Risk Factors Comparison 2025-03-20 to 2024-03-21 Form: 10-K

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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 ~~in every year~~ since our inception. We expect to continue to incur losses ~~over the next several years and may never achieve or~~ **for** ~~maintain profitability~~ **the foreseeable future** . We are ~~a clinical~~ **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, $ 148. 8 million and $ 142. 1~~ million for the years ended December 31, **2024 and** 2023 ~~, 2022 and 2021~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~878~~ **1, 099** . ~~6~~ **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 ~~no~~ **one** ~~products~~ **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 ~~, as well as to building out our commercial and manufacturing infrastructure~~ . Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront operating and capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. ~~The FDA has accepted our BLA for obe- cel for patients with relapsed / refractory (r / r) Adult B- Cell ALL, and has set a target PDUFA action date of November 16, 2024.~~ Should ~~the FDA not grant us marketing approval,~~ we ~~are~~ **be** unsuccessful in our commercialization efforts ~~or~~ **for AUCATZYL or if** the **rates of** market ~~does~~ **acceptance do** not ~~accept~~ **meet** our ~~product~~ **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 to discover and develop additional product candidates and further expand our clinical product pipeline~~ ; • seek regulatory approvals for any product candidates that successfully complete clinical trials; • ~~continue to scale up internal and external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization; • establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval; • make required milestone and royalty payments to UCLB or other third parties, under license agreements pursuant to which we were granted some of our intellectual property rights; • make required sales milestone and royalty payments to BXLS V Autobahn LP (" Blackstone ") under our collaboration and financing agreement relating to obe- cel, our lead product, and other collaboration products for B cell malignancies; • make required milestone payments to Miltenyi under our sublicense agreement relating to certain proprietary technologies incorporated in certain of our manufacturing processes; • make required revenue share interest payments to BioNTech relating to obe- cel under our license and option agreement; •~~ develop, maintain, expand and protect our intellectual property portfolio; • acquire or in- license other product candidates and technologies; • hire additional clinical, quality control and manufacturing personnel; • add clinical, operational, financial and management information systems and personnel, including personnel to support **the commercial development of AUCATZYL, as well as** our **other** product development and ~~planned~~ future commercialization efforts; • expand our operations in the United States, Europe and other geographies; and • incur additional legal, accounting and other expenses associated with operating as a public company. To become and remain profitable, we must succeed in **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. ~~Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We are a clinical- stage biopharmaceutical company with a limited operating history. As an organization, we have not demonstrated an ability to successfully obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our limited history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer.~~ We will need additional funding to **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~~ **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** ~~These programs are described in greater detail in the " Business " section of this Annual Report. Our current funding may only be sufficient~~ to **generate revenue from sales of AUCATZYL** ~~fund obe- cel through initial commercial launch~~ , ~~assuming certain timelines on successful regulatory approval, and~~ we will need to raise additional capital to reach profitability as well as to complete the development and commercialization of our other programmed T cell product candidates, and in connection with our continuing operations, strategy and other planned activities. Our future capital requirements will depend on many factors, including: • **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 ~~or ,~~ 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 ~~future~~ commercialization activities, including product manufacturing, marketing, sales and distribution, for any **future** ~~of our product candidates for which we receive marketing approval; • the revenue, if any, received from commercial sales of our~~ product candidates for which we receive marketing approval; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; and • the costs of operating as a public company. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, **AUCATZYL,** ~~our~~ **or our other** product candidates, if approved, may not achieve commercial success. Our product revenues ~~, if any,~~ **in the near term** will be derived **primarily** from sales of ~~product candidates~~ **AUCATZYL in the US, as we** that we do not expect to **generate material revenues from** ~~be obe - cel in commercially available until late 2024 at the~~ **other jurisdictions** ~~earliest, in the case of our~~ **or from** ~~existing lead program and, with respect to~~ other pipeline programs, for up to several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders may experience substantial dilution. We may sell ordinary shares or ADSs, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares or ADSs, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders. In February 2024, we issued an aggregate of approximately 91. 7 million ADSs in an underwritten offering and a private placement, resulting in substantial dilution for existing shareholders. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our shareholders and may cause the market price of our ADSs to decline. We have incurred substantial obligations under license and collaboration agreements, which could impair our flexibility and access to other capital and adversely affect our financial position, and our business would be adversely affected if we were unable to meet our obligations under these and similar future agreements. In November 2021, we entered into a collaboration agreement with Blackstone (the " Blackstone Collaboration Agreement ") pursuant to which Blackstone ~~has~~ agreed to pay us up to $ 150 million to support the continued development and ~~, following approval,~~ commercialization of **AUCATZYL /** obe- cel and next-generation product candidates (~~obe- cel and such next- generation products,~~ collectively, the " Collaboration Products ") in exchange for our agreement to make substantial payments to Blackstone following approval of such **Collaboration** ~~products~~ **Products** . These payments include a single- digit percentage payment on worldwide net sales of (i) the Collaboration Products in any indication and (ii) AUTO3 for the treatment of B- cell leukemias and lymphomas, by us and any of our licensees, as well as sales milestone payments relating to such net sales. Such payments to Blackstone could increase our cash requirements and could impair our liquidity. As of December 31, ~~2023~~ **2024** , Blackstone has paid **us the full** $ ~~120~~ **150** million ~~to us~~ 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 ~~have~~ **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. ~~In connection~~ **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** ~~Even if we obtain approvals from the FDA,the European Commission or other comparable regulatory authorities~~ and ~~are able to initiate commercialization of our clinical- stage product candidates or~~ any other product candidates ~~we develop~~ , ~~the product candidate~~ **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** ~~the other Collaboration Agreement~~ **similar actions could result in increased government regulation** , ~~Blackstone 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 ~~our~~ **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 was~~ **as** ~~granted~~ 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** ~~security~~ **severity** ~~interest~~ **of any side effects; • product labeling or product insert requirements of the FDA, the European Commission or other regulatory authorities; • limitations or warnings contained** in the labeling approved by the FDA or the European Commission ~~;• the timing of market introduction of our product candidates as well as competitive products~~ ;• the cost of treatment in relation to alternative treatments;• the amount of upfront costs or training required for physicians to administer our product **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** ~~products~~ **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 ~~our~~ **AUCATZYL and any future** ~~product~~ **products** ~~candidates~~ ,if **approved,to generate** substantially all of

