leiderman, M.D.	48	Director
Martin Murphy, Ph.D.	56	Director
Ravi Rao, M.D.	57	Director
William Young, Ph.D.	80	Director

Senior Management

Christian Itin, Ph.D. has served as our Chief Executive Officer since March 2016 and as a director since October 2014. He served as chair of our board of directors from October 2014 to September 2021. Prior to joining us, Dr. Itin served as chief executive officer and chair of the board of directors at Cytos Biotechnology Ltd, a biotechnology company, from November 2012 until it merged with Kuros Biosurgery Holding Ltd in January 2016. From January 2016 until June 2018, he served as chair of the board of directors, and from June 2018 to May 2019 as non-executive director, of Kuros Biosciences Ltd. Prior to that, 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 April 2021. Dr. Itin received a Diploma in Biology and a Ph.D. in Cell Biology from the University of Basel, Switzerland. In addition, he also 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 joined Autolus as Chief Financial Officer in 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 and the Company's financial strategy and management. Prior to that 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. He previously held senior finance positions at Moderna Therapeutics from June 2016 to May 2019, Forum Pharmaceuticals, Inc., and Human Genome Sciences, Inc., prior to its acquisition by GlaxoSmithKline. Mr. Dolski started his career at Amgen, Inc. He holds an MBA from The Wharton School and a BSc in civil engineering and strategic management from the University of Pennsylvania.

David Brochu has served as our Senior Vice President, Chief Technical Officer since January 2021. Prior to that, he served as our Senior Vice President, Head of Product Delivery from October 2019 to January 2021, and 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. Prior to Talecris, Mr. Brochu held engineering and technical operations leadership roles at Bayer and Warner Lambert in the United States, European Union and South America. Mr. Brochu has over 30 years of operational and development experience. He holds a B.S. in chemical engineering from Northeastern University.

Alex Driggs has served as our Senior Vice President, Legal Affairs and General Counsel since January 2024. He joined the Company in August 2018 as Vice President, Legal Affairs and General Counsel. Prior to joining Autolus, Mr. Driggs served in roles of escalating responsibility at Sucampo Pharmaceuticals between May 2015 and February 2018.As Senior Vice President and General Counsel he oversaw all legal aspects of Sucampo's acquisition by Mallinckrodt. Earlier in his career, he served as Associate General Counsel for Micromet prior to its acquisition by Amgen and, following the acquisition, as Senior Counsel in the licensing transactions group at Amgen. Mr. Driggs began his legal career as an associate in the Life Sciences and Technology Transactions groups at Cooley LLP. He holds a J.D. from the New York University School of Law and an A.B. in Philosophy from Harvard University.

Miranda Neville has served as our Chief Project Officer since March 2025, having previously served as the Company's Senior Vice President, Programme and Portfolio Management from July 2023 to March 2025, VP, Head of Programme and Portfolio Management from January 2023 to June 2023, VP, Global Operations & Delivery from October 2021 to January 2023, Executive Director, Global Head of Engineering from October 2020 to October 2021 and Senior Director, Global Engineering from November 2018 to September 2020. Prior to joining Autolus, Ms. Neville was a Partner at the consulting firm AllianceBio, where she spent four years supporting several clinical stage CDMO and commercial biopharmaceutical companies. She started her career at Human Genome Sciences, Inc., where she spent ten years in a variety of roles including manufacturing, engineering & program management, prior to its acquisition by GlaxoSmithKline. Ms. Neville holds a B.S. in Biology from West Virginia University.

Martin Pulé, MBBS has served as our Senior Vice President, Founder and Chief Scientific Officer since August 2014. He also served as a member of our board of directors from August 2014 to June 2018. Dr. Pulé has served as a clinical senior lecturer in the Department of Haematology at University College London Cancer Institute since 2010 and been an Honorary Consultant in Haematology at University College London 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 MBBS 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 & Site Head (US) since December 2021, having previously served as our Vice President, Chief Commercial Officer (US) from June 2020 to December 2021 and 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 November 2017 to August 2018, where he was responsible for building their Payer, Access and Reimbursement strategy and capability. Prior to joining Juno Therapeutics, Brent spent 18 years with Amgen from December 1999 to October 2017 in positions of escalating responsibility, where he was recognized as a strong cross-functional leader supporting Amgen's portfolio of products through innovative partnerships and life cycle management. Brent holds a B.A. 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. Mr. Swan joined Autolus in May 2018 as our Vice President, Human Resources and was promoted to Senior Vice President, Human Resources in October 2021. Prior to joining Autolus, he was EMEA Head of Human Resources for Kite where he was responsible for all aspects of HR, ranging from 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. In these roles, he specialized in start-up strategies and processes for HR. 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 NHS, 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 October 2016. Prior to joining us, he worked at Hoffmann-La Roche's Swiss headquarters from February 1994 to September 2016, most recently serving as its commercial director from December 2011 to September 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 of global lifecycle management of oncology products as well as implementing marketing strategy at a regional and national level. This includes supporting the launch of several oncology, immunology and transplant products in the United States, United Kingdom, Romania, Russia, South Africa and Asia. Mr. Vann holds a B.S. in Toxicology and Pharmacology from the School of Pharmacy, University of London.

Matthias Will, M.D., has served as our Chief Development Officer since September 2024. Previously, he served as Chief Medical Officer at the privately held biotech company, Dren Bio, Inc., During his tenure, Matthias led the expansion of the clinical team and oversaw the submission of two INDs for candidates to potentially treat hematologic cancers. Prior to that, he served as Vice President of Clinical Development for CRISPR Therapeutics where he led the development of their allogeneic CAR T programs targeting CD70 in T-cell lymphomas and renal cell carcinoma and the early stage CD70-NK cell program in collaboration with NKarta Inc. Previously, Dr. Will was in charge of clinical development at CytomX Therapeutics Inc. and held roles of increasing responsibility in clinical development at Gilead Sciences, Inc. and Novartis Oncology. Earlier in his career, he served at McKinsey & Company, where he strategically advised clients in the pharmaceutical industry. Dr. Will received his Medical Degree from the Hannover Medical School and his training in hematology/oncology at the University of Tübingen, Germany.

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 until February 2024, and as Vice President, Global Head of Business Development from December 2018 until October 2021. Dr. Williams was part of the team that founded Autolus Limited, our predecessor entity, in 2014 and he initially served as a non-executive director of Autolus Limited. In 2016, he transitioned into the Company to establish our business development function as Director, Business Development. Previously, he 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. Prior to that, he served as non-executive director of Orchard Therapeutics Limited, another 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 BSc in Genetics from Cardiff University.

Non-Executive Directors

Michael Bonney has served on our board of directors since April 2024. He currently serves as a director of Alnylam Pharmaceuticals, Inc., a role he has held since December 2014. He previously served as chair of the board of directors of Alnylam from December 2015 to August 2021 and as its executive chair from August 2021 to January 2023. Mr. Bonney previously served as the chair of the board of directors of Kaleido Biosciences, Inc., a biotechnology company, from June 2017 until August 2021. Between August 2018 and October 2020, he served as Kaleido's executive chair and served as Kaleido's Chief Executive Officer from June 2017 until August 2018. Mr. Bonney was a Partner at Third Rock Ventures, a healthcare venture firm, from January 2016 to July 2016. Mr. Bonney previously served as the Chief Executive Officer and a member of the board of directors of Cubist Pharmaceuticals, Inc., a biopharmaceutical company (now a wholly owned subsidiary of Merck & Co., Inc.), from June 2003 until his retirement in December 2014. From January 2002 to June 2003, he served as Cubist's President and Chief Operating Officer. Mr. Bonney previously served as the chair of the board of directors of Magenta Therapeutics, Inc. and as a director of Bristol-Myers Squibb Company, Celgene Corporation (which was acquired by Bristol-Myers Squibb), Syros Pharmaceuticals, Inc. and Sarepta Therapeutics, Inc. Mr. Bonney holds a B.A. in economics from Bates College. We believe that Mr. Bonney is qualified to serve on our board of directors because of his experience serving in leadership positions at a wide variety of biotechnology companies.

Joseph Anderson, Ph.D. has served on our board of directors since February 2016. He is a Partner at Sofinnova Partners, which he joined in October 2020. Previously, he was the Chief Executive Officer and a member of the board of directors of Arix Bioscience plc, a global life sciences investment company, where he held similar positions since January 2016. He has founded and managed public equity funds and been 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 January 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 January 2004 through December 2015. From October 1999 through December 2003, Dr. Anderson was at First State Investments in London, part of the Commonwealth Bank of Australia, where he was the head of global healthcare equities and a portfolio manager. Prior to this, he was a pharmaceuticals analyst at the investment bank Dresdner Kleinwort Benson from June 1998 through October 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 F2G Limited and previously served as a non-executive director of RedX Pharma plc between September 2023 and May 2024. Dr. Anderson holds a Doctor of Philosophy in Biochemistry from the University of Aston and a Bachelor of Science 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 serving on boards of directors of various life science companies.

Robert Azelby has served on our board of directors since January 2024. Mr. Azelby served as President and Chief Executive Officer of Eliem Therapeutics, Inc., a biopharmaceutical company, from October 2020 to February 2023. Prior to Eliem, he served as the Chief Executive Officer of Alder BioPharmaceuticals, Inc. from June 2018 until its acquisition by H. Lundbeck A/S in October 2019. Mr. Azelby previously served as Executive Vice President, Chief Commercial Officer of Juno Therapeutics, Inc. from 2015 through its acquisition by Celgene in March 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 as a non-executive director of ADC Therapeutics SA since June 2023, and of Cardinal Health since March 2024. Mr. Azelby previously served on the Board of Directors of Chinook Therapeutics Inc. between April and August 2023, Clovis Oncology Inc. from October 2018 until July 2023, Eliem Therapeutics Inc. from October 2020 until February 2023, Alder BioPharmaceuticals Inc. from June 2018 until November 2019, and Immunomedics, Inc. from February 2020 to October 2020. He holds a BA 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 June 2018. Since May 2023, she has served as the chief operating officer and chief financial officer of Mariana Oncology, a Novartis Company as of May 2024. She has also served as a non-executive director of Arvinas, Inc. since June 2020, Hemab Therapeutics since January 2022, and VBI Vaccines, Inc. between July 2021 and September 2022. Prior to joining Mariana Oncology, Ms. Bain served as the chief financial officer of Codiak BioSciences, Inc. between December 2015 and April 2023 and chief financial officer and treasurer of Avalanche Biotechnologies, Inc. from April 2014 until November 2015. Previously, Ms. Bain served at bluebird bio, Inc., a gene therapy biotechnology company, as vice president of finance and business operations from October 2011 to March 2014, and chief accounting officer and treasurer from June 2013 to March 2014. From September 2008 to September 2011, Ms. Bain served as vice president of finance at Genzyme Corporation. From September 2007 to September 2008, she served as vice president at Fidelity Investments, and from May 2000 to September 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 August 2014. He has served as chair of the board of directors of Autifony Therapeutics Ltd since 2011. He previously served as chair of the board of directors of Depixus SAS between December 2015 and August 2024, Confo Therapeutics NV between December 2016 and August 2023, ReNeuron Group plc between April 2015 and September 2020, Heptares Therapeutics Ltd from 2007 until it was sold to Sosei Group in February 2015, Algeta ASA from 2004 through its listing on the Oslo Stock Exchange in 2007 (and subsequently served as deputy chair from 2008 until it was sold to Bayer AG in 2014), and as a director of Micromet, Inc. from May 2006 until it was sold to Amgen Inc. in 2012. Prior to this, 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 Master's degree 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 March 2018. Ms. Butitta served as the executive vice president and chief financial officer of Kite Pharma Inc., a biopharmaceutical company, from January 2014 to May 2016 and as its chief operating officer from March 2014 to September 2017. From May 2011 to December 2012, she served as senior vice president and chief financial officer at NextWave Pharmaceuticals, Inc., a specialty pharmaceutical company. Prior to that, Ms. Butitta served as chief operating officer of Telik, Inc., a biopharmaceutical company, from March 2001 to December 2010 and as its chief financial officer from August 1998 to December 2010. Ms. Butitta also served as principal accounting officer of Telik, Inc. until December 2010. She has served as a member of the board of directors of UroGen Pharma Ltd. since October 2017, Olema Pharmaceuticals Inc. since August 2020 and Century Therapeutics since February 2021. Ms. Butitta holds a B.S. 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 the Executive Vice President, Global Head of Research and Development at Jazz Pharmaceuticals plc, and as their 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. Prior to that, from July 2014 to April 2018, Dr. Iannone served in the roles of Senior Vice President and Head of Immuno-oncology, Global Medicines Development and the Global Products Vice President at AstraZeneca plc, a global science-led biopharmaceutical company. From 2004 to 2014, Dr. Iannone served in management roles at Merck Co., Inc., a global biopharmaceutical company, culminating in his role as Executive Director and Section Head of Oncology Clinical Development. From 2001 to 2004, he served as Assistant Professor of Pediatrics and from 2004 to 2012 as Adjunct Assistant Professor of Pediatrics at the University of Pennsylvania School of Medicine. Dr. Iannone has been serving on the board of directors of iTeos Therapeutics, Inc., a clinical-stage biopharmaceutical company, since May 2021, and on the Cancer Steering Committee of the Foundation for the National Institutes of Health since 2011. He also served as a director of Jounce Therapeutics, Inc., a clinical-stage immunotherapy company, between January 2020 and its acquisition by Concentra Biosciences in May 2023. Dr. Iannone received a B.S. from The Catholic University of America, an M.D. from Yale University and an M.S.C.E. from University of Pennsylvania and completed his residency in Pediatrics and 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 has served as the Chief Financial & Corporate Development Officer for Dewpoint Therapeutics since June 2024. She previously served as Chief Financial Officer and Chief Business Officer at Atsena Therapeutics, a clinical-stage gene therapy company, between November 2022 and November 2023. Before joining Atsena, from September 2020 to October 2022, Dr. Leiderman was Chief Financial Officer and Head of Corporate Development at Decibel Therapeutics, a clinical stage biotechnology company developing novel gene therapeutics for restoration of hearing loss and balance disorders. 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, Dr. Leiderman was Senior Vice President, Head of Corporate Development at Fortress Biotech from November 2016 to November 2019. Earlier in her career from 2007 to 2016, Dr. Leiderman developed her 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 earned 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. 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 September 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, as the chief executive officer of Syncona Investment Management Limited from December 2016 until December 2022, and founded Syncona Partners LLP and served as its chief executive officer from May 2012 to December 2016. Prior to that, 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. Since January 2025, Dr. Murphy has served as a non-executive director of Synairgen plc, a specialist respiratory biotech company listed on the London Stock Exchange. 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.

Ravi Rao, M.D,. has served on our board of directors since April 2024. He currently serves as Chief Medical Officer of Sitryx Therapeutics, having joined the company in April 2022. He was previously Chief Medical Officer at Oxford Biomedica, between April 2022 and November 2023, and Head of Research and Development and Chief Medical Officer at Swedish Orphan Biovitrum, where he led the development of several medicines in rare diseases across immunology and hematology, between September 2020 and February 2022. Before that, he worked at Roche Genentech and GlaxoSmithKline. Dr. Rao also serves as on the board of directors of DBV Technologies SA. Dr. Rao is an accredited rheumatologist and was an academic physician-scientist at Imperial College (London). He is a Member of the Royal College of Physicians, London and an Honorary Member of the Faculty of Pharmaceutical Medicine. He received his MB. BChir from Cambridge University and his Ph.D. in vascular biology from Imperial College, completing a postdoctoral fellowship at Harvard Medical School. We believe that Dr. Rao is qualified to serve on our board of directors because of his experience leading the development of drug pipelines at several biopharmaceutical companies

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 is a Senior Advisor to the Blackstone Life Sciences group since November 2018, following Blackstone's acquisition of Clarus Ventures. Dr. Young became a Venture Partner with Clarus in 2010 after serving as CEO of Monogram Biosciences, a leader in personalized medicine, from 1999 through to the sale of the company to LabCorp in 2009. Prior to Monogram he was at Genentech since 1980 in positions of increasing responsibility, including COO, responsible for all of the biotechnology company's development, operations and commercial functions. Prior to Genentech, Dr. Young was at Eli Lilly and Company for fourteen years. Dr. Young has served as a non-executive director of Praxis Precision Medicine since December 2016, of SFJ Pharma since July 2014 and of Satellite Bio since July 2022. He also served as chair of the board of directors of Nanostring Technologies from January 2010 until April 2024, as a non-executive director of Theravance Biopharma between October 2013 and April 2014, and as its lead independent director between April 2014 and May 2023. Previously he was chair of the board of directors of Biogen (NASDAQ: BIIB) and served on the Board of Directors of BioMarin Pharmaceutical and Vertex Pharmaceuticals. Dr. Young received his Bachelor'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. He is the founder of the Young Institute for the Advanced Manufacturing of Pharmaceuticals at Purdue University and a member of the Institute's Advisory Counsel. 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 20, 2025. Our 2024 Board Diversity Matrix is included in our Annual Report on Form 10-K, filed with the SEC on March 21, 2024.

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	12			
	Male	**Female**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	9	3	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	1	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.

Insider Trading Policy

Our board of directors has adopted an Insider Trading Policy that governs all transactions involving our securities by directors, officers, employees, consultants, and contractors and is reasonably designed to promote compliance with any insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

Composition of Our Board of Directors

Our board of directors presently has twelve 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, Murphy, Rao and Young, Mses. Butitta and Bain and Messrs. Azelby, Berriman, and Bonney representing eleven of our twelve 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 Ravi Rao, Joseph Anderson, Martin Murphy and Robert Iannone, whose terms will expire at our 2025 annual general meeting;
- Class II, which consists of Michael Bonney, 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 2027 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, Mr. Azelby, 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 the 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 (chair), Itin, Murphy, Rao and 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, 2024, as well as the amount contributed by us or our subsidiaries into money purchase plans for the year ended December 31, 2024 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, 2024, 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	£ 475,200	£ 306,504	£ —	£ 1,144,526	£ 1,926,230
John H. Johnson** Chairman of the Board	£ 13,327	£ —	£ —	£ 14,777	£ 28,104
Michael Bonney* Chairman of the Board	£ 39,375	£ —	£ —	£ 349,748	£ 389,123
Joseph Anderson, Ph.D. Non-Executive Director	£ 41,874	£ —	£ —	£ 147,826	£ 189,700
Robert Azelby*** Non-Executive Director	£ 36,278	£ —	£ —	£ 334,882	£ 371,160
Linda Bain Non-Executive Director	£ 48,378	£ —	£ —	£ 147,826	£ 196,204
John Berriman Non-Executive Director	£ 41,496	£ —	£ —	£ 147,826	£ 189,322
Cynthia Butitta Non-Executive Director	£ 42,996	£ —	£ —	£ 147,826	£ 190,822
Robert Iannone, M.D., M.S.C.E Non-Executive Director	£ 43,500	£ —	£ —	£ 150,438	£ 193,938
Elisabeth Leiderman, M.D. Non-Executive Director	£ 38,004	£ —	£ —	£ 288,447	£ 326,451
Martin Murphy, Ph.D. Non-Executive Director	£ 36,504	£ —	£ —	£ 147,826	£ 184,330
Ravi Rao, M.D.**** Non-Executive Director	£ 28,125	£ —	£ —	£ 274,606	£ 302,731
William Young, Ph.D. Non-Executive Director	£ 45,252	£ —	£ —	£ 151,411	£ 196,663

* *Mr. Bonney joined the board of directors effective April 1, 2024.*

** *Mr. Johnson resigned from the board of directors effective April 1, 2024.*

*** *Mr. Azelby joined the board of directors effective January 9, 2024.*

**** *Dr. Rao joined the board of directors effective April 1, 2024.*

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 2024, 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 for the nominating and governance committee chair and member from £7,000 to £8,000 and £3,500 to £4,000, respectively.

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 U.K. 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	8,000
Additional retainer for nominating and governance committee member	4,000
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. Similarly, a non-executive director who, in connection with their initial appointment to the board, is designated to serve as chair of a committee of the board shall receive an option to purchase 25,000 of our ADSs on the date of such appointment, 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.

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, 2024, the aggregate compensation accrued or paid to the members of our senior management for services, whether or not a director, in all capacities was $13.0 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 $2,829 in the year ended December 31, 2024.

Management Incentive Compensation Plan

In May 2016, the board of directors adopted the Management Incentive Compensation Plan, which it amended in October 2024 to reflect additional management tiers added since the plan's inception. 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, 2024 the compensation committee of our board of directors determined that our corporate goals were achieved at a level of 107.5%. Pursuant to the terms of the Management Incentive Compensation Plan, our Chief Executive Officer and executive director will receive an incentive award of £306,504, based on his target bonus percentage of 60%, an overall goal achievement level of 107.5%, and his base salary of £475,200.

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 their base salary as of the end of the plan year by the participant’s “target award multiplier”, which is a percentage ranging from 5% to 70%. 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, 2024.

Name	Ordinary Share Underlying Option	Exercise Price	Grant Date	Expiration Date
Senior Management				
Alex Driggs	200,000	$ 6.11	2/23/2024	2/23/2034
Christopher Williams, Ph.D.	200,000	$ 6.11	2/23/2024	2/23/2034
Matthias Will, M.D.	800,000	$ 3.63	9/30/2024	9/30/2024
Non-Executive Directors				
Michael Bonney*	120,000	$ 5.68	4/1/2024	4/1/2034
	80,000	$ 3.48	6/28/2024	6/28/2034
Joseph Anderson, Ph.D.	80,000	$ 3.48	6/28/2024	6/28/2034
Robert Azelby**	80,000	$ 6.84	1/9/2024	1/9/2034
	80,000	$ 3.48	6/28/2024	6/28/2034
Linda Bain	80,000	$ 3.48	6/28/2024	6/28/2034
John Berriman	80,000	$ 3.48	6/28/2024	6/28/2034
Cynthia Butitta	80,000	$ 3.48	6/28/2024	6/28/2034
Robert Iannone, M.D., M.S.C.E.	80,000	$ 3.48	6/28/2024	6/28/2034
Elisabeth Leiderman, M.D.	80,000	$ 3.48	6/28/2024	6/28/2034
Martin Murphy, Ph.D.	80,000	$ 3.48	6/28/2024	6/28/2034
Ravi Rao, M.D.***	80,000	$ 5.68	4/1/2024	4/1/2034
	80,000	$ 3.48	6/28/2024	6/28/2034
William Young, Ph.D.	80,000	$ 3.48	6/28/2024	6/28/2034

* *Mr. Bonney joined the board of directors effective April 1, 2024.*

** *Mr. Azelby joined the board of directors effective January 9, 2024.*

*** *Dr. Rao joined the board of directors effective April 1, 2024.*

As of December 31, 2024, members of our board of directors and senior management held vested share options to purchase an aggregate of 7,119,049 ordinary shares. No share options were exercised by any members of our board of directors and senior management during the year ended December 31, 2024.

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 U.K. 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, 2024, 32,943,013 ordinary shares may be issued under the 2018 Plan, of which 11,464,845 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 the 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 March 1, 2025 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 March 1, 2025. These ordinary shares, however, are not included in the computation of the percentage ownership of any other person. Percentage ownership calculations are based on 266,125,337 ordinary shares outstanding (including ordinary shares in the form of ADSs) as of March 1, 2025.

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, U.K.

NAME OF BENEFICIAL OWNER	Number of Ordinary Shares Beneficially Owned (#)	Percent of Ordinary Shares Beneficially Owned (%)
5% or Greater Shareholders:		
BioNTech SE (1)	33,333,333	12.5 %
Syncona Portfolio Limited (2)	30,734,957	11.5 %
Wellington Management Co. LLP (3)	25,345,680	9.5 %
BXLS V – Autobahn LP (4)	23,750,917	8.9 %
Qatar Investment Authority (5)	15,000,000	5.6 %
PPF Capital Partners Fund B.V. (6)	14,782,275	5.6 %
Deep Track Capital, LP (7)	14,218,903	5.3 %
Senior Management and Directors:		
Christian Itin, Ph.D. (8)	2,902,250	1.1 %
Robert Dolski (9)	281,249	*
David Brochu (10)	869,165	*
Alex Driggs (11)	259,495	*
Miranda Neville (12)	209,839	*
Martin Pulé, MBBS (13)	545,032	*
Brent Rice (14)	389,599	*
Alexander Swan (15)	551,872	*
Christopher Vann (16)	954,291	*
Matthias Will, M.D. (17)	—	*
Christopher Williams, Ph.D. (18)	489,979	*
Michael Bonney (19)	89,999	*
Joseph Anderson, Ph.D. (20)	228,333	*
Robert Azelby (21)	82,221	*
Linda Bain (22)	259,730	*
John Berriman (23)	380,362	*
Cynthia Butitta (24)	285,428	*
Robert Iannone, M.D., M.S.C.E. (25)	158,333	*
Elisabeth Leiderman, M.D. (26)	84,444	*
Martin Murphy, Ph.D. (27)	228,333	*
Ravi Rao, M.D. (28)	77,777	*
William Young, Ph.D. (29)	203,333	*
All directors and senior management as a group (22 persons) (30)	**9,531,064**	**3.6 %**

* Represents beneficial ownership of less than one percent.

(1) The information shown is based, in part, upon disclosures filed on a Schedule 13D on February 21, 2024 by BioNTech SE, "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.

(2) The information shown is based, in part, upon disclosures filed on a Schedule 13G/A on November 14, 2024 by Syncona Portfolio Limited. The number reported consists of (i) 12,180,333 ordinary shares and (ii) 18,554,624 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.

It should be noted that Martin Murphy stepped down from chair of Syncona Investment Management Limited (SIML) and therefore the Company has not included Syncona's shareholding in Martin's beneficial ownership calculations.

(3) The information shown is based, in part, upon disclosures filed on a Schedule 13F on February 14, 2025 and on a Schedule 13G on November 14, 2024 by Wellington Management Co. LLP. The number consists of 25,345,680 ADSs. Wellington Management Company LLP is a wholly owned subsidiary of Wellington Management Group LLP, a publicly-listed company. The address of the principal business office of Wellington Management Co. LLP is 280 Congress Street, Boston, MA 02210.

(4) 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.

(5) 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.

(6) The information shown is based, in part, upon disclosures filed on a Schedule 13D on October 25, 2024 by PPF Capital Partners Fund B.V., PPF Group N.V. and Renata Kellnerova. The number reported consists of 14,782,275 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.

(7) The information shown is based, in part, upon disclosures filed on a Schedule 13F on February 14, 2025 and on a Schedule 13G/A on November 14, 2024 by Deep Track Capital, LP. The number reported consists of 14,218,903 ADSs. 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.

(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) 1,786,241 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(9) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(10) Consists of (i) 113,125 ordinary shares issuable upon conversion of restricted stock units and (ii) 756,040 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(11) Consists of (i) 18,418 ordinary shares issuable upon conversion of restricted ordinary shares, and (ii) 241,077 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(12) Consists of (i) 33,720 ordinary shares issuable upon conversion of restricted ordinary shares, and (ii) 176,119 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(13) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(14) Consists of (i) 9,400 ADSs and (ii) 37,907 ordinary shares issuable upon conversion of restricted stock units and (iii) 342,292 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(15) Consists of (i) 38,657 ordinary shares issuable upon conversion of restricted stock units, and (ii) 513,215 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(16) 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) 802,080 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(17) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(18) 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) 461,973 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(19) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(20) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(21) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(22) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(23) Consists of (i) 62,794 ordinary shares and (ii) 73,537 ordinary shares issuable upon conversion of restricted ordinary shares, and (iii) 244,031 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(24) Consists of (i) 10,000 ADSs and (ii) 275,428 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(25) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(26) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(27) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(28) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(29) Consists of ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

(30) Consists of (i) 19,400 ADSs, (ii) 62,794 ordinary shares, (iii) 1,259,955 ordinary shares issuable upon conversion of restricted ordinary shares, (iv) 351,635 ordinary shares issuable upon conversion of restricted stock units and (v) 7,837,280 ordinary shares underlying options that are vested and exercisable within 60 days of March 1, 2025.

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, 2024, 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 56.8% of our outstanding ordinary shares (including ordinary shares underlying ADSs) were held in the United States by 213 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:	20,754,316 (1)	$5.41 (2)	11,464,845 (3)
Total	**20,754,316**		**11,464,845**

(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, 2024 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"

Transactions with Entities Affiliated with BioNTech

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. The product option for AUTO1/22 was not exercised and has expired as of February 8, 2025;
- 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 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.

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)
Fidelity Management & Research Company, LLC (1)	5,808,333	$ 34.9
Deep Track Capital, LP (2)	3,750,000	$ 30.0

(1) Fidelity Management & Research Company, LLC was a holder of more than 5% of our share capital as of December 31, 2024.
(2) Deep Track Capital, LP was a holder of more than 5% of our share capital as of December 31, 2024.

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, 2024 and 2023.

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, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Audit fees	$ 1,750	$ 1,146
Audit-related fees	336	81
Total	**$ 2,086**	**$ 1,227**

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, 2024 were pre-approved by the audit committee.

PART IV

Item 15. Exhibit and Financial Statement Schedule

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

EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT	INCORPORATED BY REFERENCE			
		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+	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
10.5†#	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
10.6†#	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 20-F	001-38547	4.7	3/4/21
10.7	Autolus Therapeutics plc, Registration Rights Agreement, dated as June 26, 2018	Form 20-F	001-38547	2.3	11/23/18
10.8	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
10.9	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
10.10	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
10.11†#	License and Option Agreement between the registrant and BioNTech SE, dated February 6, 2024.	Form 10-K	001-38547	10.12	3/21/24

10.12	Securities Purchase Agreement between the registrant and BioNTech SE, dated February 6, 2024.	Form 8-K	001-38547	10.1	2/8/24
10.13	Registration Rights Agreement between the registrant and BioNTech SE, dated February 6, 2024.	Form 8-K	001-38547	10.2	2/8/24
10.14	Letter Agreement between the registrant and BioNTech SE, dated February 6, 2024.	Form 8-K	001-38547	10.3	2/8/24
10.15†	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
10.16†	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
10.17†#	Capital Contribution Deed, dated September 10, 2024, 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	11/12/24
10.18†#	Deed of Variation, dated September 10, 2024, 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	10.2	11/12/24
10.19†#	License for Alterations, dated September 10, 2024, 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	10.3	11/12/24
10.20*+	Amended Management Incentive Compensation Plan				
10.21*	Exclusive Distribution Agreement, effective as of April 25, 2024, by and between Cardinal Health 105, Inc. and Autolus Inc.				
19.1*	Amended and Restated Insider Trading and Window Period Policy				
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	Form 10-K	001-38547	10.12	3/21/24
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 20, 2025

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 Robert Dolski 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.	Chief Executive Officer and Director	March 20, 2025
Christian Itin, Ph.D.	*(Principal Executive Officer)*	
/s/ Robert Dolski	Chief Financial Officer	March 20, 2025
Robert Dolski	*(Principal Financial Officer)*	
/s/ Andrew Mercieca	Vice President, Finance	March 20, 2025
Andrew Mercieca	*(Principal Accounting Officer)*	
/s/ Michael Bonney	Chairman of the Board of Directors	March 20, 2025
Michael Bonney		
/s/ Joseph Anderson, Ph.D.	Director	March 20, 2025
Joseph Anderson, Ph.D.		
/s/ Robert Azelby	Director	March 20, 2025
Robert Azelby		
/s/ Linda Bain	Director	March 20, 2025
Linda Bain		
/s/ John Berriman	Director	March 20, 2025
John Berriman		
/s/ Cynthia Butitta	Director	March 20, 2025
Cynthia Butitta		
/s/ Robert Iannone, M.D., M.S.C.E.	Director	March 20, 2025
Robert Iannone, M.D., M.S.C.E		
/s/ Elisabeth Leiderman, M.D.	Director	March 20, 2025
Elisabeth Leiderman, M.D.		
/s/ Martin Murphy, Ph.D.	Director	March 20, 2025
Martin Murphy, Ph.D.		
/s/ Ravi Rao, M.D.	Director	March 20, 2025
Ravi Rao		
/s/ William Young, Ph.D.	Director	March 20, 2025
William Young, Ph.D.		

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2024 and 2023, and the related consolidated statements of comprehensive loss, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2024 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

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 Matters

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

Liabilities related to future royalties and milestones, net (the "Liabilities")

Description of the matter	As explained in note 12 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 were initially recognized as a liability. In 2024, the Company entered into a similar arrangement with BioNTech SE ("BioNTech"), as detailed in note 1 to the consolidated financial statements. As disclosed in note 2 to the consolidated financial statements, the Liabilities are remeasured when significant assumptions associated with the underlying cashflows change. These assumptions include significant unobservable inputs, such as the probability of success of the clinical trial and regulatory approval ("POS"), patient volumes, and the estimated selling prices of products in different territories. Auditing the Company's measurement of the Liabilities was especially challenging, because the measurement involves significant management judgements about future events, which are inherently uncertain. In particular, the measurement of the Liabilities was sensitive to the Company's estimates of POS, patient volumes, and pricing of the products on which royalties will be paid.
How we addressed the matter	To test the measurement of the Liabilities, our audit procedures included among others, meeting with management to understand the basis for changes in the POS, patient volumes, and forecast selling prices. We evaluated the POS assumption, with the assistance of our life sciences specialist, by assessing industry benchmarks for similar products and analysts' reports. We evaluated management's patient volume model, including assessing inputs to the model and the reasonableness of the outputs, with the assistance of our life sciences specialists, by performing procedures such as examining published data from third party sources, reperforming calculations and conducting sensitivity analyses. We evaluated management's selling price assumptions, by comparing them to competitor prices from publicly available information. With the assistance of our financial modeling specialists, we evaluated the underlying financial model by performing recalculations and sensitivity analyses on significant assumptions and comparing them to those used by management.

BioNTech Transaction

Description of the matter	On February 6, 2024, the Company entered into a transaction with BioNTech ("the Transaction") as detailed in note 1 to the Company's consolidated financial statements. The Transaction included the recording of a liability related to a revenue sharing arrangement, the sale of an intellectual property license and the issuance of new ordinary shares. Auditing the Transaction involved complex auditor judgment, since there was significant judgment and subjectivity in management's accounting assessment, particularly in determining the separate components to account for and the allocation of the Transaction's proceeds between the components.
How we addressed the matter	To audit the accounting for the Transaction, we read the various Transaction agreements, while considering relevant accounting literature, to evaluate whether management's accounting position considered the relevant facts and terms included in the agreements, including management's determination of the detachability of the various components and embedded features and whether they should be accounted for separately. To assess the value assigned to the liability related to the revenue sharing arrangement, we used our valuation specialists to compare the effective interest rate determined by management against publicly available information for comparable arrangements. For the license revenue recognized from the sale of the intellectual property license, we assessed the allocated value by considering whether there were any material rights associated with other options granted as part of the transaction and by comparing their exercise prices to similar options sold separately by the Company. For the issuance of ordinary shares we recalculated the amount allocated using publicly available per share values on the date the transaction was announced.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Reading, United Kingdom

March 20, 2025

AUTOLUS THERAPEUTICS PLC

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	Note	December 31, 2024	December 31, 2023
Assets			
Current assets:			
Cash and cash equivalents		$ 227,380	$ 239,566
Marketable securities - Available-for-sale debt securities	6	360,643	—
Restricted cash		1,425	769
Inventories, net	7	4,138	—
Prepaid expenses and other current assets	8	67,343	34,967
Total current assets		**660,929**	**275,302**
Non-current assets:			
Property and equipment, net	9	49,553	34,862
Intangible assets, net	10	12,373	—
Prepaid expenses and other non-current assets		170	380
Operating lease right-of-use assets, net	19	55,498	60,791
Long-term deposits		963	983
Deferred tax asset	18	3,239	3,063
Total assets		**$ 782,725**	**$ 375,381**
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		1,969	103
Accrued expenses and other liabilities	11	52,276	39,581
Operating lease liabilities, current	19	2,998	5,053
Liabilities related to future royalties and milestones, net - current	12	3,500	—
Total current liabilities		**60,743**	**44,737**
Non-current liabilities:			
Operating lease liabilities, non-current	19	49,631	47,914
Liabilities related to future royalties and milestones, net - non-current	12	244,600	170,899
Other long-term payables		426	357
Total liabilities		**355,400**	**263,907**
Commitments and contingencies	20		
Shareholders' equity:			
Ordinary shares, $0.000042 par value; 490,909,783 shares authorized at December 31, 2024 and 290,909,783 as of December 31, 2023; 266,121,689 and 174,101,361 shares issued at December 31, 2024 and 2023, respectively; 266,125,337 and 174,158,985 shares outstanding at December 31, 2024 and 2023, respectively	14	12	8
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at December 31, 2024 and 2023	14	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at December 31, 2024 and 2023	14	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at December 31, 2024 and 2023	14	—	—
Additional paid-in capital		1,555,593	1,018,902
Accumulated other comprehensive loss		(29,174)	(28,992)
Accumulated deficit		(1,099,224)	(878,562)
Total shareholders' equity		**427,325**	**111,474**
Total liabilities and shareholders' equity		**$ 782,725**	**$ 375,381**

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, 2024	2023
Revenue:	3		
Product revenue, net		$ —	$ —
License revenue		10,120	1,698
Total revenue, net		**10,120**	**1,698**
Cost and operating expenses:			
Cost of sales		(11,387)	—
Research and development expenses, net		(138,436)	(130,481)
Selling, general and administrative expenses		(101,086)	(46,745)
Loss on disposal of property and equipment		(223)	(3,791)
Impairment of operating lease right-of-use assets and related property and equipment		(414)	(382)
Loss from operations		**(241,426)**	**(179,701)**
Other income, net		220	222
Foreign exchange (losses) gains, net		(989)	2,639
Interest income		32,355	13,505
Interest expense, net	4	(9,294)	(45,067)
Total other income (expenses), net		**22,292**	**(28,701)**
Net loss before income tax		**(219,134)**	**(208,402)**
Income tax (expense) benefit	18	(1,528)	19
Net loss		**(220,662)**	**(208,383)**
Other comprehensive income (loss), net of tax:			
Foreign currency exchange translation adjustment		135	9,906
Unrealized holding losses on available-for-sale debt securities, net of tax of $0 and $0		(317)	—
Total other comprehensive income (loss), net of tax		**(182)**	**9,906**
Total comprehensive loss		**$ (220,844)**	**$ (198,477)**
Basic and diluted net loss per ordinary share	16	$ (0.86)	$ (1.20)
Weighted-average basic and diluted ordinary shares	16	255,161,038	173,941,926

The accompanying notes are an integral part of these consolidated financial statements.

AUTOLUS THERAPEUTICS PLC

Consolidated Statements of Changes in 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, 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	—	—	—	—	—	—	—	—	—	—	(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**
Issuance of ordinary shares, net of issuance costs of $29,360	91,666,669	4	—	—	—	—	—	—	520,613	—	—	520,617
Share-based compensation expense	—	—	—	—	—	—	—	—	15,475	—	—	15,475
Vesting of restricted stock unit awards net of shares withheld to cover tax withholding	136,824	—	—	—	—	—	—	—	—	—	—	—
Exercise of share options	216,835	—	—	—	—	—	—	—	603	—	—	603
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(182)	—	(182)
Net loss	—	—	—	—	—	—	—	—	—	—	(220,662)	(220,662)
Balance at December 31, 2024	**266,121,689**	**$ 12**	**34,425**	**$ —**	**88,893,548**	**$ 118**	**1**	**$ —**	**$ 1,555,593**	**$ (29,174)**	**$ (1,099,224)**	**$ 427,325**

The accompanying notes are an integral part of these consolidated financial statements.