our ~~assets the medical community on the benefits of our products,if approved,may require significant resources and may never be successful.Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates.Because we expect sales of our product candidates,if approved,to generate substantially all of our~~ product revenue for the foreseeable future,the failure of ~~our~~ **those** ~~product~~ **products** ~~candidates~~ to find market acceptance would harm our business and could require us to seek additional financing.In addition,although we are not utilizing embryonic stem cells or replication competent vectors,adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies,and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective,may limit market acceptance our product candidates. ~~If our product candidates are approved but fail to achieve market acceptance among physicians,patients,hospitals,cancer treatment centers or others in the medical community,we will not be able to generate significant revenue.~~ Even if our products achieve market acceptance,we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products,are more cost effective or render our products obsolete. ~~Coverage~~ **If we are unable to fully develop our sales,marketing** and ~~adequate reimbursement~~ **distribution capability on our own,or enter into sales,marketing and distribution agreements with third parties,we** may not be ~~available~~ **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** ~~our current~~ or any ~~future~~ **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 ~~Collaboration Agreement also~~ **development of sales, marketing and distribution capabilities has required and will** ~~contains~~ **continue** ~~negative covenants~~ **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 ~~restrict~~ **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 ~~from (~~ **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 ~~)~~ ~~granting liens~~ **material adverse effect** on ~~certain of~~ **our financial condition, share price and operations. If we are unable** ~~our~~ - **or decide not** ~~assets, including liens on the intellectual property relating~~ to ~~the Collaboration Products~~ **establish internal sales** , ~~except for certain permitted liens, (b) making~~ **marketing and** ~~distributions~~ - **distribution capabilities, in any territory, we would have to pursue collaborative arrangements regarding the sales and marketing of** ~~or~~ **our** ~~dividends~~ **products. However** , **we may not be successful in** ~~except for certain permitted distributions, (c)~~ entering into **arrangements** ~~development or commercialization license transactions~~ with ~~respect~~ **third parties** to **sell, market and distribute AUCATZYL / obe- cel or our** ~~the~~ **other** ~~Collaboration Products~~ - **product** ~~, except~~ **candidates or may be unable to do so on terms** that ~~we~~ are ~~permitted~~ **favorable** to ~~enter into~~ **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 ~~development~~ **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** ~~or~~ **our** ~~commercialization license transactions~~ **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** ~~certain pharmaceutical companies, including those~~ -- **the market opportunities** ~~companies that have annual sales in excess of an agreed threshold, (d) consummating certain change in control transactions, (c) selling royalties or~~ **for AUCATZYL and our** ~~entering into similar financials transactions involving the~~ **other** ~~sale of~~ **product candidates are smaller than we estimate, our** ~~revenues~~ - **revenue and** ~~or royalties, or (f) acquiring subsidiaries without joining such subsidiary as a party to the Blackstone Collaboration Agreement. These restrictions could inhibit our~~ ability to ~~pursue our business strategies~~ **achieve profitability will be adversely affected, possibly materially. The total addressable market opportunity for AUCATZYL** and ~~may limit~~ our ~~ability to~~ **other product candidates will ultimately depend upon** , among other things, ~~incur secured indebtedness~~ **acceptance by the medical community and patient access** , **product pricing and reimbursement as well as expansion into additional markets. The** ~~encumber~~ -- **number** ~~assets, pay dividends~~ **of patients who may benefit from AUCATZYL or** ~~or~~ **our other future** ~~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~~ **products may turn out** ~~revenues and our profitability,if any,would likely~~ to be lower than **expected** ~~if we were to sell~~ , ~~market~~ **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 ~~distribute any~~ **our business.We may not be successful in our efforts to identify additional** product candidates ~~that we develop ourselves~~ . **Due to our** ~~In addition,we would have~~ limited ~~control over such third parties,and any of them may fail to devote the necessary~~ resources and ~~attention~~ **access** to ~~sell and market our~~ **capital,we must prioritize development of certain** product candidates ~~effectively.If we do not establish sales~~ , ~~marketing~~ **which may prove to be the wrong choice** and **may adversely affect** ~~distribution~~

~~capabilities successfully,either on our own or~~ **our business** ~~in collaboration with third parties,we will not be successful in commercializing our product candidates in the United States or elsewhere~~ .We operate in a rapidly changing industry and face significant competition,which may result in others discovering,developing or commercializing products before or more successfully than we do.The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements.We face competition from major multi- national pharmaceutical companies,biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future.There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer.Smaller or early- stage companies may also prove to be significant competitors,particularly through collaborative arrangements with large,established companies.Potential competitors also include academic institutions,government agencies and other public and private research organizations.Due to their promising clinical therapeutic effect in clinical exploratory trials,engineered T cell therapies,redirected T cell therapies in general and antibody- drug conjugates are being pursued by multiple biotechnology and pharmaceutical companies,including Novartis AG (“ Novartis ”),Gilead Sciences,Inc.(“ Gilead ”),Bristol- Myers Squibb (“ BMS ”), **and** Janssen Biotech ~~Inc.,Bluebird bio,Inc.(“ Bluebird bio ”),Roche Holding AG,Seattle Genetics,and Amgen~~ Inc.Our competitors may succeed in developing,acquiring or licensing technologies and products that are more effective,more effectively marketed and sold or less costly than any product candidates that we may develop,which could render our product candidates non- competitive and obsolete.We **have received** ~~are developing our lead program,obe- cel,a CD19- targeting~~ **marketing** ~~programmed T cell product candidate~~ **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** ~~Obe- cel~~ is expected to compete directly with these companies and therapies.In addition,some companies,such as Cellectis,Inc.,Les Laboratoires Servier SAS ~~and~~ **,** Allogene Therapeutics Inc., **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. ~~In addition,~~ **Our commercial opportunity could be reduced** ~~our~~ **or eliminated if our** competitors ~~with development~~ ---- **develop** ~~- stage programs~~ **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 ~~marketing approval from the~~ FDA, ~~the~~ European Commission or other ~~comparable~~ regulatory ~~authorities~~ **approval** for their ~~product~~ **products candidates** ~~more rapidly than we do~~ **may obtain approval for ours** , **which** ~~and they~~ could **result in our competitors** ~~establish~~ **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 ~~study~~ **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. ~~Our commercial opportunity~~ **Coverage and adequate reimbursement may not be available for AUCATZYL or our current or any future product candidates,which** could ~~be reduced or~~ make **it difficult** ~~other distributions to holders of our capital stock, license- out the Collaboration Products, complete mergers or~~ **for us to** ~~acquisitions, or~~ sell ~~royalties~~ **profitably, if approved** . ~~If we default under~~ **Market acceptance and sales of** our ~~obligations under~~ **product and any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for** ~~the~~ **these products and related treatments** ~~Blackstone Collaboration Agreement, we~~ will be ~~obligated to~~ **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 ~~Blackstone liquidated damage payments~~ **for and establish reimbursement levels. Third- party payors** in ~~excess of~~ the ~~development~~ **United States often rely upon Medicare coverage policy and** payment ~~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** ~~drug that we commercialize~~ and,if reimbursement is available,what the level of reimbursement will be.Even if favorable coverage and reimbursement status is attained for ~~one or~~ **our** ~~more~~ **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 ~~by Blackstone. If we fail~~ to ~~make such~~ **clinical trial participants or** ~~payments~~ **patients ; • loss** ~~, Blackstone could elect to exercise its remedies in respect~~ of **revenue; and •** the ~~security interest~~ **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** ~~would seriously harm our business and ability~~ to ~~continue~~ **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 ~~going concern~~ **reasonable cost or in an amount adequate to satisfy any liability that may arise** . Risks Related to the Development of Our Product Candidates **Our** ~~All of our~~ product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed **. 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 ~~product~~ **products** ~~candidates~~ **, 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 ~~, and~~ **. Although** we ~~may not receive~~ **received** marketing approval from the FDA ~~, or~~ **for AUCATZYL in** ~~other~~ -- **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 ~~UK~~ **U. K.