AUTOLUS THERAPEUTICS PLC

Consolidated Statements of Cash Flows
(In thousands)

	December 31, 2024	December 31, 2023
Cash flows from operating activities:		
Net loss	$ (220,662)	$ (208,383)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation on property and equipment	7,554	6,565
Amortization of intangible assets	162	—
Loss on disposal of property and equipment	223	3,791
Share-based compensation net of amounts capitalized	15,472	11,204
Interest expense accrued on liabilities related to future royalties and milestones, net	8,867	44,999
Accretion of available-for-sale securities	(1,251)	—
Foreign exchange differences	1,898	(7,604)
Non-cash operating lease expense	4,716	4,058
Loss on termination of operating lease	176	95
Impairment of operating lease right-of-use assets and related property and equipment	414	382
Deferred income tax	(185)	(986)
Changes in operating assets and liabilities		
(Increase) decrease in prepaid expenses and other current assets	(33,524)	10,695
Decrease in prepaid expenses and other non-current assets	938	1,726
Increase in inventories, net	(4,229)	—
Decrease in long-term deposits	5	937
Increase (decrease) in accounts payable	1,590	(509)
Increase in accrued expenses and other liabilities	11,934	998
Decrease in operating lease liability	(369)	(13,555)
Net cash used in operating activities	**(206,271)**	**(145,587)**
Cash flows from investing activities:		
Acquisition of property and equipment	(22,075)	(10,986)
Acquisition of intangibles assets	(12,744)	—
Investment in marketable securities: available-for-sale debt securities	(359,733)	—
Net cash used in investing activities	**(394,552)**	**(10,986)**
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	549,977	—
Proceeds from exercise of share options	602	27
Proceeds from liabilities related to future royalties and milestones, net	70,000	—
Payments of equity issuance costs	(29,360)	(910)
Payments of issuance costs related to the liabilities related to future royalties and milestones, net	(1,665)	—
Net cash provided by (used in) financing activities	**589,554**	**(883)**
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(261)	15,030
Net decrease in cash, cash equivalents and restricted cash	**(11,530)**	**(142,426)**
Cash, cash equivalents and restricted cash, beginning of period	**240,335**	**382,761**
Cash, cash equivalents and restricted cash, end of period	**$ 228,805**	**$ 240,335**

AUTOLUS THERAPEUTICS PLC

Consolidated Statements of Cash Flows
(In thousands)

	December 31, 2024	December 31, 2023
Supplemental cash flow information		
Cash paid for income taxes	$ (2,391)	$ (551)
Unrealized gains on marketable securities: available-for-sale debt securities	$ 1,251	$ —
Supplemental non-cash flow information		
Property and equipment purchases included in accounts payable or accrued expenses	$ 1,793	$ 433
Leased assets terminated and obtained in exchange for operating lease liabilities, net	$ (975)	$ 3
Leased assets obtained in exchange for operating lease liabilities	$ 1,694	$ 41,148
Capitalized share-based compensation, net of forfeitures	$ 3	$ 46
Capitalized implementation costs included in accrued expenses	$ 816	$ 564
Issuance costs included in accounts payable and accrued expenses	$ —	$ 272
Reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:		
Cash and cash equivalents	$ 227,380	$ 239,566
Restricted cash	$ 1,425	$ 769
Total cash, cash equivalents and restricted cash	**$ 228,805**	**$ 240,335**

The accompanying notes are an integral part of these consolidated financial statements.

Note 1. Nature of the Business

Autolus Therapeutics plc (with its subsidiaries, collectively, "Autolus" or the "Company") is an early commercial-stage 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 target 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 to offer patients substantial benefits over the existing standard of care, including the potential for cure in some patients. On November 8, 2024 Autolus was notified by the U.S. Food and Drug Administration (the "FDA") that its biologics license application ("BLA") was approved, allowing for the marketing of AUCATZYL (obecabtagene autoleucel, also known as obe-cel) in the US for the treatment of adult patients (18 years and older) with r/r B-ALL. Obe-cel is under regulatory review in both the European Union (the "EU") and the United Kingdom (the "U.K.") for the treatment of r/r B-ALL, with marketing authorization submissions accepted by the European Medicines Agency ("EMA") in April 2024, and the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") in August 2024. The Company expects to receive notification of approval status from these authorities in the second half of 2025. The commercial launch and first sale of AUCATZYL in the US occurred in January 2025.

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 subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. The Company's product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. Although AUCATZYL has been granted marketing approval in the US by the FDA, the Company will continue to incur significant additional costs to commercialize it. These efforts will require significant amounts of capital, as well as additional personnel, infrastructure, and compliance capabilities. Even if the Company's product development efforts for obe-cel and its other product candidates are successful, it is uncertain when, if ever, the Company will become profitable.

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.

BioNTech Agreements

On February 6, 2024 (the "Execution Date"), the Company concurrently entered into a (i) Securities Purchase Agreement (the "BioNTech Securities Purchase Agreement"), (ii) a Registration Rights Agreement (the "BioNTech Registration Rights Agreement"), (iii) a Letter Agreement (the "BioNTech Letter Agreement") and (iv) a License and Option Agreement (the "BioNTech License and Option Agreement"), collectively called the "BioNTech Agreements", with BioNTech. The BioNTech Agreements were entered into and in contemplation of one another and, accordingly, the Company assessed the accounting for these agreements in the aggregate. The following descriptions of the BioNTech Agreements do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements.

(i) BioNTech Securities Purchase Agreement

Pursuant to the BioNTech Securities Purchase Agreement the Company sold to BioNTech 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 (the "Initial ADSs"), representing 33,333,333 Ordinary Shares at an offering price of $6.00 per Initial ADS. Aggregate net proceeds to the Company, after underwriting discounts and offering expenses, were $193.8 million.

In the event that BioNTech and the Company enter into a Manufacturing and Commercial Services Agreement (as defined below) within 18 months of the initial closing of the Private Placement, 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 $20.0 million. The total number of Subsequent ADSs that may be issued is subject to additional limitations and restrictions.

The BioNTech Securities Purchase Agreement contains customary representations, warranties, and covenants of each of the Company and BioNTech.

(ii) BioNTech Registration Rights Agreement

Pursuant to the BioNTech Registration Rights Agreement the Company agreed to file a registration statement with the SEC to register the resale of the Private Placement ADSs.

(iii) BioNTech Letter Agreement

The BioNTech Letter Agreement provides BioNTech with certain additional rights and subjects BioNTech's investment in the Company to certain restrictions. 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 (including in the form of ADSs) 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 shall automatically terminate upon BioNTech's ownership of Ordinary Shares dropping below certain specified percentages. Additionally, 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.

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 BioNTech Letter Agreement terminates upon the earlier of (a) the later of (i) February 6, 2027 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.

(iv) BioNTech License and Option Agreement

License and Options

The Company, through its wholly owned subsidiaries, Autolus Limited and Autolus Holdings (U.K.) Limited, entered into the BioNTech License and Option Agreement with BioNTech pursuant to which the Company granted to BioNTech:

- an exclusive, worldwide, sublicensable license (the "Binder License") to certain binders and to exploit products that express in vivo such binders (collectively, the "Binder Licensed Products"), and
- 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:
    - an option to obtain exclusive rights to co-fund development costs of the Company's development-stage programs AUTO1/22 and AUTO6NG ("Product Options"), 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 each such product candidate. The product option for AUTO1/22 was not exercised and has expired as of February 8, 2025;
    - 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").

In consideration for the Binder License and the Technology Options, BioNTech made an initial payment to the Company of $10.0 million. 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 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.

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 and planned commercialization of obe-cel (through a revenue sharing arrangement). In exchange for the grant of rights to future revenues from the sales of obe-cel products, BioNTech made an upfront payment to us of $40.0 million. The Company will pay BioNTech a low single-digit percentage of annual net sales of obe-cel products, including revenues from sales of AUCATZYL, which may be increased up to a mid-single digit percentage in exchange for milestone payments of up to $100.0 million in the aggregate on achievement of certain regulatory events for specific new indications upon BioNTech's election. The Company expects to make initial payments of the revenue interest to BioNTech in 2025.

Manufacturing and Commercial Services Agreement

Under the terms of the BioNTech License and Option 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 Services Agreement" or "MCSA"). The MCSA, if entered into, would also grant BioNTech access to the Company's commercial site network and infrastructure.

The Company concluded there were four freestanding financial instruments arising from the execution of the BioNTech Agreements, comprising:

1. the Initial ADSs representing ordinary shares purchased pursuant to the BioNTech Securities Purchase Agreement;
2. the potential Subsequent ADSs representing ordinary shares that may be purchased pursuant to the BioNTech Securities Purchase Agreement;
3. the BioNTech License and Option Agreement, and
4. the MCSA.

The Subsequent ADSs are classified as a forward instrument contingent on the MCSA being executed. As of December 31, 2024, the MCSA had not been entered into. The forward instrument has an inconsequential market value as the exercise price approximates the Company's stock price on the last trading day prior to the signing date of the MCSA. Consequently, the initial proceeds arising from the purchase of Initial ADSs pursuant to the BioNTech Securities Purchase Agreement will not be separately allocated to this freestanding financial instrument at inception of the BioNTech Agreements. Furthermore, as the MCSA has yet to be entered into no consideration will be allocated to this freestanding financial instrument at inception of the BioNTech Agreements.

Within the BioNTech License and Option Agreement, there are a number of embedded features which have each been assessed for freestanding financial instrument accounting in accordance with Accounting Standards Codification ("ASC") 480 – *Distinguishing Liabilities from Equity*. Although these embedded features are separately exercisable, they lack legal detachability and, therefore, the BioNTech License and Option Agreement is accounted for as one freestanding financial instrument. However, each embedded feature is assessed for derivative accounting in accordance to ASC 815 – *Derivative and Hedging* ("ASC 815").

The Company analyzed how it should account for the host contract (i.e., the BioNTech License and Option Agreement) as the Binder License represents an agreement with customer for goods and services and therefore should be accounted for under ASC 606 – *Revenue from Contracts with Customers* ("ASC 606"). However, as the other embedded features of the BioNTech License and Option Agreement fall under the scope of other topics that specify how to initially measure the contract (i.e., ASC 470 – *Debt* ("ASC 470")), the Company determined that the host contract should not be accounted for and initially measured pursuant to ASC 606. Furthermore, the Company determined the host contract (the BioNTech License and Option Agreement) met the scope exception of ASC 815-10-15-59(d) and therefore should not be accounted for as a derivative under ASC 815 but instead be accounted for as a debt financial instrument in accordance with ASC 470.

The four units of accounting were recorded at fair value upon initial recognition and will not be subsequently measured at fair value. The Company allocated the total gross proceeds arising from the BioNTech Securities Purchase Agreement (i.e., the Initial ADSs representing ordinary shares), and the BioNTech License and Option Agreement among the four 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)*
Initial ADSs, representing ordinary shares	$ 200.0	$ 200.0	$ 200.0	$ 193.8
Subsequent ADSs, representing ordinary shares	$ —	$ —	$ —	$ —
BioNTech License and Option Agreement	$ 50.0	$ 50.0	$ 50.0	$ 47.9
Liabilities related to future royalties and milestones, net (*Obe-cel Product Revenue Interest*)	*$ 40.0*	*$ 40.0*	*$ 40.0*	*$ 38.3*
License Revenue *(Binder License)*	*$ 10.0*	*$ 10.0*	*$ 10.0*	*$ 9.6*
MCSA	$ —	$ —	$ —	$ —
Total	**$ 250.0**	**$ 250.0**	**$ 250.0**	**$ 241.7**

** In addition, the total shared transaction costs of $8.3 million, relating to the BioNTech Agreements have been allocated to the four units of accounting on a relative fair value basis.*

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

The Company has incurred losses of $220.7 million and $208.4 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company had an accumulated deficit of $1,099.2 million. The Company has funded its operations to date primarily with proceeds from the sale of its equity securities, including ADSs, licensing and collaboration arrangements and strategic financing. 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 US 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 present value of liabilities related to future royalties and milestones, net including the related interest expense and cumulative catch-up adjustment, lease term of the Company's manufacturing facility ("The Nucleus"), incremental borrowing rates related to the Company's leased properties and allocation of transaction price using the relative standalone selling price. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

Segment Information

The Company's chief operating decision maker (the "CODM"), its Chief Executive Officer and Executive Team members, manages the Company's operations on an integrated basis for the purpose of appropriately allocating resources. When evaluating the Company's financial performance, the CODM reviews total revenue, total expenses and expenses by function and makes decisions using this information on a global basis. The Company and the CODM view the Company's operations and manage its business as a single operating and reportable segment, which is the business of developing and commercializing CAR T therapies.

Foreign Currency Translation

The reporting currency of the Company is in U.S. dollars. The Company has determined that its functional currency of the ultimate parent company, Autolus Therapeutics plc, is British Pound Sterling. The functional currency of each subsidiary's operations is the applicable local currency. Monetary assets and liabilities denominated in currencies other than the Company's 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. Translation adjustments are not included in determining net income (loss) but are included in foreign currency translation to other comprehensive loss, a component of shareholders' equity.

The Company recorded a foreign exchange loss of $1.0 million and a foreign exchange gain of $2.6 million for the years ended December 31, 2024 and 2023, respectively, which are included in foreign exchange (losses) gains in the consolidated statements of operations and comprehensive loss.

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 consolidated 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.

Cash and cash equivalents

The Company considers all highly liquid investments with a maturity at acquisition date of three months or less to be cash equivalents. Cash and cash equivalents comprise cash balances, money market funds, commercial paper, U.K. government gilt, debt securities issued by foreign government and US treasury bills. Cash equivalents are primarily accessible on demand and have a weighted average maturity date of less than three months.

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.

Marketable securities: available for sale debt securities

The Company invests excess cash balances in marketable debt securities. The Company classifies investments in marketable debt securities as available-for-sale. Management determines the appropriate classification of its investments in available-for-sale debt securities at the time of purchase and reevaluates such designation as of each reporting date. The Company reports available-for-sale debt securities at fair value at each balance sheet date, and includes any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss), a component of shareholders' equity. Realized gains and losses are determined using the specific-identification method, and are included in other income, net in the consolidated statements of operations and comprehensive loss. Interest income and amortization of premiums and discounts at acquisition are included in Interest income. The Company classifies available-for-sale debt securities as current or non-current based on management's intentions.

The Company evaluates securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the issuer, and the Company's intent and ability to hold the investment to allow for an anticipated recovery in fair value. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Any impairment that is not credit- related is recognized in other comprehensive income (loss), net of applicable taxes.

Inventories, net

The Company commences capitalization of inventory once regulatory approval is received. Until this date, the Company expenses all such costs as incurred as research and development expenses. The Company capitalizes material costs, labor and applicable overheads that are incurred in the production of its commercial product. Inventory that can be used for either clinical, research or commercial purposes is classified initially as inventory. Inventory that is subsequently used in clinical trials or research activities is expensed once it has been used for research and development purposes.

On November 8, 2024, the Company received FDA approval for AUCATZYL and commenced capitalization of inventory from this date. There is no pre-launch inventory recognized on the balance sheet as of December 31, 2024.

Inventories are measured at the lower of cost or net realizable value, with cost determined using weighted average method for different components of inventory. The Company reviews the recoverability of inventory at each reporting period to determine any changes to net realizable value arising from excess, slow-moving or obsolete inventory. If net realizable value is lower than cost, the inventory will be written down to net realizable value and an impairment charge will be recognized in cost of sales.

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.

Property and Equipment, net

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, 2024 and 2023, 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.

Intangibles

Milestone payments made to third parties either on or subsequent to regulatory approval are capitalized as an intangible asset and amortized over the remaining useful life of the product. During the year ended December 31, 2024 the Company recognized a license milestone payment $12.5 million as an intangible asset due to the technology having alternative future use in research and development projects at the time of the payment. The minimum annual royalties have been expensed as incurred.

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.

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.

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.

Liabilities related to future royalties and milestones, net and related interest expense accrued on liabilities related to future royalties and milestones, net and cumulative catch-up adjustment

The Company accounted for the Blackstone Collaboration Agreement ("Blackstone Collaboration Agreement Liability") and the BioNTech Obe-cel Product Revenue Interest, ("BioNTech Liability") as liabilities measured at amortized cost based on an effective interest rate determined at the outset of the arrangement. The Blackstone Collaboration Agreement Liability is measured based on the Company's current estimates of the timing and amount of expected future royalty and milestone payments to be paid and the Blackstone Development Payments expected to be received over the estimated term of the agreement. Similarly, the BioNTech Liability is measured based on the Company's current estimates of the timing and amount of expected future royalty expected to be paid over the estimated term of the agreement. Milestone payments ("BioNTech Milestone Payments") pursuant to the BioNTech License and Option Agreement are payable upon BioNTech's election, and therefore have not been included in the determination of the effective interest rate or in the measurement of the liability.

The liabilities are amortized using the effective interest rate, resulting in recognition of interest expense over the estimated term of the agreement. Each reporting period the Company assesses the estimated probability, timing and amount of the future expected royalty, milestone payments, over the estimated term. If there are changes to the estimates, the Company recognize the impact to the liability's amortization schedule and the related interest expense using the catch-up method. The imputed rate of interest on the unamortized portion of the Blackstone Collaboration Agreement Liability was approximately 15.80% as of December 31, 2024 and 2023, respectively. The imputed rate of interest on the unamortized portion of the BioNTech Liability was approximately 28.70% as of February 6, 2024, the execution date of the BioNTech Agreements and December 31, 2024 respectively.

The Company's estimate of the probability, timing and amount of expected future royalties and milestones to be paid by the Company, considers significant unobservable inputs. These inputs include regulatory approval, the estimated patient population, estimated selling price, estimated sales volumes, estimated peak sales and sales ramp, timing of the expected launch and its impact on the royalties as well as the overall probability of success. Additionally, the transaction costs associated with the liability will be amortized to interest expense over the estimated term of the agreements.

The carrying amount of the Blackstone Collaboration Agreement Liability and BioNTech Liability is based on the Company's estimate of the future royalties, milestones to be paid to Blackstone by the Company and the expected Blackstone Development Payment to be received over the life of the arrangement as discounted using the initial effective interest rate. On a quarterly basis, the Company assesses the amount and timing of expected royalty using a combination of internal projections and forecasts from external sources. The excess or deficit of estimated present value of future royalty, milestone payments and the future Blackstone Development Payment received over the carrying amount is recognized as a cumulative catch-up adjustment within interest expense, net using the effective interest rate.

The Company will recognize the relevant portion of royalties or sales milestones due to Blackstone and BioNTech upon the commercialization of AUCATZYL or other products as a decrease to the applicable liabilities, with a corresponding reduction in cash.

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).

Cost of sales

Cost of sales represents production costs including raw materials, employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in commercial manufacturing functions, external manufacturing costs including outsourced professional expenses services, allocated facilities costs, depreciation and other expenses, and other costs incurred in bringing inventories to their location and condition prior to sale. Cost of sales may also include costs related to excess or obsolete inventory adjustment charges and amortization expense of intangible assets.

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. Upfront and milestone payments to third parties for in-licensed products or technology which has not yet received regulatory approval and which does not have alternative future use in R&D projects or otherwise are expensed as incurred.

U.K. 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 U.K. The Company claims U.K. research and development tax credits under the regimes for small or medium-sized enterprises ("SME R&D tax credit"), and U.K. Research and Development Expenditure Credit ("RDEC"), to the extent that the Company's projects are grant funded.

The U.K. 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 U.K. 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 U.K. research and development tax credits generated are needed to offset a corporate income tax liability in the U.K., 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.

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.

Interest Income

Interest income arises on the Company's cash and cash equivalents including money market funds, short-term deposits and marketable securities classified as available for sale debt securities.

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 has elected to account for forfeitures of stock options when they occur by reversing share-based compensation expense previously recognized, in the period the award is forfeited, for an award that is forfeited before completion of the requisite service period.

The fair value of each share option grant is estimated on the date of grant using the Black-Scholes option pricing model. See Note 15, "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 historically lacked company-specific historical and implied volatility information for the Company's ADSs for expected terms greater than 6.08 years. Up to June 30, 2024, the Company used 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. From July 1, 2024, the Company used its own historical 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 a delegate of the Compensation Committee.

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 U.K. 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.

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 to 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 16, "Net Loss Per Share".

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents, restricted cash and marketable securities: available-for-sale debt securities. 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.

Recently Issued Accounting Pronouncements

In January 2025, the FASB issued ASU 2025-01—*Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date,* to clarify the effective date of *ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* FASB clarified that all public business entities should initially adopt the disclosure requirements in the ASU 2024-04 in the first annual reporting period beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03—*Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses,* to improve the disclosures about entity's expenses. The amendments apply to all public business entities. The ASU is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027 with early adoption permitted. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In March 2024, the FASB issued ASU 2024-02—*Codification Improvements—Amendments to Remove References to the Concepts Statements*, that contains amendments to the Codification that remove references to various FASB Concepts Statements. This effort facilitates Codification updates for technical corrections such as conforming amendments, clarifications to guidance, simplifications to wording or the structure of guidance, and other minor improvements. The amendments are effective for public business entities for fiscal years beginning after December 15, 2024, with early adoption permitted. Early application of the amendments in this ASU is permitted for all entities, for any fiscal year or interim period for which financial statements have not yet been issued (or made available for issuance). If an entity adopts the amendments in an interim period, it must adopt them as of the beginning of the fiscal year that includes that interim period. The Company is currently assessing the effect of this ASU on its consolidated financial statements and related disclosures.

In March 2024, the FASB issued ASU 2024-01—*Compensation—Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards,* to improve GAAP by adding an illustrative example that includes four fact patterns to demonstrate how an entity should apply the scope guidance in paragraph 718-10-15-3 to determine whether a profits interest award should be accounted for in accordance with Topic 718, Compensation—Stock Compensation. For public business entities, the amendments in this ASU are effective for annual periods beginning after December 15, 2024, and interim periods within those annual periods. Early adoption is permitted for both interim and annual financial statements that have not yet been issued or made available for issuance. If an entity adopts the amendments in an interim period, it should adopt them as of the beginning of the annual period that includes that interim period. The Company does not expect the adoption of ASU 2024-01 to have a material effect on its financial statements and related 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 Company intends to adopt the guidance in the fiscal year beginning January 1, 2025. The Company does not expect the adoption of ASU 2023-09 to have a material effect on its financial statements and related disclosures.

In November 2023, the 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. The amendments should be applied retrospectively to all prior periods presented in the financial statement. The Company adopted the guidance in its Annual Report on Form 10-K for the year ended December 31, 2024 and additional disclosures have been included in Note 22.

Note 3. Revenue

Product revenue, net

On November 8, 2024 the Company was notified by the FDA that the Company's BLA was approved, allowing for the marketing of AUCATZYL in the US for the treatment of adult patients with r/r B-ALL. The Company has not recognized product revenue during the year ended December 31, 2024.

License revenue

License revenue by geographical location for the years ended December 31, 2024 and 2023 comprised of the following (in thousands):

	Year Ended December 31,	
	2024	2023
License revenue		
United Kingdom	$ —	$ 346
United States	—	1,352
Europe	10,120	—
Total License revenue	**$ 10,120**	**$ 1,698**

License and Option Agreement with BioNTech

See Note 1 for a description of the BioNTech License and Option Agreement, under which the Company recognized revenue during the year ended December 31, 2024. For further details on the terms and accounting treatment considerations for the BioNTech Agreement, refer to following notes to these consolidated financial statements:

- Note 1, "Nature of the Business"
- Note 2, "Summary of Significant Accounting Policies"
- Note 12, "Liabilities Related to Future Royalties and Milestones, Net"
- Note 14, "Shareholders' Equity"
- Note 20, "Commitments and Contingencies"

As the BioNTech License and Option Agreement has been accounted for as one freestanding financial instrument with various embedded features, including the Binder License and related transfer of know-how, Technology Options, and Product Options, the Company is required to consider if the embedded features are required to be bifurcated from the host contract and therefore accounted for as a separate derivative. The Company concluded the Binder License and related transfer of know-how, Technology Options, and Product Options meet the scope exception set out in ASC 815-10-15-59(d) and therefore not accounted for as derivatives under ASC 815.

Binder License

The Company applied ASC 606 to account for the Binder License and related know-how as functional intellectual property. The Binder License and related transfer of know-how were not distinct from one another and must be combined as a performance obligation, as BioNTech requires the know-how to derive benefit from the license. Based on these determinations, the Company identified one combined distinct performance obligation at the inception of the BioNTech License and Option Agreement.

The Company further determined the consideration received included in the transaction price at contract inception, is to be allocated to the one combined 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 Binder License to BioNTech. The Company recognized total license revenue of $10.1 million (net of foreign exchange differences), related to the BioNTech License and Option Agreement during the year ended December 31, 2024.

The Company is eligible to receive milestone payments of up to $32.0 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 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 BioNTech License and Option 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. Milestone payments and royalty payments are regarded as variable consideration and will be evaluated under the most likely amount method. Milestone payments and royalty payments were not included in the transaction price, as these amounts were fully constrained as of December 31, 2024.

Technology Options

The Company applied ASC 606, considering particularly the accounting guidance related to any options granted to customers to purchase additional goods or services at a future date as this could provide a material right to the customer. A material right is a promise embedded in a current contract that should be accounted for as a separate performance obligation. The Company determined the Technology Options were not offered at a significant and incremental discount. Accordingly, the Technology Options granted to BioNTech do not represent a material right and, therefore, were not a performance obligation at the outset of the arrangement. The Technology Option exercise fee equates to the standalone selling price of the technologies underlying each option and consequently, the transaction price of $10.0 million was not allocated to the Technology Options' performance obligation. No Technology Options were exercised during the year ended December 31, 2024.

Product Options

As the Product Options are precluded from being accounted for under ASC 815 due to the scope exception, management considered the terms of the Product Options and concluded that they should be accounted for as a gain contingency under the scope of ASC 450 - *Contingencies* ("ASC 450"). The Product Options, unlike the Technology Options, are 1) still subject to negotiation as to the specific activities to be performed by each party, which will be determined and agreed before the Product Options can be exercised, and 2) have not been exercised upon signature of the BioNTech License and Option Agreement. As a result, Product Options are not accounted for under to ASC 606, and no recognition is required under ASC 450, until the Product Options are exercised. No Product Options were exercised during the year ended December 31, 2024.

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. No license revenue was recognized related to the Cabaletta Agreement for the year ended December 31, 2024.

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.

The future milestones, which represent variable consideration, will be evaluated under the most likely amount method, and were not included in the transaction price, as these amounts were fully constrained as of December 31, 2024. For the year ended December 31, 2024 and 2023, the Company has not recognized any variable consideration with regards to the development milestones and sales-based milestones with its customers as they are deemed not probable.

For the years ended December 31, 2024 and 2023, the Company has not recognized any royalty revenue from the license agreements that were executed in the current and prior periods.

Note 4. Interest Expense, Net

Interest expense, net consisted of the following (in thousands):

	Year Ended December 31,	
	2024	**2023**
Interest expense accrued on liabilities related to future royalties and milestones, net (refer to Note 12)	$ 39,510	$ 19,892
Cumulative catch-up adjustment arising from the liabilities related to future royalties and milestones, net (refer to Note 12)	(30,644)	25,107
Other interest expense	428	68
	$ 9,294	**$ 45,067**

Note 5. 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, 2024			
	Aggregate estimated fair value	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Assets classified as cash equivalents:				
Money market funds	$ 113,447	$ 113,447	$ —	$ —
Commercial paper	14,301	—	14,301	—
Debt Securities issued by Foreign Government	54,897	—	54,897	—
U.K. Government Gilts	29,358	—	29,358	—
US Treasury Bills	7,989	7,989	—	—
	$ 219,992	**$ 121,436**	**$ 98,556**	**$ —**
Assets classified as marketable securities: available-for-sale debt securities				
Commercial paper	$ 21,141	$ —	$ 21,141	$ —
Corporate debt securities	151,124	—	151,124	—
Debt Securities issued by Foreign Government	72,012	—	72,012	—
U.K. Government Gilts	69,295	—	69,295	—
US Treasury Bills	47,071	47,071	—	—
	$ 360,643	**$ 47,071**	**$ 313,572**	**$ —**
	$ 580,635	**$ 168,507**	**$ 412,128**	**$ —**

	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)
Assets classified as cash equivalents:				
Money market funds	$ 184,635	$ 184,635	$ —	$ —
	$ 184,635	**$ 184,635**	**$ —**	**$ —**

The Company estimates the fair value of available-for-sale debt securities using actual trade and indicative prices sourced from third-party providers on a daily basis to estimate the fair value. If observed market prices are not available (for example securities with short maturities and infrequent secondary market trades), the securities are priced using a valuation model maximizing observable inputs, including market interest rates.

As of December 31, 2024 and 2023, the Company did not have non-financial assets measured at fair value on a recurring basis. During the years ended December 31, 2024 and 2023, there were no transfers between levels.

Note 6. Marketable Securities: Available-For-Sale Debt Securities

As of December 31, 2024, the Company has the following investments in available-for-sale debt securities, which are categorized as marketable securities: available-for-sale debt securities on the balance sheet depending on their maturity at acquisition (in thousands):

	December 31, 2024				
	Remaining contractual maturity	Amortized cost	Gross unrealized gains	Gross unrealized losses	Aggregate estimated fair value
Marketable securities: available-for-sale debt securities:					
Commercial paper	within 1 year	$ 21,145	$ 3	$ (7)	$ 21,141
Corporate debt securities	within 1 year	91,853	5	(70)	91,788
Debt Securities issued by Foreign Government	within 1 year	72,056	—	(44)	72,012
U.K. Government Gilts	within 1 year	69,320	—	(25)	69,295
US Treasury Bills	within 1 year	29,663	12	—	29,675
Corporate debt securities	1 to 5 years	59,530	—	(194)	59,336
US Treasury Bills	1 to 5 years	17,393	7	(4)	17,396
Total		**$ 360,960**	**$ 27**	**$ (344)**	**$ 360,643**

There were no available-for-sale debt securities as of December 31, 2023.

The number of securities held by the Company and aggregate fair value (in thousands) and in an unrealized loss position as of December 31, 2024 are as follows (in thousands):

	December 31, 2024		
	Number of securities held	Gross unrealized losses	Fair market value of investments in an unrealized loss position
Marketable securities: available-for-sale debt securities in a continuous loss position for less than 12 months:			
Commercial paper	3	$ (6)	$ 8,944
Corporate debt securities	41	(264)	133,078
Debt Securities issued by Foreign Government	5	(45)	72,012
U.K. Government Gilts	3	(25)	69,295
US Treasury Bills	4	(4)	9,905
Total	**63**	**$ (355)**	**$ 356,957**

The aggregated net unrealized loss on available-for-sale debt securities in the amount of $0.3 million has been recognized in accumulated other comprehensive loss in the Company's consolidated balance sheet as of December 31, 2024.

At December 31, 2024, the Company held 63 marketable securities: available-for-sale debt securities out of its total investment portfolio that were in a continuous unrealized loss position. As of December 31, 2024, no allowance for expected credit losses has been recognized in relation to securities in an unrealized loss position. The related unrealized losses are not severe, have been for a short duration and are due to normal market, exchange rate fluctuations and all securities have an investment-grade credit rating. The Company neither intend to sell these investments nor conclude that the Company are more-likely-than-not that it will have to sell them before recovery of their carrying values. The Company also believe that it will be able to collect both principal and interest amounts due to the Company at maturity.

There were no amounts reclassified out of other comprehensive income (loss), net of tax during the year ended December 31, 2024.

Note 7. Inventories, Net

Inventories consisted of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 1,956	$ —
Work in progress	16	—
Finished goods	140	—
Consumables	2,026	—
Total inventories, net	**$ 4,138**	**$ —**

There were no inventory write-downs recorded for the year ended December 31, 2024.

Note 8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2024	2023
Research and development claims receivable	$ 38,242	$ 19,209
Prepayments	15,212	8,638
VAT receivable	5,996	2,771
Accrued interest income	2,566	999
Deferred cost	2,320	1,787
Other assets	1,571	—
Lease and lease deposit receivable	930	938
Other receivable	491	516
Accounts receivable	15	109
Total prepaid expenses and other current assets	**$ 67,343**	**$ 34,967**

Note 9. Property and Equipment, Net

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

	December 31,	
	2024	2023
Lab equipment	$ 41,728	$ 32,232
Office equipment	6,330	3,777
Furniture and fittings	2,359	2,360
Leasehold improvements	14,116	12,728
Assets under construction	19,638	12,539
Less: accumulated depreciation	(34,618)	(28,774)
Total property and equipment, net	**$ 49,553**	**$ 34,862**

Depreciation expense recorded for the years ended December 31, 2024 and 2023 was $7.6 million and $6.6 million, respectively.

Note 10. Intangible Assets, Net

The following table summarizes the carrying amount of the Company's intangible assets, net of accumulated amortization (in thousands):

	December 31,	
	2024	2023
Licensed IP rights	$ 12,535	$ —
Less: accumulated amortization	(162)	—
Total intangibles assets, net	**$ 12,373**	**$ —**

Amortization expense was $0.2 million and nil for the year ended December 31, 2024 and 2023, respectively. The estimated aggregate amortization expense expected to be recorded in respect of this asset for each of the five years ended 2029 is $1.1 million annually.

Note 11. Accrued Expenses and Other Liabilities

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

	December 31, 2024	December 31, 2023
Compensation and benefits	$ 19,681	$ 14,757
Research and development costs	13,372	19,825
Professional fees	9,075	4,466
Other accrued expenditure	6,075	—
VAT payable	3,594	—
Other liabilities	479	533
Total accrued expenses and other liabilities	**$ 52,276**	**$ 39,581**

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 12. Liabilities Related to Future Royalties and Milestones, Net

The following table summarizes the carrying amount of the Company's liabilities related to future royalties and milestones, net (in thousands):

	Amount in thousands
Balance at December 31, 2022	**$ 125,900**
Interest expense accrued on liabilities related to future royalties and milestones, net	19,892
Cumulative catch-up adjustment	25,107
Balance at December 31, 2023	**$ 170,899**
Initial recognition of BioNTech liability	38,335
Proceeds from Blackstone Development Payments received	30,000
Interest expense accrued on liabilities related to future royalties and milestones, net	39,510
Cumulative catch-up adjustment	(30,644)
Balance at December 31, 2024	**$ 248,100**

The following table summarizes the current versus non-current split of the liabilities related to future royalties and milestones, net (in thousands):

	December 31, 2024	December 31, 2023
Current portion of liabilities related to future royalties and milestones, net	$ 3,500	$ —
Non-current portion of liabilities related to future royalties and milestones, net	244,600	170,899
Total liabilities related to future royalties and milestones, net	**$ 248,100**	**$ 170,899**

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 14. “Shareholders' Equity”;

(iii) Warrant Agreement (the “Blackstone Warrant”) - refer to Note 13, “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 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 ("B-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. In December 2024, the remaining $30 million Blackstone Development Payment was paid to the Company on the approval of AUCATZYL by the FDA. The Company considers the achievement of the specified regulatory milestone as probable when actually achieved (i.e., when the contingency resolves).

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 granted a security interest in its subsidiary Autolus Limited to Blackstone in certain intellectual property and financial assets of the Company and its subsidiaries. The security interest terminated in January 2025 upon the first commercial sale of AUCATZYL in the U.S. (such time, the "Release Time").

The Blackstone Collaboration Agreement contains certain restrictive negative covenants that also expired 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. The Company will recognize the relevant portion of royalties or sales milestones due to Blackstone upon the commercialization of AUCATZYL or other products as a decrease to the applicable liabilities, with a corresponding reduction in cash.

On February 6, 2024, the Company concurrently entered into the BioNTech Agreements.

For further details on the terms and accounting treatment considerations for these contracts, refer to following notes to these interim condensed consolidated financial statements:

- Note 1, "Nature of the Business"
- Note 2, "Summary of Significant Accounting Policies"
- Note 3, "Revenue"
- Note 14, "Shareholders' Equity"
- Note 20, "Commitment and Contingencies"

Obe-cel Product Revenue Interest

Under the BioNTech License and Option Agreement, BioNTech has agreed to financially support the expansion of the clinical development program and planned commercialization of obe-cel. In exchange for the grant of rights to future revenues from the sales of obe-cel products, including AUCATZYL, BioNTech made an upfront payment to the Company of $40.0 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 $100.0 million in the aggregate on achievement of certain regulatory events for specific new indications upon BioNTech's election.

As the BioNTech License and Option Agreement has been accounted for as one freestanding financial instrument with various embedded features, (e.g. the Obe-cel Product Revenue Interest, milestone payments and royalties), the Company is required to consider if these embedded features are required to bifurcated from the host contract and therefore accounted for as a separate derivative. The Company determined the host contract to be debt-like and therefore the embedded features were analyzed pursuant to a debt host contract. The Company concluded the BioNTech License and Option Agreement (the host contract) should not be accounted as a derivative in accordance with ASC 815-10-15-59(d) but rather as a debt instrument under ASC 470.

The Company has accounted for the Obe-cel Product Revenue Interest as a liability primarily due to the Company's significant continuing involvement in generating the royalty stream. In February 2024, the Company initially recognized the BioNTech Liability at $38.3 million being the face value less debt issuance costs. Once the Company commences commercial sales of AUCATZYL that generate royalties, which the Company expect will occur in the first quarter of 2025, the Company will recognize the portion of royalties paid to BioNTech as a decrease to the liability with a corresponding reduction in cash.

The carrying amount of the BioNTech Liability is based on the Company's estimate of the future royalties to be paid to BioNTech to be received over the life of the arrangement as discounted using an effective interest rate. The excess or deficit of estimated present value of future royalties over the initial carrying amount, is recognized using the cumulative catch-up method within interest expense, net using the initial effective interest rate. The imputed rate of interest on the unamortized portion of the BioNTech Liability was approximately 28.70% as of February 6, 2024 and December 31, 2024,

Note 13. 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 considered whether the warrants were freestanding financial instruments, met the definition of a liability or whether the warrants met all of the requirements for equity classification, including whether the warrants were indexed to the Company's own shares, among other conditions for equity classification.

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 the Blackstone Warrant using the Black-Scholes option pricing model to be $10.7 million on November 6, 2021. As the Blackstone Warrant is classified as equity, it will not be remeasured at each reporting date.

Note 14. 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 (the "Board")and declared by the shareholders. As of December 31, 2024, 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 2024 (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, 2024, the Company's issued capital share consisted of (i) 266,121,689 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.

Restricted Stock Units

At December 31, 2024, restricted stock unit awards for 3,648 ordinary shares had vested but the underlying shares had not been issued. However, these vested restricted stock unit awards have been included in the calculation of the Company's outstanding shares at December 31, 2024 as they are considered issuable for little or no cash consideration. Subsequent to December 31, 2024, all of the underlying ordinary shares were issued.

Initial Public Offering ("IPO") 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 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 net proceeds to the Company, after underwriting discounts and offering expenses, were $326.8 million.

BioNTech Securities Purchase Agreement

Concurrently with the execution of the BioNTech License and Option Agreement (see Note 1 and Note 3), the Company and BioNTech entered into the BioNTech Securities Purchase Agreement pursuant to which the Company sold ADSs, each representing one ordinary share, to BioNTech in a Private Placement transaction. 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 net proceeds to the Company, after underwriting discounts and offering expenses, were $193.8 million.