** and EU. We are sponsoring active, recruiting clinical trials for ~~two of our product candidates,~~ obe- cel **in additional indications** ~~(AUTO1),~~ and AUTO4. We are also collaborating with our academic partner UCL to support clinical trials sponsored by them of ~~our product candidates (~~ obe- cel **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 ~~. We do not currently have any approved or commercialized products~~ . Some of our product candidates employ a dual- targeting mechanism. By targeting two separate antigens on the cancer cell surface, we believe these product candidates have the potential to improve durability of treatment response and reduce the frequency of cancer relapse as compared to other currently available single- targeting T cell therapies. AUTO4, our product candidate for the treatment of T cell lymphoma, employs a novel approach to killing malignant T cells that aims to preserve approximately half of the normal, healthy T cells. Some of our product candidates include a " safety switch " that is designed to allow for the elimination of the engineered T cells if a patient experiences severe adverse side effects from the treatment. However, this " safety switch " technology has not been activated to date in our clinical studies, and we do not know whether it would have the intended effect if used. Additionally, as with other targeted therapies, off- tumor or off- target activity could delay development or require us to re- engineer or abandon a particular product candidate. Because programmed T cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment and autoimmune diseases generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including: • obtaining regulatory approval for our product candidates, as the FDA, the European Commission and other regulatory authorities have limited experience with programmed T cell therapies for cancer; • sourcing clinical and, if approved, commercial supplies of the materials used to manufacture our product candidates; • developing programming modules with the desired properties, while avoiding adverse reactions; • creating viral vectors capable of delivering multiple programming modules; • developing a reliable and consistent vector and cell manufacturing process; • establishing manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical studies and our projected commercial requirements; • achieving cost efficiencies in the scale- up of our manufacturing capacity; • developing protocols for the safe administration of our product candidates; • educating medical personnel regarding our programmed T cell therapies and the potential side effect profile of each of our product candidates, such as potential adverse side effects related to CRS; • establishing integrated solutions in collaboration with specialty treatment centers in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies; • establishing sales and marketing capabilities to successfully launch and commercialize our product candidates if and when we obtain any required regulatory approvals, and risks associated with gaining market acceptance of a novel therapy if we receive approval; and • obtaining coverage and adequate reimbursement from third- party payors for our novel and personalized therapies in connection with commercialization of any approved product candidates. We may not be able to successfully develop our programmed T cell product candidates or our T cell programming technologies in a manner that will yield products that are safe and effective, scalable or profitable. Additionally, because our technology involves the genetic modification of patient cells ex vivo, we are subject to additional regulatory challenges and risks, including regulatory requirements governing genetically modified organisms that have changed frequently and will likely continue to change in the future, and that may limit or delay our ability to import our product candidates into certain countries for use in clinical trials or for commercial sale even if we receive applicable marketing approvals. Moreover, public perception and awareness of T cell therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Physicians, hospitals and third- party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of programmed T cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs. Our future success is highly dependent on the regulatory approval of our ~~current~~ **other** clinical- stage programmed T cell product candidates and our preclinical programs. **Our** ~~All of our~~ product candidates will require significant clinical or preclinical testing before we can seek regulatory approval for and launch a product commercially. **Although we** ~~We do not~~ have **received FDA** ~~any products that have gained regulatory~~ approval ~~. Our~~ **for AUCATZYL in r / r B- ALL, our** business ~~is~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **U. K.** ILAP designation in r / r ~~adult~~ 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. ~~To date, we have had only limited interaction with the FDA, MHRA, the EMA and the European Commission, regarding our product candidates.~~ Prior to seeking approval for any of our **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** ~~Examples of this include an expanded conflict in Eastern Europe and severe volcanic activity in Iceland, either of which has the potential to disrupt international air traffic~~ for ~~weeks.~~ **AUCATZYL in r / r B- ALL, and** ~~Even~~ **even** if ~~a~~ **any of our other** product ~~candidate~~ **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, ~~any~~ **the** regulatory approval of **AUCATZYL,** ~~our~~ **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 ~~anti- tumor~~ activity, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, achieve market acceptance or obtain reimbursements from third- party payors. If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our ADSs. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or to commercialize these programs on a timely basis or at all, which would have an adverse effect on our business. Many of our product candidates are in the preclinical development stage. The risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on IND applications in effect in the United States and clinical trial applications (" CTAs ") in the EU and other European countries. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the competent authorities of EU Member States or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA, the competent authorities of EU Member States or other regulatory authorities allowing clinical trials to begin. Clinical trials are difficult to design and implement, involve uncertain outcomes and may not be successful. Human clinical trials are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for biologic products proceeding through clinical trials, which may be higher for our product candidates because they are based on new technology and engineered on a patient- by- patient basis. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in preclinical testing and earlier- stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects. Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials. Results from preclinical studies are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. For example, we have treated only a small number of patients in some of our ongoing clinical trials. For that reason, we do not know whether these candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. This failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates. We depend on enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the ~~study~~ **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 ~~study~~ **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** ~~relapsed or refractory acute B lymphoblastic leukemia (" B- ALL ")~~, or pediatric or adult ALL, and ~~relapsed or refractory~~ **r / r** DLBCL, ~~relapsed or refractory~~ **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 ~~study~~ **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 ~~certain of~~ our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect. ~~For instance, cancer~~ **Cancer** therapies are sometimes characterized as first line, second line or later lines, and the FDA often approves new therapies initially only for later line use. When blood cancers are detected, they are treated with the first line of therapy with the intention of curing the cancer. This generally consists of chemotherapy, radiation, antibody drugs, tumor- targeted small molecules, or a combination of these. In addition, sometimes a bone marrow transplantation can be added to the first line therapy after the combination chemotherapy is given. If the patient' s cancer relapses, e. g. a B- cell malignancy, then they are given salvage therapies which can consist of more chemotherapy, radiation, CAR T cell products, antibody drug conjugates, tumor- targeted small molecules, or a combination of these, or a bone marrow transplant. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy in the treatment of lymphoma and myeloma is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations. ~~We are currently developing obe- cel for treatment of relapsed / refractory adult patients with B- ALL. As a next step, obe- cel could be developed in newly diagnosed patients with B- ALL as a consolidation strategy in first complete remission in order to replace or avoid allogeneic transplantation. AUTO4 is currently being developed as a treatment option for relapsed / refractory TRBC1- positive T cell lymphoma patients. If AUTO4 is eventually approved as a second line therapy, we may seek to initiate a trial to position it as a consolidation therapy after first line chemotherapy in T cell lymphoma.~~ There is no guarantee that any of our product candidates, even if approved in later lines, would be approved for an earlier line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to gaining approval for the earlier line of therapy. Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, in our clinical trial for AUTO4, we are initially targeting a small patient population that suffers from peripheral T cell lymphoma, a rare and heterogeneous form of NHL. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenues without obtaining regulatory approval for additional indications or as part of earlier lines of therapy. Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following any potential marketing approval. In clinical trials conducted by other companies involving CAR T cells, the most prominent acute toxicities included symptoms thought to be associated with CRS, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, or neurotoxicity, such as confusion, tremor, cranial nerve dysfunction, seizures and speech impairment. CAR T cell associated neurotoxicity is also known as ICANS. Adverse events with the worst grades and attributed to CAR T cells were severe and life threatening in some patients. The life- threatening events were related to cardiac dysfunction, kidney dysfunction and neurotoxicity. Severe and life-threatening toxicities occurred mostly in the first two weeks after cell infusion and generally resolved within three ~~-~~ **to** four weeks, but several patients died in clinical trials involving CAR T cells developed by other companies and academic institutions. For example, ~~at the ASH Annual Meeting in December 2023 we presented safety data from a pooled analysis of 127 patients treated in the FELIX trial, where we observed that 2 % of patients, had equal to or greater than Grade 3 CRS and that 7 % of patients, had equal to or greater than Grade 3 ICANS. In addition,~~ the FDA ~~-~~ ~~recently announced a requirement that~~ approved **label** ~~BCMA- directed or~~ **for AUCATZYL carries** ~~CD19- directed autologous CAR T cell immunotherapies carry~~ a boxed warning ~~in their labeling~~ 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** , ~~AUTO4~~ or any of our other product candidates will not experience more severe CRS, unacceptable levels of neurotoxicity or other serious adverse events. Our clinical trials include cancer patients who are very sick and whose health is deteriorating, and we expect that additional clinical trials of our other product candidates will include similar patients with deteriorating health. It is possible that some of these patients may experience similar adverse side effects as were observed in clinical trials conducted by other companies and

academic institutions involving CAR T cells, and that additional patients may die during our clinical trials for various reasons, including as a result of receiving our product candidates, because the patient' s disease is too advanced, or because the patient experiences medical problems that may not be related to our product candidate. Even if the deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidate. Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our therapeutic candidates, could result in the delay, suspension, clinical hold or termination of clinical trials by us, the FDA, the competent authorities of EU Member States or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly. If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA and the European Commission or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA, the European Commission or other comparable regulatory authority, and we may never receive such approvals. ~~It~~ **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- ~~vein product~~ delivery cycle. We have constructed and use a new facility (which we call " The Nucleus ") in Stevenage, ~~UK~~ **U. K.** which we believe will support our ~~clinical manufacturing capacity and potential~~ 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 ~~expect that the establishment of our own commercial cell manufacturing facilities will provide us with enhanced control of product supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long- term cost margins. However, we~~ have limited experience as a company in designing and operating a commercial cell therapy or vector manufacturing facility and may ~~never~~ **not** be successful in ~~developing~~ **sustaining** our own manufacturing ~~facility or~~ capability. We may establish additional manufacturing sites as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. **Our** ~~Even if we are successful, our~~ manufacturing operations could be affected by cost ~~–~~overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors, or we may not be successful in establishing sufficient capacity to produce our product candidates in sufficient quantities to meet the requirements for the potential launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. We may not be successful in achieving cost of goods at commercial scale that provide for an attractive margin. We believe that our current, enclosed manufacturing processes are fit for commercial scale and we anticipate they will enable commercial supply at an economical cost. However, we have not yet ~~established~~ **sustained** manufacturing capacity at commercial scale and may underestimate the cost and time required to do so, ~~or~~ **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** ~~our product candidates~~ is complex and we may encounter difficulties in production, particularly with respect to process development or scaling- out of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients ~~, if approved,~~ could be delayed or stopped. We have developed a process for manufacturing programmed T cells in a fully enclosed system designed to minimize the risk of contamination, and we have improved the viral transduction process to help eliminate processing inconsistencies. We believe that our current processes are suitable for commercialization. While we have established a process which we believe is scalable for commercial production, each manufacturing process must be validated through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. We have not yet manufactured or processed our product candidates on a commercial scale and may not be able to do so for any of our **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 ~~reported at~~ **as published in** the ~~ASH Annual Meeting~~ **New England Journal of Medicine** in December ~~2023~~ **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 ~~vein- to- vein~~ supply chain, the manufacturing process for that patient will need to be restarted ~~and~~ **, 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** ~~it is common that various aspects of the development program, such as manufacturing methods,~~

~~are altered along the way~~ in an effort to optimize processes **or clinical approach. Any changes to a process or clinical approach must serve the needs of the patient** and ~~results~~ **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 ~~candidate~~ **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. ~~Our most advanced product candidate, obe- cel, may face this challenge.~~ For example ~~, ALL patients could have received currently approved therapies such as Blincyto or Kymriah or Tecartus, or a CD19 ADC, or a CD22 targeting CAR T, or CD22 ADC, like Besponsa, or similar products or product candidates prior to receiving obe- cel. Similarly~~, patients with autoimmune diseases receive multiple types of treatment including toxic lympho- depleting chemotherapies, ~~these~~ **which** may ~~also~~ have an impact ~~of~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~. This agreement provides details on how some aspects of the UK and EU' s relationship will operate going forwards however there are still uncertainties~~ . The TCA primarily focuses on ensuring free trade between the EU and the ~~UK~~ **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** ~~many aspects of the~~ EU regulatory rules, ~~particularly~~ **including** in relation to trade in ~~goods~~ **medical devices, but not in relation to medicinal products** . As part of the TCA, the EU and the ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **U. K.** must be retested and re- released when entering the EU market for commercial use. ~~As it relates to marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU Member States no longer encompasses Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market in Great Britain. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission.~~ On February 27, 2023, the ~~UK~~ **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. ~~If~~ **Under** the **Windsor Framework, effective** ~~changes are adopted in the form~~ **from** ~~proposed~~ **January 1, 2025**, medicinal products to be placed on the market in the ~~UK~~ **U. K. (including in Northern Ireland)** will be authorized solely in accordance with ~~UK~~ **U. K.** laws. Northern Ireland **is** ~~would be~~ reintegrated back into a ~~UK~~ **U. K.** - only regulatory environment under the authority of the MHRA with respect to all medicinal products. ~~The implementation of the Windsor Framework would occur in stages, with new arrangements relating to the supply of medicinal products into Northern Ireland anticipated to take effect in 2025.~~ A significant proportion of the regulatory framework in the ~~UK~~ **U. K.** applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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~~ **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** ~~will need~~ to **continue to expand** ~~manage the size of~~ our ~~organization~~ **development**, **commercial** and **regulatory capabilities and have recently developed sales, marketing and distribution capabilities, and as a result,** we may ~~experience~~ **encounter** difficulties **in managing our growth, which could disrupt our operations**. As of December 31, ~~2023~~ **2024**, we had ~~471~~ **650** employees, ~~463~~ **647** of whom are full- time. ~~As~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **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 become more common and~~ has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We rely on third- party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third- party research collaborators, CROs, contract manufacturers, and suppliers for many aspects of our business, including research and development in connection with our clinical trial activities. Our reliance on such third- party service providers, technologies and collaborators could introduce new cybersecurity risks and vulnerabilities, including supply- chain attacks, and other threats to our business operations. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If ~~our~~ **the** third ~~- party service providers~~ **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 ~~our~~ **the** third ~~- party service providers~~ **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 ~~our~~ **that of the** third ~~- party partners~~ **parties** ~~' supply chains~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **work**). We ~~may~~ **have** not **and may not in the future** , however, ~~be able to~~ detect and remediate all such vulnerabilities, including on a timely basis. Further, we **have (and** may **in the future)** ~~experience~~ **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. ~~Any~~ **Certain** of the previously identified or similar threats ~~could~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **work** . ~~A~~ **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 ~~upon which~~ **with whom** we ~~rely~~ **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 ~~may~~ require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive data. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party ~~upon which~~ **with whom** we ~~rely~~ **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 £ ~~6~~ **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; ~~loss of customers or sales;~~ and other adverse business consequences. In the ordinary course of business, we process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, and data we collect about trial participants in connection with clinical trials. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. ~~An~~ **Outside of the U. S., an** increasing number of laws, regulations, and industry standards ~~may~~ govern data privacy and security. For example, the EU GDPR and the ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~interpretations of their~~ data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA, the UK, and Switzerland to the United States in compliance with law, such as the EEA standard contractual clauses, the ~~UK~~ **U. K.** ' s International Data Transfer Agreement / Addendum, the Swiss- U. S. Data Privacy Framework ~~(once officially recognized as a valid data transfer mechanism by the Swiss government)~~ , and the EU- U. S. Data Privacy Framework and the ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~— including California, Virginia, Colorado, Connecticut, and Utah —~~ have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive data, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example the CCPA provides fines ~~of up to $ 7, 500 per intentional violation~~ and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA **and other comprehensive U. S. state privacy laws** ~~exempts~~ **exempt** some data processed in the context of clinical trials, ~~the~~ **these** ~~CCPA~~ **developments may further complicate compliance efforts and** increases compliance costs and potential liability **for us and the third parties** with **whom** ~~respect to other personal data~~ we **work** ~~maintain about~~