In the event that BioNTech and the Company enter into the MCSA within 18 months of the initial closing of the Private Placement, BioNTech will purchase up to 15,000,000 ADSs for an aggregate purchase price of up to $20.0 million, subject to additional limitations and restrictions.

Note 15. 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 U.K. employees and for the grant of options to its U.S. employees.

In June 2018, the Company's the Board 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 32,943,013 as of December 31, 2024. As of December 31, 2024, 11,464,845 ordinary shares were available for future grant. 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 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, 2024 and 2023 were as follows:

	Year Ended December 31,	
	2024	**2023**
Expected option life (years)	3.14 to 6.08	5.19 to 6.08
Risk-free interest rate	3.56% to 4.86%	3.37% to 4.86%
Expected volatility	79.48% to 83.87%	83.25% to 85.51%
Expected dividend yield	0%	0%

Share Options

The table below summarizes Company's share option activity during the year ended December 31, 2024.

	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, 2023	17,956,385	$ 5.64	8.35	$ 48,968
Granted	4,283,550	4.09	—	62
Exercised	(216,835)	2.78	—	482
Forfeited	(962,370)	3.29	—	113
Expired	(306,414)	8.55	—	7
Outstanding as of December 31, 2024	20,754,316	$ 5.41	7.78	$ 1,536
Exercisable as of December 31, 2024	11,050,183	$ 7.34	6.91	$ 708
Vested and expected to vest as of December 31, 2024	20,754,316	$ 5.41	7.78	$ 1,536

(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, 2024

The total intrinsic value of options exercised was $0.5 million and $0.01 million, for the years ended December 31, 2024 and 2023, 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 $12.9 million and $11.4 million, for the years ended December 31, 2024 and 2023, respectively.

The weighted average grant-date fair value of share options granted was $2.96 and $1.69 per option for the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, the total unrecognized compensation expense related to unvested share options without performance conditions was $11.4 million, which the Company expects to recognize over a weighted average vesting period of 2.98 years.

Performance based share options

The Company did not grant share options with a specified regulatory performance condition during the year ended December 31, 2024, 15,000 performance-based share options were forfeited or expired. In addition, during the year ended December 31, 2024, 573,850 performance-based share options vested upon the achievement of the relevant regulatory milestone.

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, 2024 and 2023, all the performance condition related to these performance-based share options were met. As a result, $2.9 million and $1.0 million share-based compensation expense was recognized for the years ended December 31, 2024 and 2023, respectively.

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. 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 2023, the Company granted 90,000 RSU awards with a performance condition related to a specified regulatory milestone. These performance-based RSU awards have vested 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, 2024:

	Number of restricted units	Weighted average grant date fair value
Unvested and outstanding at December 31, 2023	116,436	$ 3.43
Vested	(82,848)	3.08
Forfeited	(1,176)	6.20
Unvested and outstanding at December 31, 2024	**32,412**	**$ 4.22**

As of December 31, 2024, there was less than $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 1.26 years.

The total fair value of share RSU awards vested (including performance-based RSU awards) amounted to $0.5 million and $1.3 million for the years ended December 31, 2024 and 2023, respectively.

Performance-based RSU awards

During the year ended December 31, 2024, the Company did not grant RSU awards with performance conditions.

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, 2024 there was no unrecognized share-based compensation expense relating to performance based RSU awards.

During the year ended December 31, 2024, 3,648 RSU awards vested but were not issued as of December 31, 2024, and as such are not included in the Company's outstanding shares at December 31, 2024. The shares corresponding to these RSUs awards were issued in January 2025.

Share-based compensation expense

Share-based compensation expense recorded as research and development expenses, selling, general and administrative expenses and cost of sales is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expenses	$ 5,593	$ 6,777
Selling, general and administrative expenses	9,622	4,473
Cost of sales	260	—
Capitalized to intangible assets, net / property and equipment	(3)	(46)
Total share-based compensation expense	**$ 15,472**	**$ 11,204**

Note 16. 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,	
	2024	**2023**
Numerator		
Net loss	$ (220,662)	$ (208,383)
Net loss attributable to ordinary shareholders - basic and diluted	**$ (220,662)**	**$ (208,383)**
Denominator		
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	255,161,038	173,941,926
Net loss per share - basic and diluted	**$ (0.86)**	**$ (1.20)**

For all periods presented, outstanding but 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,	
	2024	**2023**
Unvested RSUs	32,412	116,436
Share options	20,754,316	17,956,385
Warrants	3,265,306	3,265,306
Total	**24,052,034**	**21,338,127**

Note 17. 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. On November 8, 2024 the Company was notified by the FDA that the Company's BLA was approved, allowing for the marketing of AUCATZYL in the US for the treatment of adult patients (18 years and older) with r/r B-ALL. Consequently, the Company paid a regulatory milestone payment of £10.0 million to UCLB.

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 the Company and the passage of time. During the year ended December 31, 2024, $0.1 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.

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. There were no additional milestone payments deemed probable during the year ended December 31, 2024.

Note 18. Income Taxes

Loss before income tax benefit (expense) is as follows (in thousands):

	Year Ended December 31,	
	2024	**2023**
U.K.	$ (221,661)	$ (209,766)
U.S.	2,108	1,082
Switzerland and Germany	419	282
Net loss before income taxes	**$ (219,134)**	**$ (208,402)**

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

	Year Ended December 31,	
	2024	2023
U.S.		
Federal	$ (1,228)	$ (859)
State and local	(24)	(5)
U.K.	8	—
Switzerland and Germany	(459)	(104)
Total current tax expense	**(1,703)**	**(968)**
U.S.		
Federal	(140)	1,002
State and local	4	(15)
U.K.	—	—
Switzerland and Germany	311	—
Total deferred tax benefit	**175**	**987**
Total income tax (expense) benefit	**$ (1,528)**	**$ 19**

The Company recorded an income tax expense of $1.5 million and income tax benefit of less than $0.1 million, for the years ended December 31, 2024 and 2023, respectively.

Deferred tax assets consisted of the following at December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Other differences	$ 18,761	$ 14,834
Tax losses	136,406	104,534
Fixed assets	5,069	6,653
Total deferred tax assets	160,236	126,021
Valuation allowances	(156,997)	(122,958)
Net deferred tax asset	**$ 3,239**	**$ 3,063**

The movements in the deferred tax asset valuation allowance consisted of the following at December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Valuation allowance as of January 1,	$ (122,958)	$ (95,955)
Decrease in valuation allowance through net loss	(36,670)	(21,245)
Foreign currency translation adjustments	2,631	(5,758)
Valuation allowance as of December 31,	**$ (156,997)**	**$ (122,958)**

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,	
	2024	2023
Net loss before taxes	$ (219,134)	$ (208,402)
U.K. statutory tax rate	25.0%	23.5%
Income tax benefit at U.K. statutory tax rate	54,783	48,974
Tax-exempt reimbursable tax credits included within research and development expense	4,934	4,589
Non-deductible expenses	(26,810)	(31,268)
Adjustments in respect of prior years	2,316	(96)
Valuation allowance changes affecting the provision for income taxes	(36,670)	(21,245)
Other, net	(175)	(961)
Foreign rate differential	94	26
Total income tax (expense) benefit	$ (1,528)	$ 19
Current income tax expense	$ (1,703)	$ (968)
Deferred income tax benefit	$ 175	$ 987
Effective rate of income tax	0.7%	—%

The Company is headquartered and has subsidiaries in the United Kingdom. Additionally, the Company has subsidiaries in the United States, Germany and Switzerland. The Company incurs tax losses in the United Kingdom. The U.K. corporate income tax rate for the year ended December 31, 2024 was 25%, and was 23.5% for the years ended December 31, 2023. 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, 2024 and 2023.

Deferred tax assets resulting from loss carryforwards, fixed assets and retirement benefits, with total deferred tax assets increasing by $0.2 million in 2024. The Company has recorded a valuation allowance against the net deferred tax asset where the recoverability due to future taxable profits is unknown. The $3.2 million deferred tax asset balance is related to the Company's U.S. subsidiary entity.

At December 31, 2024, the Company had U.K. trading losses carryforward of $545.6 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, 2024:

Jurisdiction	Open Tax Years Based on Originally Filed Returns
United Kingdom	2022 - 2023
United States	2020 - 2023

Research and development U.K. tax credits

The benefits from U.K. 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 U.K..

The Small Medium Enterprise 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. The U.K. Government also enacted further changes to the SME regime effective from April 1 2023 (with some amendments effective for accounting periods commencing after April 1 2024) which included the introduction of a new rate for R&D intensive companies of 27% . 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 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 the Company's 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 contained in the Finance Act 2024 (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 U.K. or such workers are not subject to U.K. 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. These changes take effect from periods commencing after April 1 2024.

During the year ended December 31, 2024, the Company met the conditions of the SME regime, but it could also make claims under the RDEC regime to the extent that its projects are grant funded.

In the accounting period to December 2023, based on the relevant tax legislation, the Company considered that it met the conditions of the R&D intensive scheme, and have made a claim on this basis. This is subject to agreement by the U.K. tax authority who, based on their non-statutory guidance, considers the basis for calculating whether a company meets the intensive criteria includes expenditure which is in conflict with the tax legislation. The position is uncertain and the legislation is currently untested in the U.K. courts. If the Company's claim is unsuccessful, normal SME relief will be available and there will be a material reduction in the value of the tax credit obtained (18.6% as opposed to 26.97% net benefit).

From January 2025, the Company does not qualify as a small or medium-sized enterprise under the SME program, based on size criteria concerning employee headcount, turnover and gross assets. However, the Company may make a claim under the merged RDEC regime beginning with periods 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 $19.7 million and $19.5 million were recognized for the years ended December 31, 2024 and 2023, respectively, and are recorded as offsets to research and development expense in the Company's consolidated statement of operations and comprehensive loss.

Note 19. Leases

Operating Leases

Since September 2017, the Company has had an arrangement with Cell Therapy Catapult Limited to lease manufacturing suites at the Cell and Gene Therapy Catapult manufacturing center in Stevenage, United Kingdom. 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, 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 August 2024, one of the leased manufacturing suites ended and the Company exited the suite. In September 2024, the Company extended the lease term from August 2024 to December 2026 for the remaining manufacturing suite.

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. 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. 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, 2024 which resulted the recognition of a $0.4 million impairment of operating lease right-of-use assets and related property and equipment.

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.

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 which may be required to be removed at the end of the lease term. On September 10, 2024, the Company completed a variation of the lease for the manufacturing facility, related to additional works at the site. The landlord will provide funding for certain specified improvements to the facility (the "Works"), which the Company commits to undertake on a mutually agreed schedule. Funding received for the Works done are deemed lease incentives in accordance to ASC 842. Once the Works are complete, the rental payments under the lease will be increased according to a specified formula for the remainder of the lease term. The deed of variation does not affect the lease term, which continues to run for 20 years from September 19, 2023.

The following table shows the lease balance sheet classification of leases for the years ended December 31, 2024 and 2023 (in thousands):

	As of December 31,	
	2024	**2023**
Assets		
Operating lease right-of-use assets, net	**$ 55,498**	**$ 60,791**
Liabilities		
Current		
Operating lease liabilities, current	2,998	5,053
Non-current		
Operating lease liabilities, non-current	49,631	47,914
Total lease liabilities	**$ 52,629**	**$ 52,967**

The following table shows the lease costs for the years ended December 31, 2024 and 2023 (in thousands):

		Year ended December 31,	
Lease costs	**Statement of Operations classification**	**2024**	**2023**
Operating lease costs	Operating expenses: research and development	$ 6,642	$ 6,340
Variable costs	Operating expenses: research and development	1,281	1,041
Short term lease costs	Operating expenses: research and development	258	786
Operating lease costs	Operating expenses: general and administrative	1,393	956
Variable costs	Operating expenses: general and administrative	318	51
Short term lease costs	Operating expenses: general and administrative	117	90
Operating lease costs	Operating expenses: cost of sales	558	—
Variable costs	Operating expenses: cost of sales	64	—
Total lease costs		**$ 10,631**	**$ 9,264**

	Year ended December 31,	
Other information	**2024**	**2023**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases (in thousands)	$ 4,258	$ 10,407
Weighted-average remaining lease term - operating leases (in years)	15.9 years	16.0 years
Weighted-average discount rate - operating leases	8.15 %	7.44 %

Future fixed payments for non-cancellable operating leases in effect as of December 31, 2024 are payable as follows:

Maturity of lease liabilities for the years ending December 31,	**Operating Leases** (in thousands)
2025[(1)]	$ (1,931)
2026[(1)]	8,049
2027	8,352
2028	7,637
2029	5,745
Thereafter	77,421
Total lease payments	105,273
Less: imputed interest	(52,644)
Present value of lease liabilities	**$ 52,629**

(1) Includes lease incentives from The Nucleus lease variation amounting to $10.2 million and $0.9 million, for the year ended December 31, 2025 and 2026, respectively.

Note 20. Commitments and Contingencies

Contractual obligations

In July 2022, the Company renegotiated a master services agreement (the "Adaptive Master Services Agreement") with Adaptive Biotechnologies Corporation ("Adaptive"), under which Adaptive's assay is used to analyze patient samples from r/r B-ALL patients. During the year ended December 31, 2023, the Company recognized all contractual milestones relating to this contract. Under the then-current agreement, the Company would be 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.

In previous periods, the Company has entered into agreements with certain advisory firms. The Company is obligated to make specified payments upon the achievement of certain strategic transactions involving the Company. During the year ended December 31, 2024, the Company paid a fee under these agreements.

The Company has estimated the probability of the Company achieving each potential milestone in relation to the agreements with UCLB, Miltenyi and its agreements with certain advisory firms in accordance with ASC 450. The Company considers the regulatory approval, commercial milestones and execution of collaboration agreements probable when actually achieved. Furthermore, the Company recognizes expenses for clinical milestones when their achievement is deemed probable. The Company concluded that, as of December 31, 2024, there were no other milestones or contingencies for which the likelihood of achievement was currently probable.

Capital Commitments

As of December 31, 2024, the Company's unconditional purchase obligations for capital expenditure totaled $17.5 million and included signed orders for capital equipment and capital expenditure for construction and related expenditure relating primarily to its properties in the United Kingdom. The Company expects to incur the full amount of these obligations within one year.

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 commercial, preclinical and clinical 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 the Company's 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, 2024, the Company's unconditional purchase obligations for reagents and disposables totaled $0.6 million, which the Company expects to incur within one year.

Distribution Commitments

The Company entered into an Exclusive Distribution Agreement, effective as of April 25, 2024 (the "Effective Date"), with Cardinal Health 105, LLC ("Cardinal Health"). Pursuant to, and subject to the terms and conditions of, the Exclusive Distribution Agreement, the Company engaged Cardinal Health as its exclusive third-party logistics distribution agent for sales of AUCATZYL in the US. The Exclusive Distribution Agreement runs for an initial term of three years following commercial launch and automatically renews for additional terms of one year each, unless either party elects not to renew. Under the terms of the Exclusive Distribution Agreement, the Company must pay to Cardinal Health a one-time start-up fee, and a monthly account management fee upon the Company's commercial launch of AUCATZYL, and other fees for various services, including post-launch program implementation, information systems, warehouse operations and financial services.

BioNTech Agreements

BioNTech License and Option Agreement - Product Options gain contingency

As the Product Options within the BioNTech License and Option Agreement were an embedded feature within a freestanding financial instrument, the Company assessed if the Product Options should be accounted for as a derivative under ASC 815. However, the Company determined the Product Options met the scope exception for derivative accounting under ASC 815 and therefore should be accounted for a gain contingency under the scope of ASC 450. As of December 31, 2024, Product Options were not exercised and therefore no amounts were recognized.

Refer to Note 12, "Liabilities Related to Future Royalties and Milestone, Net" for further details about the BioNTech's Obe-cel Product Revenue Interest.

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, 2024 and 2023.

Indemnification Agreements

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because they involve claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with the indemnification agreements entered into with relevant individuals in accordance with the Company's Articles of Association, the Company has indemnification obligations to its directors, officers and members of senior management for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date under these indemnification agreements, and the Company has director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

SME R&D tax credit

In the accounting period to December 2023, based on the relevant tax legislation, the Company had met the conditions of the R&D intensive scheme, and therefore submitted its corporate tax return on this basis. This is subject to agreement by the U.K. tax authority who, based on their non-statutory guidance, considers the basis for calculating whether a company meets the intensive criteria includes expenditure which is in conflict with the tax legislation. The position is uncertain and the legislation is currently untested in the U.K. courts. If the Company's claim is unsuccessful, normal SME relief will be available and there will be a material reduction in the value of the tax credit obtained (18.6% as opposed to 26.97% net benefit). Should the uncertainty be resolved in the Company's favor, this would result in a gain and accounted for a gain contingency under the scope of ASC 450.

Note 21. Employee Benefit Plans

In the United Kingdom, Germany and Switzerland, the Company makes contributions to defined contribution pension schemes on behalf of its employees. The Company expensed $2.7 million and $2.0 million in the years ended December 31, 2024 and 2023, 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 four percent of the employee's annual salary. The Company expensed $1.0 million and $0.4 million in contributions in the years ended December 31, 2024 and 2023, respectively. The Company pays all administrative fees related to the plan.

Note 22. Segment reporting

Long-lived assets

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

	December 31,	
	2024	**2023**
United Kingdom	$ 104,160	$ 94,033
United States of America	891	1,620
Total long-lived assets	**$ 105,051**	**$ 95,653**

For the year ended December 31, 2024, 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 Enfield, United Kingdom. For the year ended December 31, 2023, the Company 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, United Kingdom.

Revenue

Revenue recognized by geographic area are disclosed in Note 3, "Revenue".

Major customers

During the year ended December 31, 2024, 100% of the Company's license revenues were generated from BioNTech. For the year ended December 31, 2023, 76% and 20% of the Company's license revenues were primarily generated from Cabaletta and an investee of Syncona Portfolio Limited, respectively.

Segment profit or loss

The table below is a summary of the segment profit or loss, including significant segment expenses (in thousands):

	December 31,	
	2024	**2023**
License Revenue	$ 10,120	$ 1,698
Less operating expenses:		
Research and clinical development	(37,831)	(50,585)
Product delivery	(89,815)	(60,290)
Commercial and Medical affairs	(55,219)	(14,955)
Support functions	(66,300)	(48,809)
Other segment expenses, net [(1)]	(2,381)	(6,760)
Total operating expenses	**(251,546)**	**(181,399)**
Operating loss	**(241,426)**	**(179,701)**
Other income, net	220	222
Foreign exchange (losses) gains	(989)	2,639
Interest income	32,355	13,505
Interest expense, net	(9,294)	(45,067)
Income tax (expense) benefit	(1,528)	19
Segment and consolidated net loss	**$ (220,662)**	**$ (208,383)**

(1) Other segment expenses, net include U.K. research and development tax credits, depreciation, amortization and share-based compensation expenses.

Note 23. Related Party Transactions

Blackstone

On November 6, 2021, the Company concurrently entered into the Blackstone Agreements. Refer to Note 12, "Liabilities Related to Sales of Future Royalties and Milestones, Net", Note 13, "Warrants" and Note 14, "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, 2024, the carrying amount of the Blackstone Collaboration Agreement liability was $211.6 million, which included aggregated accrued interest expense and cumulative catch-up adjustment, of $10.7 million and $45.0 million for the years ended December 31, 2024 and 2023, respectively. Refer to Note 12, "Liabilities Related to Sales of Future Royalties and Milestones, Net" for further details.

BioNTech Agreements

In February 2024, the Company concurrently entered into the BioNTech Agreements. Upon the execution of the BioNTech Agreements, BioNTech became a related party of the Company. BioNTech owns more than 10% of the Company's outstanding voting securities and is therefore one of the principal owners of the Company. In addition, BioNTech has the right to nominate one director to the Board of Directors of the Company which BioNTech has not yet exercised.

As of December 31, 2024, the carrying amount of the BioNTech Liability was $36.5 million which included aggregated accrued interest expense and cumulative catch-up adjustment of $(1.8) million for the year ended December 31, 2024. Refer to Note 12, "Liabilities Related to Sales of Future Royalties and Milestones, Net" for further details.

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, the 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, 2024.

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)
Fidelity Management & Research Company, LLC (1)	5,808,333	$ 34.9
Deep Track Capital, LP (2)	3,750,000	$ 30.0

(1) Fidelity Management & Research Company, LLC was a holder of more than 5% of our share capital as of December 31, 2024.
(2) Deep Track Capital, LP was a holder of more than 5% of our share capital as of December 31, 2024.

Note 24. Subsequent Events

The Company evaluated subsequent events through March 20, 2025, the date on which these consolidated financial statements were issued. The Company has concluded that no subsequent event has occurred that requires disclosure.

Exhibit 10.20

Management Incentive Compensation Plan

(effective March 1, 2025)

1. Purpose of the Plan

The Management Incentive Compensation Plan (the "**Plan**") of Autolus Therapeutics plc and its group companies (collectively, "**Autolus**") is designed to offer incentive compensation to officers and managers of Autolus (the "**Associates**") 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 Plan will create an environment that will focus Associates on the achievement of objectives. Since cooperation between departments and Associates is required to achieve the corporate goals and because such corporate goals represent a significant portion of the incentive compensation paid under the Plan, the Plan fosters teamwork and a cohesive management team. The Plan is designed to:

- Provide an incentive program to achieve overall corporate objectives and to enhance shareholder value
- Reward those individuals who significantly impact corporate results
- Encourage increased teamwork among all disciplines within Autolus
- Incorporate an incentive program in the overall compensation program of Autolus to help attract and retain key Associates

2. Plan Governance

The Chief Executive Officer of Autolus (the "**CEO**") will be responsible for the administration of the Plan for Associates of Autolus, except that the Compensation Committee (the "**Committee**") of the Board of Directors of Autolus (the "**Board**") will be responsible for approving any incentive awards to the CEO and the executive officers of Autolus (each of whom is hereafter referred to as an "**Executive Officer**").

3. Plan Year

The period for the measurement of performance is the fiscal year of the Company, which is currently Jan 1 to Dec 31 (the "**Plan Year**"), unless otherwise determined by the Committee.

4. Eligibility

4.1. The Executive Officers are eligible to participate in the Plan. Any other Associates who may be eligible to participate in the Plan will be selected at the sole discretion of Autolus. Each Executive Officer and each Associate selected to participate in the Plan is hereafter referred to as a "**Plan Participant**".

4.2. In order to be eligible to receive any incentive award under this Plan, an Associate (a) must have been employed by Autolus for at least three (3) consecutive months during the Plan Year, and (b) must reach a personal goal rating of at least 75%.

5. Form of Incentive Award Payments

Incentive award payments may be made in cash, or, at the discretion of the Committee and subject to the approval of the Board, through the issuance of vested stock or stock options, or by a combination of cash, stock and/or stock options. In the event that the Committee and the Board elect to pay incentive awards in stock or stock options, the Committee, in its sole discretion, will make a determination of the number of shares of stock or stock options to be issued to each Plan Participant based, in part, upon the Plan Participant's achievement of corporate and personal goals as described below. Stock options will be subject to the terms and conditions of Autolus' then-current equity incentive plan.

6. **Target Award Multiplier**

The target incentive award of each Plan Participant is determined by applying a "target award multiplier" to the base salary of the Plan Participant. The target award multiplier is dependent on the management level of the Plan Participant. The following target award multipliers will apply to determine the target incentive award of the Plan Participants for the Plan Year, provided that the Committee, based on individual circumstances and in its discretion, may approve a target award multiplier for a Plan Participant that is different from that listed below:

Position	Target Award Multiplier
CEO	70%
Executive Officer (C-level)	45%
Senior Vice President	35%
Vice President	30%
Executive/Senior Director	25%
Director	20%
Associate Director	15%
Manager and Group Leader	10%
Team Leader and General Staff	5%

7. Corporate and Personal Goals

7.1. Prior to the beginning of the Plan Year, the CEO will present to the Committee a list of the overall corporate goals for the Plan Year, which are subject to approval of the Committee and the Board. The Committee assigns a percentage to each corporate goal based on the relative importance of the goal compared to the other corporate goals, with the sum of all percentages amounting to 100%. In addition to the Corporate Goals all Plan Participants except for the CEO develop a list of personal goals, which must be approved by the immediate supervisor and the EM Member responsible for the applicable department, or by the CEO for personal goals of the other EM Members. The supervisor assigns a percentage to each personal goal based on the relative importance of the goal compared to the other personal goals, with the sum of all percentages amounting to 100%.

7.2. The Plan calls for incentive awards based on the achievement of annual corporate and personal goals that have been approved as described in Section 7.1 above. The relative weight between corporate goals and personal goals varies based on the Plan Participant's level within the organization. The weighting of the corporate goals relative to the personal goals for the Plan Year is as follows:

Position	Weighting of Corporate Goals	Weighting of Personal Goals
CEO	100%	0%
Executive Officer (C-level)	75%	25%
Senior Vice President	75%	25%
Vice President	75%	25%
Executive/Senior Director	50%	50%
Director	50%	50%
Associate Director	25%	75%
Manager and Group Leader	25%	75%
Team Leader and General Staff	0%	100%

8. Performance Assessment

8.1. Achievement of Corporate Goals

Within 30 days after the end of the Plan Year, the Chief Executive Officer will present to the Committee his assessment of the achievement of the corporate goals for that Plan Year. The Committee will review and discuss the assessment with the Chief Executive Officer, and will determine the percentage of the achievement of the corporate goals during a meeting of the Committee in a closed session. The payment multiplier for the corporate goals determined by the Committee will be used for all Plan Participants in any given year. The Committee may, in its discretion, include achievements that have not been established as corporate goals at the beginning of the Plan Year or determine that the level of achievement of a particular corporate goal exceeds 100%.

8.2. Achievement of Personal Goals

Within 30 days after the end of the Plan Year, the Chief Executive Officer will present to the Committee his assessment of the achievement of the personal goals of each other Executive Officer for that Plan Year. The Committee will review and discuss the assessment with the Chief Executive Officer, and will determine the percentage of the achievement of the personal goals during a meeting of the Committee in consultation with the Chief Executive Officer.

Each supervisor will determine the achievement of the personal goals of the Associates reporting to him, subject to the approval of the Executive Officer responsible for the applicable department. The final determination of the achievement of the personal goals will be made by the executive

management team taking into account the variances in goal setting and assessment practices across the departments of Autolus.

The Committee and the supervisors may, in their discretion, include achievements that have not been established as personal goals at the beginning of the Plan Year or determine that the level of achievement of a particular personal goal exceeds 100%.

9. Calculation of Cash Incentive Award

9.1. The target award of a Plan Participant is calculated by multiplying the Plan Participant's base salary as of the last day of the Plan Year by the target award multiplier. This amount is then divided between its corporate component and its individual component based on the weighting assigned for the specific management level. After the end of the Plan Year, the achievement of the corporate and personal goals (each expressed as a percentage) will be established as described in Section 8 above. The corporate award multiplier, which is based on overall corporate performance, is used to calculate corporate goal component of the incentive award by multiplying the target award for the corporate goal component by the percentage of the corporate goal achievement determined by the Committee. The percentage determined by the Compensation Committee or the responsible supervisor for the achievement of the personal goals of a Plan Participant is used in the same way to calculate the personal goal component of the incentive award.

Example:

Position:	**Vice President**	
Base Salary:	GBP 150,000	
Target Award Multiplier:	30%	
Target Award:	GBP 45,000	(GBP150,000 x 30%)
Weighting of corporate goal component:	75%	
Weighting of personal goal component:	25%	
Target Award Calculation:		
Target Award based on corporate goals:	GBP 33,750	(GBP 45,000 x 75%)
Target Award based on personal goals:	GBP 11,250	(GBP 45,000 x 25%)
Actual achievement of corporate goals:	90%	
Actual achievement of personal goals:	95%	
Actual Incentive Award:		
Corporate goals component:	GBP 30,375	(GBP 33,750 x 90%)
Personal goals component:	GBP 10,688	(GBP 11,250 x 95%)
Total Incentive Award:	**GBP 41,063**	

9.2. Any incentive award payable to a Plan Participant who has a part-time work schedule will be based on the actual base salary paid to such Plan Participant during the Plan Year.

9.3. Any incentive award payable to a Plan Participant who has been eligible for an incentive award payment under the Plan for less than a full Plan Year will be pro-rated based on the number of days in which such Plan Participant was in an eligible position.

9.4. If a Plan Participant is promoted during the Plan Year from one target award multiplier level to another, such Plan Participant's incentive award will be calculated based on their base salary on the last day of the Plan Year, but based on the amount of time during the Plan Year served at each target award multiplier level.

10. Payment of the Incentive Award

Annual performance reviews for Plan Participants will be completed before March 31 of the year following the Plan Year. Payment of incentive awards will be made as soon as practicable thereafter. Incentive award payments to the CEO and to the Executive Officers must be approved by the Committee.

11. Termination

If a Plan Participant has given or received a notice of termination or if a Plan Participant's employment is terminated prior to the payment of the incentive award under this Plan, Autolus will have sole and absolute discretion as to whether or not to pay an incentive award. If Autolus decides to pay an incentive award to such Plan Participant, Autolus will have sole and absolute discretion as to whether to pay the full amount or a portion of the amount of the incentive award that may be payable to the Plan Participant in accordance with the provisions of this Plan.

12. Absolute Right to Alter or Abolish the Plan

Autolus reserves the right in its absolute discretion to abolish the Plan at any time or to alter the terms and conditions under which incentive compensation will be paid. Such discretion may be exercised any time before, during, and after the Plan Year is completed.

13. No Right to Incentive Award Payments

No Plan Participant will have any vested right to receive any compensation under the Plan until actual delivery of such compensation. If an eligible Associate has been on probation for performance or other issues at any time during the Plan Year or during the period from the end of the Plan Year until the time at which incentive award determinations are made, any award to such individual will be subject to the discretion of Autolus. The Associate will not have any right to receive any such incentive award payment and any payments made cannot be taken as a precedent for future or further incentive award payments.

14. Employment Relationship

This Plan does not, and Autolus's policies and practices in administering this Plan do not, constitute a contract or other agreement concerning the duration of any Plan Participant's employment with Autolus. The employment relationship of each Plan Participant of Autolus is governed by the employment agreement of the Plan Participant and applicable law, and may be terminated by Autolus or by the Plan Participant in accordance with the terms of such agreement and applicable law. To the extent that an employment agreement contains provisions regarding

incentive or bonus awards or payments that are inconsistent with any provisions of the Plan, the provisions that are more favorable to the Associate will apply.

Exhibit 10.21

Autolus/Cardinal Health:
Distribution Services Agreement

This Distribution Services Agreement (together with all attached Exhibits, the "Agreement"), effective as of the last date of signature (the "Effective Date"), is entered into by and between:

1) Autolus, Inc. with offices at 15810 Gaither Drive, Suite 230, Gaithersburg, MD 20877-1440 ("Client"); and

2) Cardinal Health 105, LLC, with offices at [***] ("Cardinal Health").

Client and Cardinal Health are each referred to individually as a "Party" and collectively as the "Parties."

WHEREAS:

A. Client is in the business of developing and manufacturing certain CAR T-cell products and therapies.

B. Cardinal Health is, among other things, in the business of distributing pharmaceutical products to wholesalers, specialty distributors, physicians, clinics, hospitals, pharmacies, and other health care providers in the Territory (as defined below), and of providing information systems and other services that support its clients' use of its third-party logistics distribution capabilities.

C. Client wishes to appoint Cardinal Health as its third-party logistics and distribution agent within the Territory for the performance of the Services (as defined below) in accordance with the terms of this Agreement.

D. Client also wishes to appoint [***].

THEREFORE, in consideration of the mutual covenants, terms and conditions set forth below, the Parties agree as follows:

1. Definitions and Scope

1.1 The following definitions shall apply in this Agreement:

a) Affiliate. Any legal entity which, during the Term hereof, a Party controls, is controlled by, or is under common control with, such Party. For the purposes of this definition, an entity is deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting interest of all equity interests of the other entity (or other such comparable ownership interest for an entity other than a corporation).

b) Autolus Terms. The commercial terms included in Exhibit D of this Agreement.

c) Autolus UK. Autolus Limited, which is a UK company having its registered address at 191 Wood Lane, London W12 7FP, and which is both an Affiliate of the Client and manufacturer of the Product.

d) [***]

e) Change of Control. Occurs in the event of the then-current shareholders of a Party disposing of more than 50.00% of their shares in a sale, merger or other disposal transaction, such disposal being measured by the number of shares owned by such shareholders in the aggregate.

f) Client Data. Any non-public information or data owned, controlled or processed by Client or any of

its Affiliates which is: (i) held, maintained or hosted on the System; or (ii) otherwise provided by the Client to Cardinal Health under this Agreement in connection with the Services.

g) Confidential Information. All non-public or proprietary information furnished by a Party (or its Representatives or Affiliates) to the other Party (or its Representatives or Affiliates) in connection with the Services or performance of this Agreement, whether furnished before, on or after the date of this Agreement and furnished in any form, including but not limited to written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions, and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either Party (or their Representatives or Affiliates), containing or based in whole or in part on any such information furnished by the other Party (or their Representatives or Affiliates). The existence of this Agreement and its terms and Client Data shall be considered Confidential Information.

h) Counterfeit Goods. Any product that (a) is not manufactured by Autolus UK; and (b) is labeled or otherwise purported to be the Product.

i) [***]

j) Data Protection Laws. All applicable laws and regulations regarding privacy and personal data (including Health Insurance Portability and Accountability Act (HIPAA), General Data Protection Regulation ((EU) 2016/679) and the Data Protection Act 2018), and any privacy laws and regulations of any other jurisdiction in which personal data is controlled or processed pursuant to this Agreement.

k) Depot. The approved depot facility of Cardinal Health located in Tennessee, which is authorized to hold and/or store Product in the Territory until final release to Qualified Centers.

l) Operating Guidelines or OPG. The operating guidelines attached in Exhibit A of this Agreement.

m) [***]

n) Price List. The list of prices in respect of Products, as determined by Client in accordance with Section 2.3 of this Agreement.

o) Product. Obecabtagene autoleucel for patients with relapsed/refractory (r/r) Adult B-Cell Acute Lymphoblastic Leukemia (ALL), manufactured by Autolus UK, which for the avoidance of doubt: (i) includes all dosage forms, strengths and package sizes of such Product; (ii) includes [***] of such Product; and (iii) excludes any generic versions of such Products (namely, any product that is marketed, sold, or distributed directly or indirectly under a different labeling, packaging, product code, labeler code, trade name, or trade mark than the original, branded and approved product under the same Biologics License Application).

p) Qualified Center. Any center or site within the Territory that is qualified and approved by Client to purchase Products hereunder, subject to the rights of Cardinal Health under Section 7 hereunder.

q) Quality Agreement. The quality agreement attached in Exhibit C of this Agreement.

r) Representatives. The employees, officers, directors, agents, consultants, or other authorized representatives of a Party.

s) Return Goods Policy. The current Autolus returns good policy which is applicable to Qualified Centers at any given time.

t) Services. Cell therapy distribution services set forth in the OPG, including without limitation: order to cash services, drop ship logistics, depot model logistics, direct shipment logistics, returns processing, customer support, system access support, order facilitation and processing, contract pricing administration, and accounts receivable processing, including provision of the System, and as further detailed in the Operating Guidelines (Exhibit A of this Agreement).

u) Service Fees. The fees set forth in Exhibit B-1 of this Agreement.

v) System. Cardinal Health's web-enabled operating system base and certain support services associated therewith, as further set forth in the OPG.

w) Term. The meaning set forth in Section 3.1 of this Agreement.

x) Termination Fee. The one-time payment set forth in Exhibit B-2 of this Agreement which applies if Client terminates for convenience during the Initial Term.

y) Territory. The United States of America, its territories and possessions.

z) Trade Policy. The current Autolus trade policy which is applicable to Qualified Centers at any given time.

aa) Wholesale Acquisition Cost or WAC. Client's then-current published list price as established by Client. WAC does not include the discounts from invoice price, rebates, chargebacks, administrative fees and equivalent adjustments.

1.2 A reference to any laws, rules, regulations, guidelines and generally accepted standards and requirements is a reference to those laws, rules, regulations, guidelines and generally accepted standards and requirements as they are amended, modified, updated and in force from time to time.

1.3 The Exhibits form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to "this Agreement" includes the Exhibits, as listed below:

Exhibit A – Operating Guidelines
Exhibit B-1 – Service Fees
Exhibit B-2 – Additional Financial Terms
Exhibit C – Quality Agreement
Exhibit D – Autolus Terms

1.4 [***].

1.5 This Agreement (including the Exhibits) may only be varied or amended by written agreement of both Parties.

2. Appointment and Pricing

2.1 During the Term of this Agreement, Client hereby appoints Cardinal Health to act as Client's sole and exclusive distributor of Products within the Territory. Cardinal Health accepts the foregoing appointment on the terms and conditions described in this Agreement, the OPG and Quality Agreement. The Parties agree to finalize and execute a mutually agreeable OPG and Quality Agreement prior to the commercial launch of Product. Once mutually agreed, the OPG and Quality Agreement are considered attached hereto as Exhibits and incorporated by reference. To the extent that there are any conflicts between this Agreement, the OPG, or the Quality Agreement, this Agreement controls, and the Quality Agreement controls solely with respect to quality-related matters. [***].

2.2 Cardinal Health agrees to only accept purchase orders for Products submitted by Qualified Centers to Cardinal Health ("QC-PO"), in accordance with the Price List.

2.3 [***].

2.4 Cardinal Health shall pay Client in respect of all Product purchased by Cardinal Health in accordance with the terms of Section 7 and Exhibit D.

3 Term and Termination

3.1 This Agreement begins on the Effective Date and shall continue in force for an initial period of three (3) years following Commercial Launch (the "Initial Term"), unless terminated earlier pursuant to the terms of this Agreement; and after expiry of the Initial Term, this Agreement shall automatically renew annually in one (1) year instalments, unless either Party elects not to renew by providing at least ninety (90) days written notice to the other Party, or unless terminated earlier pursuant to the terms of this Agreement (collectively, the "Term"). "Commercial Launch" means the date on which the first shipment of FDA approved Product is shipped to a Qualified Center.

3.2 Either Party has the right to terminate this Agreement if:

a. the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within thirty (30) days; or

b. the other Party materially breaches any of the provisions of this Agreement, and such breach is not cured within thirty (30) days after giving written notice; provided, however, that in the case of a breach that cannot be cured within thirty (30) days, the Parties agree to meet in good faith and within thirty (30) days after the giving of written notice, formulate a mutually agreeable plan to cure such breach within a reasonable period of time.

3.3 Client has the right to terminate this Agreement [***] by giving Cardinal Health [***] written notice, provided that if Client terminates this Agreement pursuant to this Section 3.3 during the Initial Term, Client shall pay Cardinal Health [***].

3.4 [***].

3.5 Termination of this Agreement is without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination. In addition to any applicable Termination Fees (if any), Client agrees to pay Cardinal Health for all Services performed up to the date of termination and to reimburse Cardinal Health for all reasonable costs and expenses incurred, and all non-cancelable commitments made, in the performance of Services.

4. Obligations of Client

4.1 Client agrees that it shall:

a. comply with all applicable laws and regulations, obtain and maintain all necessary licenses and consents;

b. not reverse engineer, reverse assemble, decompile, create derivative works, modify, or otherwise attempt to derive the source code of any software on the System or copy, download, modify, or create

derivative works of such software;

c. not permit access to the System or related documentation to any third party without written consent from Cardinal Health, which shall not be unreasonably withheld;

d. make payment, when due, of any Cardinal Health invoice, to the extent not otherwise disputed as provided in Section 6.5 below;

e. not do or omit to do anything which may cause Cardinal Health to lose any license, authority, consent or permission on which it relies for the purposes of conducting its business;

f. sell Products to Cardinal Health in accordance with the terms of this Agreement, including all applicable representations and warranties, and the Autolus Terms;

g. not knowingly send, transfer, distribute or sell to Cardinal Health any Counterfeit Goods or Product that otherwise qualified as suspect or illegitimate product as defined in the Drug Supply Chain Security Act (DSCSA); and

h. comply with the provisions of the Exhibits, as well as the Trade Policy and Return Goods Policy.

4.2 Client must comply with all applicable laws, regulations and guidance/codes relating to anti-bribery, anti-corruption, anti-slavery, human trafficking or human exploitation.

5. Obligations of Cardinal Health

5.1 Cardinal Health agrees that it shall:

a. [***];

b. comply with all applicable laws and regulations, and obtain and maintain all necessary licenses and consents;

c. comply with the provisions of the Exhibits, as well as the Trade Policy and Return Goods Policy;

d. [***];

e. use personnel who are suitably skilled and experienced to achieve the required Service levels;

f. [***];

g. [***];

h. [***];

i. [***];

j. comply with any special shipping, storage or handling requirements of Client for the Products to the extent mutually agreed to by Client and Cardinal Health in the OPG;

k. store, transport and handle Product in accordance with the OPG;

l. [***];

m. [***];

n. sell Products only to Qualified Centers and no other third parties; and

o. [***].

5.2 Cardinal Health must comply with all applicable laws, regulations and guidance/codes relating to anti-bribery, anti-corruption, anti-slavery, human trafficking or human exploitation.

6. Service Fees and Payment by Client

6.1 As compensation for the performance of the Services, Client agrees to pay Cardinal Health the Service Fees set forth in Exhibit B-1. Cardinal Health shall not be entitled to invoice the Client for any fee, cost or expense which is not included in Exhibit B-1. The Parties also agree to the additional terms set forth on Exhibit B-2.

6.2 [***].

6.3 [***].

6.4 [***].

6.5 [***].

6.6 [***].

6.7 The Parties each covenant that: (1) it has negotiated at arm's length with the other Party; (2) the services compensated for by the Service Fee would not be provided to Client by Cardinal Health in the absence of this Agreement; and (3) the Service Fees paid under this Agreement are not intended to be passed through, in whole or in part, to Qualified Centers.

6.8 Client agrees to pay all sales, use, gross receipts, excise and personal property taxes associated with the Product (excluding any personal property tax associated with Cardinal Health's equipment used in connection with the Services), and other taxes now or hereafter imposed as a result of the transactions contemplated by this Agreement, none of which have been included in the fees payable to Cardinal Health under this Agreement; provided that the amounts payable by Client under this Section do not include taxes based on the net income of Cardinal Health.

7. Client Invoices & Cardinal Health Payment, Qualified Centers Purchase & Payment Terms

7.1 [***].

7.2 [***].

7.3 [***].

7.4 [***].

7.5 [***].

7.6 Financial Statements. Client agrees to provide to Cardinal Health, upon request, Client's most recent audited year-end consolidated financial statements and quarterly year-to-date updates to such financial statements.

7.7 [***].

7.8 [***].

8. System & Client Data

8.1 During the Term, Cardinal Health agrees to make the System available to Client at the fees set forth in Exhibit B of this Agreement. Cardinal Health agrees to use reasonable efforts to make the System available for access twenty-four (24) hours a day, seven (7) days a week absent scheduled and emergency maintenance periods, as set forth in the OPG.

8.2 The System and all parts thereof, in all their tangible and intangible manifestations, all existing or new enhancements, developments, derivative works, and other modifications to the System (or any part thereof), and all related proprietary rights, are and remains the exclusive property of Cardinal Health.

8.3 Client may use password(s) and identification number(s) provided by Cardinal Health to remotely access data (including Client Data) on the System provided that such access is restricted to Client's Representatives and for Client's internal business purposes. Client is responsible for all use of the passwords and identification elements and must ensure that they are used solely to affect the limited access authorized herein. Client agrees to access the System solely to access Client Data and further agrees not to access or attempt to access any other data, systems, or software. The limited license to access the System granted herein does not include the right to copy, download or otherwise use any software or non-Client Data maintained on the System.

8.4 Cardinal Health acknowledges and agrees that Client has and will retain all right, title, interest, and ownership in and to Client Data. Client grants Cardinal Health a limited right to use such Client Data in the performance of its Services for the duration of the Term or as necessary to conduct its own internal business operations with respect to the Services. All such Client Data that Cardinal Health or any of its Representatives obtains or which Cardinal Health or Cardinal Health's Representatives is given access pursuant to or in connection with this Agreement is and remains the sole property of Client, and Cardinal Health has no rights or interests (except as expressly provided herein) to or in such Client Data. The return or destruction of any Client Data: (a) is subject to the prior written approval of Client; and (b) must be documented in an appropriate certification provided to Client upon request.

8.5 During the Term, Cardinal Health agrees to employ reasonable security measures and policies that are no less secure than those utilized to secure its own Confidential Information and that are designed to safeguard the integrity, accessibility, and confidentiality of Client Data. Cardinal Health agrees to establish and maintain reasonable disaster and emergency recovery plans designed to minimize disruption of the Services or provision of the System.

8.6 [***].

8.7 THE SYSTEM, THE SOFTWARE THEREON AND ANY RESULTS OBTAINED THEREFROM ARE PROVIDED ON AN "AS IS" BASIS, WITHOUT WARRANTY OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE. CARDINAL HEALTH MAKES NO REPRESENTATIONS OR WARRANTIES, AND HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, RELATING DIRECTLY OR INDIRECTLY TO THE SYSTEM OR ANY PART THEREOF INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE. IF THE SOFTWARE IS FOUND TO INFRINGE ANY THIRD PARTY'S INTELLECTUAL PROPERTY RIGHTS, CARDINAL HEALTH AGREES TO, AT ITS EXPENSE AND ITS SOLE OPTION, EITHER (i) REPLACE THE INFRINGING SOFTWARE WITH NONINFRINGING SOFTWARE, OR (ii) SECURE ADDITIONAL RIGHTS NECESSARY TO MAKE THE SOFTWARE NONINFRINGING.

9. Title & Risk, Shipment of Product, Product Recalls

9.1 Transfer of Title and Risk of Loss

9.2 [***].

9.3 [***].

9.4 [***].

9.5 Client is solely responsible for all Product recalls or voluntary or involuntary withdrawal of Product. Client agrees to reimburse Cardinal Health for all non-recoverable costs and expenses incurred by Cardinal Health for Services provided in connection with the recall or withdrawal, provided however that Cardinal Health is responsible for Product recalls to the extent solely arising from Cardinal Health's gross negligence or willful misconduct.

9.6 In the event Product is subject to recall, or Client, on its own initiative, recalls or withdrawals any Product, Cardinal Health agrees to provide assistance to Client as set forth in the OPG or as mutually agreed upon in writing by the Parties.

10. Inspection and Audit Rights

10.1 [***]:

10.2 Audits shall be performed at mutually agreed times during normal business hours (i.e., 8:00 a.m. to 5:00 p.m.) and shall not unreasonably disrupt Cardinal Health's business operations. If the timing of such audit falls during "quarter-end" or "year-end" then Cardinal Health agrees to use best efforts to accommodate Client's request. Audits and any resulting restitution will be limited to the twelve (12) month period immediately prior to the original request to audit. Should the audit identify a discrepancy or variance which may result in restitution to Client, Cardinal Health will correct the variance or discrepancy within a reasonable period of time. Should the audit identify a discrepancy or variance which may result in restitution to Cardinal Health, Client will correct the variance or discrepancy within a reasonable period of time.

10.3 If Client elects to use the services of a third-party independent professional auditor, such auditor shall be mutually acceptable to the Parties and Cardinal Health shall not unreasonably withhold, condition or delay its approval of any auditor acceptable to Client. No auditor shall be allowed to perform an audit without first executing a confidentiality agreement reasonably acceptable to the Parties. Any such audit shall be completed within thirty (30) days of the date that Cardinal Health provides the available documentation to the auditor. Any information obtained by the audit shall be kept confidential and shall not be disclosed to a third party unless disclosure is required by applicable laws or regulations. Client shall provide a copy of the audit report to Cardinal Health upon receipt thereof.

10.4 Cardinal Health shall retain its records relating to the Services during the Term of this Agreement and for the retention periods set forth in the OPG.

11. Representations and Warranties

11.1 Cardinal Health represents and warrants to Client that:

a. Cardinal Health has, maintains, and shall continue to maintain liability insurance coverage and Cardinal Health holds all necessary federal, state, and local licenses and permits for Cardinal Health to provide all Services in accordance with all applicable laws and regulations;

b. There are no actions or proceedings, pending or threatened, within the knowledge of Cardinal Health, that would in any way jeopardize any such licenses and permits;

c. Cardinal Health has all corporate authority to perform the Services and that such performance will not violate any agreement to which it is a party;

d. Cardinal Health shall make no statements about the information on the Products' labels that are materially inconsistent with the statements on the Products' labels;

e. Cardinal Health shall at all times remain fully liable for all acts and omissions of its agents and sub-contractors providing Services hereunder and also for its Affiliates in receipt of Client's Confidential Information hereunder.

11.2 Client represents and warrants to Cardinal Health that:

a. The Product is not adulterated or misbranded as provided in the Food, Drug and Cosmetic Act, as amended from time to time;

b. Client's activities relating to the promotion, sale and distribution of the Product comply with all applicable laws, rules, regulations, and guidelines;

c. It has all necessary authority and right, title and interest in and to any intellectual property related to the Product for Cardinal Health to perform its obligations herein and the Product does not actually infringe (and Client has no knowledge of any allegation by any third party that the Product infringes) any valid patent, trade secret, copyright, trademark, or other proprietary rights of any third party within the Territory;

d. It has provided all safe handling instruction, health and environmental information and material safety data sheets applicable to the Product or to any materials supplied by Client in writing in sufficient time for review and training by to Cardinal Health prior to the commencement of the Services.

11.3 Each Party represents and warrants to the other Party that:

a. Such Party (i) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, and (ii) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted;

b. Such Party (i) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

c. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable laws; and (ii) do not materially conflict with or constitute a material default or require any consent under, any contractual obligation of such Party.

d. All necessary consents, approvals and authorizations of all regulatory authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained;

e. Neither it nor its principals was or is debarred, suspended, proposed for debarment or otherwise determined to be ineligible to participate in federal health care programs or convicted of a criminal offense related to the provision of health care items or services, but has not yet been debarred, suspended, proposed for debarment or otherwise determined to be ineligible to participate in federal

health care programs. In the event that a Party, or any of its principals, is debarred, suspended, proposed for debarment or otherwise determined to be ineligible to participate in federal health care programs or convicted of a criminal offense related to the provision of health care items or services, such Party will promptly notify the other Party and such Party may terminate this Agreement immediately upon the effective date of any such debarment, suspension, proposal for debarment or other determination of ineligibility.

11.4 THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS SECTION 11 ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

12. Trademarks

12.1 Neither Party has the right to use the name of the other Party or any Affiliate of the other Party, or the other Party's or such Affiliates' trademarks, service marks, logos, or other similar marks in any manner except with the prior written approval of that Party, provided that the foregoing does not prohibit Cardinal Health's use of Client's names or marks in connection with the performance of the Services in a manner consistent with this Agreement.

13. Confidentiality

13.1 While performing their respective obligations under this Agreement, one Party (the "Discloser") may disclose to the other Party (the "Recipient") certain Confidential Information. The Recipient is not permitted to use the other Party's Confidential Information except as necessary for Recipient to perform its obligations under this Agreement. The Recipient is not permitted to disclose the Discloser's Confidential Information to any third party without the prior written consent of the Discloser. Notwithstanding the foregoing, the Recipient may disclose the Discloser's Confidential Information to the extent required by law, regulation or court or administrative order, if the Recipient gives the Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances.

13.2 Notwithstanding the foregoing, the Recipient may disclose the Discloser's Confidential Information to any of Recipient's Affiliates or Representatives that need to know such Confidential Information for the purpose of performing its obligations under this Agreement. Prior to such Affiliate or Representatives receiving the Discloser's Confidential Information, (A) Recipient must advise the Affiliate or Representatives of the contents of this Section, and (B) such Affiliate or Representatives must agree to be bound by the terms of this Section or agree to be bound by confidentiality and use obligations no less restrictive than those set forth in this Section. The Recipient agrees to use all reasonable safeguards to prevent unauthorized use by such Affiliates and Representatives and further agrees to immediately notify the Discloser upon becoming aware of any breach of the confidentiality obligations of this Section.

13.3 Notwithstanding anything herein to the contrary, Confidential Information does not include information that (A) is or becomes generally available to the public other than as a result of a breach of this Agreement, or (B) is already known by the Recipient at the time of disclosure as evidenced by the Recipient's written records, or (C) becomes available to the Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (D) was or is independently developed by or for the Recipient without reference to the Confidential Information, as evidenced by the Recipient's written records.

13.4 The Recipient obtains no right of any kind or license under any patent application or patent by reason of

this Agreement. All Confidential Information remains the sole property of the Discloser.

13.5 Upon expiry or termination of this Agreement, the Recipient agrees to, upon request, promptly return within thirty (30) days all Confidential Information, including any copies thereof, and cease its use or, at the request of the Discloser, Recipient agrees to promptly destroy the same and certify such destruction to the Discloser; except for a single copy thereof, which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement. Notwithstanding the foregoing, neither Party is required to destroy any back-up tapes, archival systems, or similar inactive databases so long as such tapes, systems or databases are not readily accessible and are routinely deleted or overwritten pursuant to an established record retention program, and such destruction does not require a Party to erase or delete information using special programs or techniques.

13.6 The confidentiality obligations of this Section continue for five (5) years after termination or expiry of this Agreement.

14. Indemnification

14.1 [***].

14.2 [***].

14.3 [***].

15. Limitation of Liability

15.1 [***].

15.2 [***].

15.3 [***].

16. Insurance Requirements

16.1 [***]:

a. [***].

16.2 [***]:

a. [***].

16.3 The Parties hereby acknowledge and agree that Cardinal Health may self-insure and self-administer all or any portion of the required insurance, and to the extent that Cardinal Health does self-insure, such insurance will not be deemed to exceed the scope of coverage and/or limits that would have been provided in an actual policy of insurance that satisfies the insurance requirements herein. Further, no insurance coverage maintained by Cardinal Health, whether self-insurance or otherwise, will be construed to expand any indemnification obligations that may be contained in this Agreement.

16.4 Waiver. Each Party agrees to obtain a waiver from any insurance carrier with whom such Party carries Property Insurance releasing its subrogation rights against the other Party except for losses resulting solely from the gross negligence or willful misconduct of the other Party. Each Party agrees not to seek reimbursement for any property claim, or portion thereof that is not fully recovered from such Party's property insurance except for losses resulting solely from the gross negligence or willful misconduct of the other Party.

16.5 Client agrees to name Cardinal Health, Inc. as additional insureds under the Product liability insurance policy with respect to the Products. Client agrees that such insurance is primary (with respect both to any insurance issued to Cardinal Health and to any self-insured amount retained by Cardinal Health) regarding Cardinal Health's liability for damage arising out of those products for which they have been added as additional insureds. Such additional insurance status continues during the Term and, if the policies are written on a claims-made basis, continues for not less than five (5) years following termination or expiration of this Agreement.

16.6 Client's all-risk property insurance applies to all losses and is primary (with respect both to any insurance issued to Cardinal Health and to any deductible amount or self-insured amount retained by Cardinal Health) except for losses resulting solely from the gross negligence or willful misconduct of Cardinal Health.

16.7 Client shall furnish certificates of insurance to Cardinal Health evidencing the required insurance and additional insured status as soon as practicable after the Effective Date and within thirty (30) days after renewal of such policies. Client will endeavor to provide thirty (30) days written notice of any cancellation prior to the policy(ies) expiration date(s). Cardinal Health will make available to Client an Evidence of Coverage evidencing the required insurance at[***]. Each insurance policy that is required under this article shall be obtained from an insurance carrier with an A.M. Best rating of at least A-VII.

17. Intellectual Property

17.1 [***].

17.2 [***].

18. Data Protection

18.1 [***].

19. Notices

19.1 All notices and other communications hereunder must be made in writing and are deemed given: (A) when delivered personally; (B) when delivered by e-mail transmission (if e-mail address is provided below and receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by courier service, to the Parties at the following addresses:

[***]	[***]

20. Miscellaneous

20.1 This Agreement constitutes the entire understanding between the Parties and supersedes any contracts, agreements or understanding (oral or written) of the Parties with respect to the subject matter hereof. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement continue in full force and effect.

20.2 The Parties agree to execute, acknowledge, and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

20.3 Waiver by either Party of any term of this Agreement in any one or more instances is not deemed to be a waiver of its rights with respect to any subsequent failure.

20.4 The relationship of the Parties is that of independent contractors, and neither Party is permitted to incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or should be construed as creating between the Parties the relationship of joint venturers, co-partners, employer/employee or principal and agent.

20.5 Cardinal Health may not subcontract all or any portion of the Services without the prior written consent of Client. For clarity, shipping services provided by common transportation carriers (including Cardinal Health's Exclusive Pharmaceutical Transportation Network or EPTN) and Product destruction services provided by a third-party vendor are not considered to be contracted services as related to this Agreement and therefore the businesses performing such services are not considered subcontractors. It is expressly understood that Cardinal Health is not responsible for the performance of shipping services by common carriers for or on behalf of Client unless otherwise stated in this Agreement.

20.6 Neither Party is permitted to make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under applicable law or by any governmental agency, in which case the Party required to make the press release or public disclosure agrees to use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure. Cardinal Health is not permitted to make any promotion or advertisement, including any activity on social media, which relates to any Product or any [***], without the prior written consent of Client.

20.7 Neither Party is liable in damages for or is considered in breach of this Agreement due to any delay or default in such Party's performance hereunder if such default or delay is caused by events beyond such Party's reasonable control including, but not limited to, acts of God, regulation or law or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or storm, labor disturbances, epidemic; provided however, that the Party seeking relief hereunder is required to immediately notify the other Party of such cause(s) beyond such Party's reasonable control. The Party that may invoke this Section is required to use all reasonable endeavors to reinstate its ongoing obligations to the other Party. If the cause(s) continues unabated for thirty (30) days, then both Parties agree to meet to discuss modifications to this Agreement that should result from such force majeure event.

20.8 This Agreement is binding upon and inures to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, voluntarily or involuntarily, whether by operation of law or any other manner, without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may assign all of its rights and obligations under this Agreement to an Affiliate, provided such Party notifies the other Party in advance and such Affiliate is not related to the assigning party as the consequence of a Change of Control. For the avoidance of doubt, an assignment for purposes of this Section includes a Change of Control.

20.9 [***].

20.10 In the event that any applicable federal, state or local law, rule, regulation, policy, or any interpretation thereof, during the Term, is modified, implemented, threatened to be implemented, or determined to prohibit, substantially restrict or in any way materially affect this Agreement or either Party's performance under the terms of this Agreement (each of the foregoing being hereinafter referred to as a "Change"), then the Parties agree to promptly negotiate an amendment to this Agreement to preserve the expectations of the Parties to the greatest extent possible in a manner consistent with any such Change.

20.11 This Agreement is governed by and construed under the laws of Delaware. If any dispute, controversy, or disagreement arises between the Parties ("Dispute"), the Parties agree to present such Dispute to the respective presidents or senior executives of Cardinal Health and Client for their consideration and resolution. If such Parties cannot reach a resolution of the Dispute within sixty (60) days, either Party may submit the Dispute to the courts of Delaware.

20.12 This Agreement may be executed in one or more counterparts, each of which is deemed an original but all of which together constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement constitutes an original.

In witness whereof, the undersigned, duly authorized, has executed this Agreement:

Cardinal Health 105, LLC	Autolus, Inc.
By: /s/ Joel Wayment	By: /s/ Brent Rice
Name: Joel Wayment	Name: Brent Rice
Title: Vice President, Operations	Title: Chief Commercial Officer
Date: Apr 25, 2024	Date: 23-Apr-2024

Exhibit A - Operating Guidelines

[***]

Exhibit B-1 - Service Fees

[***]

Exhibit B-2 - Additional Financial Terms

[***]

Exhibit C – Quality Agreement

[to be agreed]

Exhibit D - Autolus Terms

[***]

Exhibit 19.1

AUTOLUS THERAPEUTICS PLC

INSIDER TRADING AND WINDOW PERIOD POLICY

(REVISED OCTOBER 16, 2020)

INTRODUCTION

During the course of your relationship with **AUTOLUS THERAPEUTICS PLC** ("***Autolus***"), you may receive important information that is not yet publicly available ("***inside information***") about Autolus or other publicly traded companies that Autolus has business relationships with. Inside information may give you or someone you pass that information on to an advantage over others who do not have that information when deciding whether to buy, sell, or otherwise deal in Autolus' equity securities or the equity securities of another publicly traded company. This policy sets forth acceptable transactions in Autolus securities by our employees and directors and.

INSIDER TRADING POLICY

Securities Transactions

Using inside information for personal gain or passing this information (also known as a "***tip***") to someone who uses it for personal gain (a "***tippee***") is illegal and prohibited by this policy and applicable laws in the jurisdictions in which we operate. Exploiting inside information like this is unlawful regardless of how many shares are bought or sold. You can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. Although it is imperative to refrain from any insider trading, it is equally important to avoid even the appearance of insider trading.

Inside Information

It is not always easy to determine whether you possess inside information. The key factor for determining whether nonpublic information is inside information is whether publicizing the information would likely affect the market price of that company's securities. This determination is often made in retrospect with the benefit of 20/20 hindsight, so it is advisable to be very conservative in making this assessment. Keep in mind that both positive and negative information can be material. As a rule of thumb, any nonpublic information that makes you want to trade is inside information as it would probably have the same effect on others.

The following items may be considered inside information until publicly disclosed. There may be other types of information that would qualify as inside information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- communications with government agencies, primarily the U.S. Food and Drug Administration and the European Medicines Agency;
- scientific breakthroughs, clinical data or financial results relating to the Company's products or product candidates;
- strategic plans;
- acquisitions or dispositions of assets, divisions, or companies;
- pending public or private sales of debt or equity securities;
- share splits, dividends, or changes in dividend policy;

- major contract awards or cancellations;
- scientific, clinical or regulatory results or timelines for pre-clinical studies or clinical trials;
- notice of issuance of patents;
- key management or control changes;
- possible tender offers or proxy fights;
- significant accounting writeoffs;
- actual or threatened major litigation, SEC or other investigations, or a major development in or the resolution of any such litigation or investigation;
- impending bankruptcy;
- gain or loss of a significant licensor, customer or supplier;
- unusual gains or losses in major operations; and
- execution of new collaborations or changes to existing collaborations with major industry partners.

If you do possess inside information, you may not trade in a company's securities, advise anyone else to do so, or communicate the information to anyone else until you know that the information has been publicly disseminated. This policy also applies to all family members, other household members of individuals covered by this policy, and all companies controlled by individuals covered by this policy. You should never recommend to another person that they buy, hold, or sell our securities. In some circumstances, you may need to forgo a planned transaction even if you had planned it before learning of the inside information. This prohibition is absolute. So even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait. "***Trading***" includes engaging in short sales, transactions in put or call options, hedging transactions, and other inherently speculative transactions.

The prohibition on trading when you have inside information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disclosed through a press release, an SEC filing, or other public announcement and enough time must have passed for the information to be widely known. Generally speaking, information will be considered publicly disseminated after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce inside information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday.

TRADING BY AUTOLUS EMPLOYEES AND DIRECTORS

Because our workplace culture tends to be open, odds are that the vast majority of our employees and directors will possess inside information at certain points throughout the year. To minimize even the appearance of insider trading among our employees and directors, we have established blackout periods during which our employees and directors—regardless of whether they possess insider information or not—may not conduct any trades in Autolus securities. That means that all Autolus employees and directors will be able to sell Autolus securities only during limited trading windows that open after Autolus has disseminated its quarterly or semi-annual and annual financial results.

Covered Insiders

Our insider trading policy sets forth a basic set of rules for all employees and directors and a separate set of more stringent rules for officers, directors, and other members of management. What's more, any entities, immediate family members, or others whose trading activities are controlled by persons subject to this policy are likewise generally subject to the same restrictions.

Open Window

Generally, except as described in this policy and until Autolus files or furnishes quarterly financial results, all Autolus employees and directors may buy or sell Autolus securities only during an "open window" which shall open after the close of business in the United States on the second trading day following the public dissemination of the Company's annual financial results and shall close on the last trading day before the end of each fiscal year. At such time as Autolus regularly files or furnishes quarterly financial results, all Autolus employees and directors may buy or sell Autolus securities only during an "open window" which shall open after the close of business in the United States on the second trading day following the public dissemination of the Company's quarterly financial results and shall close on the last trading day before the end of each fiscal quarter. In each case, this open window may be closed early or may not open at all if, in the judgment of the Chief Executive Officer, Chief Financial Officer, or Compliance Officer, there exists undisclosed information that would make trades by employees and directors inappropriate. This open window may be closed early or may not open at all if, in the judgment of the Chief Executive Officer, Chief Financial Officer, or Compliance Officer, there exists undisclosed information that would make trades by employees and directors inappropriate. The fact that the open window has closed early or has not opened should be considered inside information. An employee, director, or consultant who believes that special circumstances require them to trade outside the open window should consult the Compliance Officer. Permission to trade outside the open window will be granted only where the circumstances are extenuating and there appears to be no significant risk that the trade may be subsequently questioned.

Exceptions to Open Window Period

1. ***Option Exercises and RSU Net Settlement***. Employees and directors may (i) exercise options granted under Autolus' equity incentive plans for cash, and (ii) net settle restricted share units ("***RSUs***") and have Autolus withhold shares to satisfy tax withholding obligations when RSUs settle. But this insider trading policy would then apply to any later sales of shares (including sales of shares in a cashless exercise) that were acquired on the exercise of options or delivery of the vested RSUs.

2. ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), employees and directors may establish a trading plan under which a broker is instructed to buy and sell Autolus securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established under applicable law, purchases and sales of Autolus securities pursuant to that plan may be made at any time—even in a blackout period. An employee's, director's, or consultant's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 and Autolus' 10b5-1 Trading Plan Guidelines when they lacked inside information about Autolus and when Autolus was not in a trading blackout period. Moreover, all Trading Plans must be reviewed by Autolus before being established. That is because Autolus wants to confirm that the Trading Plan complies with all pertinent company policies and the securities laws. Autolus must be notified before a Trading Plan is established, amended, or terminated.

Prohibition of Speculative or Short-term Trading

No employee, director, or consultant to Autolus may engage in short sales, transactions in put or call options, hedging transactions, margin accounts, pledges, or other inherently speculative transactions with respect to Autolus' securities.

Pre-Clearance and Advance Notice of Transactions

In addition to the requirements above, Autolus employees and directors face a further restriction: even during an open trading window, they may not engage in any transaction in Autolus' securities, including any purchase or sale in the open market, loan, or other transfer of beneficial ownership without first obtaining pre-clearance of the transaction from Autolus' Compliance Officer at least two business days before the proposed transaction. The Compliance Officer will then determine whether the transaction may proceed and, if applicable, will assist with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within five business days will require new pre-clearance. Autolus may choose to shorten this period.

Persons subject to pre-clearance must also provide advance notice of gifts or plans to exercise an outstanding option to the Compliance Officer. Autolus intends to advise all relevant persons when the reporting requirements under Section 16(a) of the Exchange Act become applicable. Following the date specified in that notice, once any transaction takes place, the officer, director, or applicable member of management must immediately notify the Compliance Officer and any other individuals identified under the heading "Notification of Execution of Transaction" in Autolus' Section 16 Compliance Program so that Autolus may assist in any Section 16 reporting obligations.

Control Shares and Short-Swing Trading

Officers and directors may also be subject to restrictions on sales of shares by control persons (Rule 144 under the U.S. Securities Act of 1933, as amended). In addition, once Autolus is no longer a foreign private issuer, officers and directors subject to the reporting obligations under Section 16 of the Exchange Act will also be subject to the prohibition on short-swing trading (Section 16(b) of the Exchange Act). Officers and directors should take care not to violate these rules and to file any notices of sale required by Rule 144.

Prohibition of Trading During Pension Fund Blackouts

In accordance with Regulation BTR under the Exchange Act, once Autolus is no longer a foreign private issuer, no director or executive officer of Autolus may, directly or indirectly, purchase, sell or otherwise acquire or transfer any equity security of Autolus (other than an exempt security) during any "blackout period'' (as defined in Regulation BTR) with respect to such equity security, if a director or executive officer acquires or previously acquired such equity security in connection with his or her service or employment as a director or executive officer. This prohibition does not apply to any transactions that are specifically exempted, including but not limited to, purchases or sales of Autolus' securities made pursuant to, and in compliance with, a Trading Plan; compensatory grants or awards of equity securities pursuant to a plan that, by its terms, permits executive officers and directors to receive automatic grants or awards and specifies the terms of the grants and awards; acquisitions or dispositions of equity securities involving a bona fide gift or by will or the laws of descent or pursuant to a domestic relations order. Autolus will notify each director and executive officer of any blackout periods in accordance with the provisions of Regulation BTR.

Exceptions

The only exceptions to these trading restrictions are permitted transactions directly with Autolus, such as option exercises for cash. However, the subsequent sale, including the sale of shares in a cashless exercise or other disposition of shares is subject to these restrictions.

POLICY DURATION

This policy continues to apply to your transactions in Autolus' securities or the securities of other public companies engaged in business transactions with Autolus even after your relationship with Autolus has ended. If you possess inside information when your relationship with Autolus ends, you may not trade Autolus' securities or the securities of other companies until the inside information has been publicly disseminated or is no longer material.

PENALTIES

Anyone who engages in insider trading or otherwise violates this insider trading policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Autolus, including termination. Anyone who has questions about this policy should contact their own attorney or Autolus' Compliance Officer, at compliance@autolus.com. Please also see Frequently Asked Questions, which are attached as **EXHIBIT A**.

AUTOLUS THERAPEUTICS PLC

INSIDER TRADING AND WINDOW PERIOD POLICY

CERTIFICATION

To: **AUTOLUS THERAPEUTICS PLC**

I, _____, have received and read a copy of the **AUTOLUS THERAPEUTICS PLC** Insider Trading and Window Period Policy. I hereby agree to comply with the specific requirements of the policy in all respects during my employment or other service relationship with **AUTOLUS THERAPEUTICS PLC.** I understand that this policy constitutes a material term of my employment or other service relationship with **AUTOLUS THERAPEUTICS PLC** (or a subsidiary thereof) and that my failure to comply in all respects with the policy is a basis for termination for cause.

_____
(Signature)

_____
(Name)

_____
(Date)

EXHIBIT A
INSIDER TRADING AND WINDOW PERIOD POLICY
FREQUENTLY ASKED QUESTIONS

1. ***What is insider trading?***

A: Insider trading is the buying or selling of stocks, bonds, futures, or other securities by someone who possesses material nonpublic information. Insider trading also includes trading in options (puts and calls) where the price is linked to the underlying price of a company's shares. It does not matter how many shares you buy or sell, or whether it has an effect on the ADS or share price. Bottom line: If you have material nonpublic information and you trade, you have broken the law.

2. ***Why is insider trading illegal?***

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who have inside information to disclose the information to the public or refrain from trading.

3. ***What is material nonpublic information?***

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond future, or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions, or major contracts to name just a few. Information is nonpublic if it has not yet been released and disseminated to the public.

4. ***Who can be guilty of insider trading?***

A: Anyone who buys or sells a security while possessing material nonpublic information can be guilty of insider trading. This applies to all individuals, including officers, directors, and others who don't even work at Autolus. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you or one of your associates trades using that material information, you can be found guilty of insider trading.

5. ***Does Autolus have an insider trading policy?***

A: Yes. Please contact our Compliance Officer to receive a copy.

6. ***What if I work in a foreign office?***

A: The same rules apply to U.S. and foreign employees and consultants. Because our American Depository Shares, or ADSs, representing ordinary shares, trade on a U.S. securities exchange, the insider trading laws of the United States apply. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as an Autolus employee or consultant, our policies apply to you no matter where you work.

7. ***What if I don't buy or sell anything, but I tell someone else the information and they buy or sell?***

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, you might still be guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members might be guilty of insider trading too. To prevent this, you should not discuss material nonpublic information about the company with anyone outside Autolus, including spouses, family members, friends, or business associates. This includes anonymous discussions on the internet about Autolus or companies with which Autolus does business.

8. ***What if I don't tell them the information itself; I just tell them whether they should buy or sell?***

A: That is still tipping, and you can still be responsible for insider trading. You should not recommend to another person that they buy, hold, or sell our ADSs, ordinary shares or any derivative security related to our ordinary shares, since that could be a form of tipping.

9. ***What are the penalties if I trade on inside information or tip off someone else?***

A: In addition to disciplinary action by Autolus—which may include termination—you may be liable for civil penalties for trading on inside information. The penalties for doing so may include paying the U.S. government up to three times any profit made or any loss avoided. Persons found liable for tipping inside information, even if they did not trade themselves, may also face a penalty of up to three times the amount of any profit gained or loss avoided by everyone in the chain of tippees. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

10. ***What is "loss avoided"?***

A: If you sell ADSs, ordinary shares or a related derivative security before negative news is publicly announced, and as a result of the announcement the price declines, you have avoided the loss caused by the negative news.

11. ***Am I restricted from trading securities of any companies other than Autolus, for example a customer or competitor of Autolus?***

A: Possibly. U.S. insider trading laws restrict everyone from trading in a company's securities based on material nonpublic information about that company, regardless of whether the person is directly connected with that company. Therefore, if you have material nonpublic information about another company, you should not trade in that company's securities. You should be particularly conscious of this restriction if, through your position at Autolus, you sometimes obtain sensitive, material information about other companies and their business dealings with Autolus.

12. ***So if I do not trade Autolus securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?***

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Autolus securities as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

13. ***So when can I buy or sell my Autolus securities?***

A: If you have material nonpublic information, you may not buy or sell our ADSs or ordinary shares until the second trading day after that information is released or announced to the public. At that point, the information is considered public. You must also obtain pre-clearance of the transaction from Autolus' Compliance Officer at least two business days before the proposed transaction. **Even if you do not have material, nonpublic information, you may not trade our ADSs or ordinary shares or other securities during any trading "blackout" period**. Our insider trading policy describes the quarterly blackout period, and additional trading blackout periods may be announced by email.

14. ***If I have an open order to buy or sell Autolus securities on the date the trading window closes, can I leave it to my broker to cancel the open order and avoid executing the trade?***

A: No. If you have any open orders when the trading window closes, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after the trading window closes, you will have violated our insider trading policy and may also have violated insider trading laws.

15. ***Am I allowed to trade derivative securities of Autolus? Or short Autolus ADSs or ordinary shares?***

A: No. Under our policies, you may not trade in derivative securities related to our ordinary shares, which include publicly traded call and put options. In addition, under our policies, you may not engage in short selling of our ADSs or ordinary shares at any time.

"Derivative securities" are securities other than ADSs or ordinary shares that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee share options, which are not derivative securities**.**

"Short selling" is profiting when you expect the price of the shares to decline, and includes transactions in which you borrow shares from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the share price decreases during the period of borrowing.

16. ***Why does Autolus prohibit trading in derivative securities and short selling?***

A: Many companies with volatile share prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in share prices, without actually holding the underlying ADSs or ordinary shares, and encourages speculative trading. We agree. After all, because we are dedicated to building shareholder value, short selling our ADSs or ordinary shares conflicts with our values and would not be received well by our shareholders.

17. ***Can I purchase Autolus securities on margin or hold them in a margin account?***

A: Under our policies, you may not purchase our ADSs or ordinary shares on margin or hold it in a margin account at any time.

"Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

18. ***Why does Autolus prohibit me from purchasing Autolus securities on margin or holding them in a margin account?***

A: Margin loans are subject to a margin call whether or not you possess insider information at the time of the call. If a margin call were to be made at a time when you had insider information and you could not or did not supply other collateral, you and Autolus may be restricted based on your insider trading activities because of the sale of the securities (through the margin call) when you possessed material nonpublic information. The sale would be attributed to you even though the lender made the ultimate determination to sell. The Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

19. ***Can I pledge my Autolus shares as collateral for a personal loan?***

A: No. Pledging your shares as collateral for a personal loan could cause you to transfer your shares during a closed window period. As a result, you may not pledge your shares as collateral for a loan.

20. ***Can I exercise share options during a trading blackout period or when I possess material nonpublic information?***

A: Yes. You may exercise the option and receive shares, but you may not sell the ADSs or shares (even to pay the exercise price or any taxes due) or net settle the option during a trading blackout period or any time that you have material nonpublic information. Also note that if you choose to exercise and hold the shares, you will be responsible at that time for any taxes due.

21. ***Am I subject to the trading blackout period if I am no longer an employee or consultant of Autolus?***

A: It depends. If your employment with Autolus ends on a day that the trading window is closed, you will be subject to the trading blackout period then in effect. If your employment with Autolus ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave Autolus, you should not trade in Autolus securities if you possess material nonpublic information. That restriction stays with you as long as the information you possess is material and not released by Autolus.

22. ***Can I gift shares while I possess material nonpublic information or during a trading blackout period?***

A: Because of the potential for the appearance of impropriety, you may not make gifts, whether to charities, a trust, or otherwise, of our ADSs or ordinary shares when you possess material nonpublic information or during a trading blackout period.

23. ***What if I purchased publicly traded options or other derivative securities before I became an Autolus employee, contractor, or consultant?***

A: The same rules apply as for employee share options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you have material nonpublic information.

24. ***May I own shares of a mutual fund that invests in Autolus?***

A: Yes.

25. ***Are mutual fund shares holding Autolus ADSs or ordinary shares subject to the trading blackout periods?***

A: No. You may trade in mutual funds holding Autolus ADSs or ordinary shares at any time.

26. ***May I use a "routine trading program" or "10b5-1 plan"?***

A: Yes, subject to the requirements discussed in our insider trading policy and Rule 10b5-1 trading plan guidelines. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your broker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact the Compliance Officer for approval.

27. ***What happens if I violate our insider trading policy?***

A: Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with Autolus. In addition, you may be subject to criminal and civil actions.

28. ***Who should I contact if I have questions about our insider trading policy?***

A: You should contact our Compliance Officer at compliance@autolus.com.

Exhibit 21.1

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,
(6) Registration Statement (Form S-3 No. 333-278320) of Autolus Therapeutics plc,
(7) Registration Statement (Form S-8 No. 333-283229) pertaining to the Autolus Therapeutics plc 2018 Equity Incentive Plan;

of our report dated March 20, 2025, 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, 2024.

/s/ Ernst & Young LLP
Reading, United Kingdom
March 20, 2025

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 20, 2025

/s/ Christian Itin, Ph.D.
Name: Christian Itin, Ph.D.
Title: Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

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 20, 2025

/s/ Robert Dolski.
Name: Robert Dolski
Title: Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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, 2024, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, 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 20, 2025

/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)