~~California residents~~ . Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. ~~While these state laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.~~ In addition to data privacy and security laws, we are **contractually** subject to industry standards adopted by industry groups and **we are, and** may become **in the future,** subject to such obligations ~~in the future~~ . We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements ~~regarding~~ **concerning** data privacy and security. ~~If~~ **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 ~~upon~~ **with** whom we ~~rely~~ **work** may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties ~~upon~~ **with** whom we ~~rely~~ **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 ~~Israel- Hamas conflict~~ **conflicts** in ~~Gaza~~ **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** ~~current Israel- Hamas conflict, with Israel having declared war on Hamas, a U. S. designated Foreign Terrorist Organization, due to recent attacks~~ . Although, to date, our business has not been materially impacted by the events described above, it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of the conflicts in Ukraine and Gaza, geopolitical tensions, record inflation and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks we face. As a public company with operations in the EU, we may be subject to the sustainability disclosure requirements set out in the EU Corporate Sustainability Reporting Directive. A ~~growing~~ number of investors, regulators, self- regulatory organizations and other stakeholders have expressed an interest in Environmental, Social and Corporate Governance (" ESG ") matters, and are requiring more robust ESG disclosures. The related legislative landscape in the EU has been evolving ~~accordingly~~ **rapidly** . For example **, the EU adopted an ESG reporting rule** , EU Directive No 2464 / 2022 on Corporate Sustainability Reporting (" CSRD ") **that** ~~was adopted and~~ entered into force on January 5, 2023 ~~, amending the current EU Accounting Directive No 2013 / 34~~ . The CSRD introduces new mandatory reporting obligations **for in- scope companies** that ~~will~~ require the publication of **fulsome** audited ~~sustainability information~~ **ESG disclosures, including disclosures under the EU Taxonomy Regulation 2020 / 852** . The CSRD **currently** ~~is supplemented by EU Delegated Regulation No 2023 / 2772 which establishes the first set of European Sustainability Reporting Standards (" ESRS "), which are applicable to in- scope EU~~

~~entities. Further reporting standards are due to be adopted by June 2026, including for in- scope non- EU entities. The CSRD and ESRS require certain mandatory disclosures, as well as disclosures of certain " material " sustainability matters in the company' s own operations, those of their subsidiaries and those of their value chain. The identification of material sustainability matters requires a " double materiality " assessment. This means that in- scope entities will have to assess both financial materiality, which are sustainability matters which generate risks or opportunities that affect, or could reasonably be expected to affect, the company' s financial position, financial performance, cash flows, access to finance or cost of capital over the short-, medium- or long- term, and impact materiality, which are the company' s material actual or potential, positive or negative impacts on people or the environment over the short-, medium- and long- term.). Sustainability matters are material if they satisfy one or both of these materiality tests. The CSRD~~ applies to entities with securities admitted to trading on an EU regulated market, as well as large EU companies, EU parents of a " large group ", and to listed EU small or medium- sized enterprises, amongst others. It will also apply to non- EU companies that have a certain threshold of EU- generated turnover and an in- scope EU subsidiary or EU branch meeting the turnover thresholds. Companies subject to the CSRD are required to fulfil their reporting obligations in accordance with a staggered timeline depending on the category of company. The first reports are ~~expected in~~ **being published during** 2025 for the 2024 financial year, predominantly ~~for~~ **by** entities with securities admitted to trading on an EU regulated market **. In February** ~~, and in 2026 for the~~ 2025 **,** ~~financial year for many other~~ -- **the** EU ~~companies (including~~ **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 ~~subsidiaries of non- EU parents) that are not listed on an EU regulated market but meet the relevant size thresholds~~ . In response to new ESG initiatives and regulations we may ~~voluntarily elect, or~~ be required ~~,~~ to adopt strategies, policies, or procedures related to ESG matters and report on these. Reporting **could involve** ~~on ESG goals and objectives may cause us to expend significant~~ capital and human resources ~~,~~ and could ~~divert management' s attention from central operational matters. Reports could also~~ lead to the disclosure of information that ~~which~~ may have a negative impact on our operations and reputation which may lead to additional exposure. Failure to accurately comply with any ESG reporting obligations may result in enforcement actions, sanctions, reputational harm or private litigation. Risks Related to Our Dependence on Third Parties We are dependent on intellectual property obtained or licensed from third parties, and if we were to fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose intellectual property rights that are important to our business and we may not be able to continue developing or commercializing our product candidates, if approved. We are party to an exclusive intellectual property license agreement with UCLB, the technology- transfer company of UCL, which is important to our business and under which we have acquired or licensed patent rights related to 17 patent families and other intellectual property related to our business. We expect to enter into additional license agreements in the future. Our existing license agreement with UCLB imposes, and we expect that future license agreements will impose, various due diligence, milestone payment, royalty, insurance and other obligations on us. Any uncured, material breach under the UCLB license agreement could result in our loss of rights to practice the patent rights (including those that have been assigned to us from UCLB) and other intellectual property licensed to us, and could compromise our development and commercialization efforts for our **products and** ~~current or any future~~ product candidates. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. For example, under our license agreement with UCLB, our exclusive rights under certain of the patents is subject to specified exclusions. Our right to enforce any patents that may issue from such patent rights similarly excludes enforcing them in such excluded fields, and obligates us to coordinate our enforcement efforts with a third- party licensee, if any, with rights in that excluded field. If a third party- licensee has the right to enforce those patents in their field, it could put a patent that may issue from this family at risk of being invalidated or construed narrowly, in which case we would no longer have the benefit of the patents for our own exclusivity. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including disputes regarding: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our obligations to third parties; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us; • our right to transfer or assign the license; and • the effects of termination. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates ~~. See the section of this Annual Report titled " Business- Our License Agreement with UCL Business Ltd. " for a more detailed description of our license agreement with UCLB, as well as our rights and obligations under the agreement~~ . We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements. We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical and clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as GLP and GCP, for conducting, recording and reporting the results of preclinical and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial

participants are protected. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (the " ICH "). Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA or comparable foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing our clinical- stage product candidates or any future product candidates. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government- sponsored databases, such as ClinicalTrials. gov and foreign equivalents, within specified timeframes. Failure to do so by us or third parties can result in FDA or comparable foreign regulatory authority refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions. Cell- based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products. Manufacturing our product **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 ~~CAR T~~ product candidates, which requires significant resources. A failure to successfully operate our manufacturing facility could lead to substantial delays and adversely affect our research and development efforts, including clinical trials, and ~~the future~~ commercial ~~viability~~ **success of AUCATZYL and our product candidates** , if approved ~~, of our CAR T product candidates~~ . We are also obligated to share some of the capabilities of the manufacturing facility with BioNTech under the BioNTech License Agreement. Our clinical and commercial manufacturing facility, The Nucleus, must be periodically inspected and licensed by the appropriate authorities. While we will continue to source raw materials from external CMOs, we plan to make the transition from external CMOs to our manufacturing facility and we expect our manufacturing facility to be the sole source supplier of clinical materials for our clinical trials and for commercial products, once approved. This sole source reliance increases the risk that we will not have sufficient quantities of our CAR T product candidates at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts, if approved. In addition, under the terms of the BioNTech License Agreement, we granted BioNTech the option to negotiate a joint Manufacturing and Commercial Agreement pursuant to which the parties may access and leverage each other' s manufacturing and commercial capabilities, in addition to Autolus' commercial site network and infrastructure, with respect to certain of each parties' CAR T products, including BioNTech' s product candidate BNT211 (the " Manufacturing and Commercial Agreement "). The Manufacturing and Commercial Agreement, if entered into, would also grant BioNTech access to our commercial site network and infrastructure. If required under the Manufacturing and Commercial Agreement, we may need to subordinate production of our CAR T products in order to BioNTech' s products. Sharing The Nucleus facility with BioNTech increases the risk that we will not have sufficient quantities of our CAR T product candidates at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts, if approved. In either case, if we are unable to manufacture sufficient clinical or commercial materials at our manufacturing facility, we may be forced to contract with external CMOs, which we may not be able to do on commercially reasonable terms, if at all. Even if commercially reasonable terms are available, any transition of manufacturing from our manufacturing facility to an external CMO could be time- consuming and require significant effort and expertise because there may be a limited number

of qualified replacements. In some cases, the technical skills or technology required to manufacture our CAR T product candidates may be unique or proprietary and we may have difficulty transferring such skills or technology to another CMO and a feasible alternative may not exist. If we fail to manufacture at our manufacturing facility, or obtain from a CMO, a sufficient supply of clinical materials for our clinical trials **, 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 ~~future~~ commercial **success** ~~viability, if approved,~~ 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** ~~investee of Syncona Portfolio Limited~~ . These agreements provide us with important funding for our programs. If our therapeutic programs and related collaborations do not result in the successful development and commercialization of products or if one of our collaborators or licensees terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments associated with such collaboration or license arrangement. In addition, any termination of an agreement by the relevant collaborators could affect our ability to develop further such product candidates or adversely affect how we are perceived in scientific and financial communities. All of the risks **we face** relating to product development, regulatory approval and commercialization ~~described in this Annual Report~~ also apply to the activities of our program collaborators. In our collaboration arrangements, we depend on the performance of our collaborators. Our licensees have the right to make decisions regarding the development and commercialization of product candidates under the collaborations without consulting us and may make decisions with which we do not agree. Our collaborators may fail to perform their obligations under the collaboration agreements or may not perform their obligations in a timely manner. If conflicts arise between our collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Furthermore, our collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. In addition, we cannot control the amount and timing of resources our collaborators may devote to our product candidates. They

may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Even if our collaborators continue their contributions to the strategic collaborations, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Additionally, if our collaborators pursue different clinical or regulatory strategies with their product candidates based on similar technology as used in our product candidates, adverse events with their product candidates could negatively affect our product candidates. Any of these developments could harm our product development efforts. If our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. Furthermore, if our collaborators do not prioritize and commit sufficient resources to our product **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 ~~collaboration~~ **collaborators** ~~partners~~. Consequently, our ability to inform our shareholders about the status of such product candidates, and to make informed operational and investment decisions about the product candidates to which we have retained development and commercialization rights, may be limited. We do not and will not have access to all information regarding the product candidates being developed and potentially commercialized by BioNTech, including potentially material information about clinical trial design and execution, regulatory affairs, process development, manufacturing, marketing and other areas known by BioNTech. In addition, we have confidentiality obligations under our agreement with BioNTech. Thus, our ability to keep our shareholders informed about the status of product candidates under our collaboration will be limited by the degree to which BioNTech keeps us informed and allows us to disclose such information to the public. We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Additionally, although we intend to develop product candidates through our own internal research, we may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business. We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon an assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator' s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership regardless of the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue. Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters **Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.** Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post- market information, are subject to comprehensive regulation by the FDA, the EU and other comparable regulatory authorities in other jurisdictions. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate ~~. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction~~. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third- party CROs, to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’ s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit

commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process demonstrating the products quality to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or the European Commission or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies including further manufacturing process or quality control data. In addition, varying interpretations of the data obtained from manufacturing procedures, quality control, preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be impaired. In order to market and sell our products in the EU and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Obtaining and maintaining regulatory approval of **AUCATZYL** ~~our~~ **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 ~~if~~ **though** the FDA ~~grants~~ **granted** marketing approval **for AUCATZYL in the U. S. for the treatment** of ~~a product candidate~~ **r / r B- ALL** , comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion of ~~the product candidate~~ **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 ~~if~~ **though** we **have** ~~obtain~~ **obtained** marketing ~~approvals~~ **approval by the FDA** for **AUCATZYL** ~~our product candidates~~ , the terms of approvals and ongoing regulation of **AUCATZYL** ~~our products~~ may limit how we manufacture and market **AUCATZYL** ~~our products~~ and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue. Even ~~if~~ **though we have been granted** marketing approval **by the FDA for AUCATZYL** ~~of a product candidate is granted~~ , an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, pharmacovigilance oversight, storage, advertising, promotion, sampling, and recordkeeping, including the potential requirements to implement a REMS program in the United States or comparable foreign strategies, or similar schemes in other countries, or to conduct costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for **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 ~~, if we receive marketing approval for one or more of our product candidates~~ , we and suppliers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post- approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. ~~Any~~ **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 ~~UK~~ **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 ~~may~~ **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 ~~UK~~ **U. K.** GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the EU and ~~UK~~ **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 ~~UK~~ **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 ~~in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further,~~ on August 16, 2022, ~~President Biden~~ **the Inflation Reduction Act was** signed ~~the IRA,~~ into law, which among other things (i) ~~directs~~ **directed** HHS to negotiate the price of certain high- expenditure, single- source ~~drugs and~~ biologics **that have been on the market for at least 11 years** covered under Medicare **(the " Medicare Drug Price Negotiation Program ")** and (ii) ~~imposes~~ **imposed** rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions **took** ~~will take~~ effect progressively starting in fiscal year 2023. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed- upon reimbursement prices** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare ~~drug~~ **Drug price** **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** is currently subject to legal challenges. ~~It is currently unclear how the IRA~~ **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** ~~be implemented but is likely~~ to ~~have a significant impact on the pharmaceutical industry. In response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three~~ -- **the Medicare Drug Price Negotiation Program** ~~new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future~~ . Further, on December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **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. ~~Outside~~ **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 ~~UK~~ **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 ~~product~~ **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. ~~While Congress has not passed repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, includes a provision repealing, effective January 1, 2019, the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or~~ **For example** ~~part of a year that is commonly referred to as the " individual mandate ". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA- mandated " Cadillac " tax on high- cost employer- sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50 % to 70 % the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole ". On June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further~~ , the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program ~~. It is unclear how additional changes, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business~~ . In addition, other federal health reform measures have been proposed and adopted in the United States. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2 % per fiscal year until 2032 unless additional Congressional action is taken. ~~Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program (" Quality Payment Program "), under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. The Quality Payment Program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models (" APMs "), and the Merit- based Incentive Payment System (" MIPS "). Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.~~ In December 2021, Regulation No 2021 / 2282 on HTA ~~amending Directive 2011 / 24 / EU~~ , was adopted in the EU. This Regulation, which entered into ~~force in~~ **application on** January **12,** ~~2022 and will apply as of January~~ 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 ~~foresees a three- year transitional period and will permit~~ **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 ~~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. **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 ~~, or~~ **(“** CTR **”)** , which was adopted in April 2014 and repeals the EU Clinical Trials Directive **(“ CTD ”)** , became applicable on January 31, 2022. The CTR ~~permits~~ **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 ~~of some elements of the application~~ by all EU Member States **concerned** ~~in which the trial is to be conducted~~ , and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State’ s decision is communicated to the sponsor through a centralized EU portal ~~,~~ **. Once** the ~~Clinical~~ **clinical** ~~Trial~~ **trial approved** ~~Information System~~ , ~~or CTIS~~ **clinical study development may proceed** . The CTR ~~provides~~ **foresaw** a three- year transition period **that ended on January 31, 2025** . ~~The extent to which~~ **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 ~~will be~~ **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 ~~varies. For~~ **was required for** clinical trials ~~in relation to~~ which ~~an~~ **had at least one site active in the EU on January 30, 2025. A transitioning** application ~~for approval was made on~~ **had to be submitted to** the ~~basis~~ **competent authorities** of **EU Member States through** the Clinical Trials ~~Directive before~~ **Information Systems and related regulatory approval obtained to continue the clinical trial past** January ~~31~~ **30** , ~~2023~~ **2025 . This required financial** , **technical and human resources. It is currently unclear to what extent** the ~~CTD~~ **UK** will ~~continue~~ **seek** to **align its regulations with** ~~apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to~~ the ~~provisions of~~ **EU in** the ~~CTR~~ **future** . The ~~CTR will apply~~ **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 ~~earlier date~~ **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** ~~the~~ **their** ~~related~~ **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 ~~trial~~ **trials** ~~application~~ **in the UK** ~~was~~ **as opposed to other countries and / or** ~~made~~ **make it harder to seek a marketing authorization for the Company' s product candidates** on the basis of ~~the CTR or if the~~ clinical ~~trial~~ **trials conducted in** ~~has already transitioned to~~ the **United Kingdom** ~~CTR framework before January 31, 2025~~ . In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **U. K.** Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the ~~UK~~ **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, ~~UK~~ **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 ~~have~~ **previously** identified ~~a~~ material ~~weakness~~ **weaknesses** in our internal control over financial reporting. If **we experience additional** ~~our remediation of the~~ material ~~weakness~~ **weaknesses** ~~is~~ **or otherwise fail to maintain an effective system of internal controls in the future, we may** not ~~effective~~ **be able to accurately report** ~~or our~~ ~~if we fail to develop and maintain effective internal control over~~ 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** ~~our ability to produce timely and accurate financial information or comply with Section 404~~ of the Sarbanes- Oxley Act of 2002 ~~could be impaired, which could have a material adverse effect on our business and the trading price of our ADSs. As a public company, we are subject to the reporting requirements of the Exchange Act~~ , as ~~well as~~ **amended (** the **"** ~~requirements of the~~ Sarbanes- Oxley Act **"** ~~of 2002, as amended (the" Sarbanes- Oxley Act"~~), and the listing standards of the Nasdaq Stock Market. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. It also requires management to perform an annual assessment of the effectiveness of our internal control over financial reporting and disclosure of any material weaknesses in such controls. In connection with the audit of our financial statements for the year ended December 31, 2023, we ~~have~~ identified a material weakness in our internal control over financial reporting in connection with the historic misinterpretation and application of ASC 740 ~~- Income Taxes~~ , resulting in our **U. K.** ~~UK small and medium enterprise (~~ SME ~~)~~ tax credits being incorrectly presented in income tax benefit (expense). Refer to Note 3, Restatement of

Previously Issued Consolidated Financial Statements, in the Consolidated Financial Statements in Part II, Item 8 of ~~this~~ **our Annual** ~~report~~ **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 ~~this~~ **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 ~~weakness~~ **weaknesses** ~~identified in connection with the restatement~~ described **above** ~~in this report~~ , or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements. We continue to evaluate steps to remediate the material weakness **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 the Commercialization of Our Product Candidates If..... that may arise. Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for our T cell programming technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired. Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States, the EU, the ~~UK~~ **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 ~~2023 and~~ 2025 ~~,~~ and **2038.** ~~there~~ **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** . ~~If regulatory approval is received for obe- cel, unless~~ **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** ~~obe- cel~~ in the United States could be adversely impacted. Moreover, we may fail to identify relevant third party patents or patent applications, or we may incorrectly conclude that the claims of an issued patent are invalid or are not infringed by our activities. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that any of our product candidates may infringe, or which such third parties claim are infringed by our technologies. If we are found to infringe a third party' s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required or may choose to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if successful, the defense of any claim of infringement or misappropriation is time- consuming, expensive and diverts the attention of our management from our ongoing business operations. We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents ~~, if issued~~ , trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain

the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace. We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, and our founder and Chief Scientific Officer, Dr. Martin Pulé, is currently employed both by us and UCL. Although we try to ensure that our employees do not use the proprietary information or know- how of third parties in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non- solicitation agreement. Litigation may be necessary to defend against these potential claims. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own. As of December 31, ~~2023~~ **2024** , our patent portfolio ~~is~~ **was** comprised of ~~81~~ **83** patent families, of which 17 patent families originated from UCLB, the technology- transfer company of UCL, ~~3 patent families are in- licensed from Noile- Immune Biotech, Inc.,~~ and ~~61~~ **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. ~~Any~~ **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 ~~from the products of our competitors~~ . 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** ~~continues to be~~ volatile. The stock market in general, and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors, including economic conditions and other adverse effects or developments relating to geopolitical instability, may negatively affect the market price of our ADSs, regardless of our actual operating performance. As a result of this volatility, you may not be able to sell your ADSs at or above the price paid for the ADSs. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this ~~Annual Report~~ **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** ~~of obecel and any other~~ product candidates; • the clinical or commercial success of competitive drugs, therapies or technologies; • positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors; • the loss of any of our key scientific or management personnel; • regulatory or legal developments in the **US** ~~United States~~ , ~~UK~~ **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 ~~program~~ **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 ~~UK~~ **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 ~~. As of March 20, 2024, approximately 265. 8 million of our ordinary shares (including ordinary shares in the form of ADSs) were issued and outstanding~~ . Sales of a substantial number of shares of our ADSs in the public market, or the perception that these sales might occur, could depress the market price of our ADSs and could impair our ability to raise capital through the sale of additional equity securities. We have filed registration statements on Form S- 8 under the Securities Act to register ordinary shares (including in the form of ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans, and we have also filed an automatic shelf registration statement on Form S- 3 under the Securities Act to register an unspecified number of securities. In addition, in the future, we may issue ordinary shares, ADS or other securities if we need to raise additional capital. The number of new ordinary shares or ADSs, or securities convertible into our ordinary shares or ADSs, issued in connection with raising additional capital could represent a material portion of our then- outstanding ordinary shares. For example, in February 2024, we sold ADSs representing 58. 3 million ordinary shares in an underwritten offering resulting in gross proceeds of $ 350. 0 million, and we also sold ADSs representing 33. 3 million ordinary shares to BioNTech in a private placement, resulting in gross proceeds of $ 200. 0 million. We ~~are contractually obligated to file~~ **filed** a resale registration statement ~~,~~ on ~~form~~ **Form** S- 3 ~~,~~ to register the ADSs we sold to BioNTech in February 2024 ~~. Upon the effectiveness of that registration statement, those ADSs will be freely tradeable~~ . Additionally, in 2022, we filed two " resale " registration statements on Form F- 3 under the Securities Act to register a total of approximately 33. 4 million of our ordinary shares, or securities convertible into our ordinary shares, held by certain of our investors, allowing these shares or ADSs to be sold in the public market. If these shares or ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline. Our senior management, directors and principal shareholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to our shareholders for approval. Members of our senior management, directors and current beneficial owners of 5 % or more of our ordinary shares and their respective affiliates beneficially own, in the aggregate, a majority of our outstanding ordinary shares (including ordinary shares in the form of ADSs). As a result, if these shareholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may harm the market price of our ADSs by: • delaying, deferring, or preventing a change in control; • entrenching our management and / or the board of directors; • impeding a merger, scheme of arrangement, consolidation, takeover, or other business combination involving us; or • discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. In addition, some of these persons or entities may have interests different than yours. For example, because many of these shareholders purchased their shares at prices substantially lower than our current trading price and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders. The rights of our shareholders may differ from the rights typically offered to shareholders of a U. S. corporation. We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of our ADSs, are governed by English law, including the provisions of the U. K. Companies Act 2006 (the " Companies Act "), and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U. S. corporations. Holders of our ADSs may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise their right to vote.

Holders of the ADSs do not have the same rights as our shareholders and in accordance with the provisions of the deposit agreement, will not be able to exercise voting rights attaching to the ordinary shares evidenced by the ADSs on an individual basis. The Depositary or its nominee will act as the representative for the holders of the ADSs and will exercise the voting rights attached to the ordinary shares represented by the ADSs. Holders of our ADSs may not receive voting materials in time to instruct the Depositary to vote, and it is possible that they, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the Depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise voting rights and may lack recourse if their ADSs are not voted as requested. In addition, holders of our ADSs will not be able to call a shareholders' meeting. Holders of our ADSs may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs. Although we do not have any present plans to declare or pay any dividends, in the event we declare and pay any dividend, the Depositary for the ADSs has agreed to pay to holders of our ADSs the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. Holders of our ADSs will receive these distributions in proportion to the number of our ordinary shares their ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of the ADSs. We have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that holders of our ADSs may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have an adverse effect on the value of the ADSs. Because we do not anticipate paying any cash dividends on our ADSs in the foreseeable future, capital appreciation, if any, will be our ADS holders' and shareholders' sole source of gains and they may never receive a return on their investment. Under current English law, a company' s accumulated realized profits must exceed its accumulated realized losses (on a non- consolidated basis) before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, on our ADSs will be our ADS holders' sole source of gains for the foreseeable future, and they will suffer a loss on their investment if they are unable to sell their ADSs at or above the price at which they purchased the ADSs. If we are a PFIC, there could be adverse U. S. federal income tax consequences to U. S. Holders. Under the Internal Revenue Code of 1986, as amended, (the " Code "), we will be a PFIC, for any taxable year in which (1) 75 % or more of our gross income consists of passive income or (2) 50 % or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income, including cash (other than certain cash held in non- interest bearing accounts for short- term working capital needs). For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non- U. S. corporation that directly or indirectly owns at least 25 % by value of the shares of another corporation is treated as if it held its proportionate share of the assets and **directly** received ~~directly~~ its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U. S. holder holds our ADSs, the U. S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. Based on our analysis of our income, assets, activities and market capitalization, we believe we were not a PFIC for our taxable year ended December 31, ~~2023~~ **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, ~~2023~~ **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 ~~. The IRA enacted in the United States introduced, among other changes, a 15 % corporate minimum tax on certain United States corporations and a 1 % excise tax on certain stock redemptions by United States corporations (which the U. S. Treasury indicated may also apply to certain stock redemptions by a foreign corporation funded (or deemed funded) by certain United States affiliates. In addition, effective in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures in the current period and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Internal Revenue Code Section 174~~ . Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non- realization of expected benefits. A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, His Majesty' s Revenue & Customs (" HMRC "), the U. S. IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a ' ' permanent establishment'' under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable. We may be unable to use net operating loss and tax credit carryforwards and certain built- in losses to reduce future tax payments or benefits from favorable ~~UK~~ **U. K.** tax legislation. As a ~~UK~~ **U. K.** resident trading entity, we are subject to ~~UK~~ **U. K.** corporate taxation. Due to the nature of our business, we have generated losses since inception. As of December 31, ~~2023~~ **2024** , we had cumulative carryforward tax losses of $ ~~418~~ **545** . ~~1~~ **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 ~~UK~~ **U. K.** government. As a company that carries out extensive ~~research and development~~ **R & D** activities, we benefit from the ~~UK research and development~~ **U. K. R & D** tax credit regime **. In respect of** ~~under the scheme for small or~~ **our accounting period commencing January 1, 2024, we expect to qualify as a Small and** ~~medium~~ **Medium** - sized ~~enterprises~~ - **Enterprise** , or ~~SMEs~~ - **SME** , ~~and also claim a Research and Development Expenditure Credit, or RDEC, to the extent~~ that **is not " R & D- intensive " for** ~~our projects are grant funded. The SME Program has been particularly beneficial to us, as under such program~~ the **purposes of the U. K. R & D tax credit regime. We may therefore surrender** trading losses that arise from our ~~qualifying~~ R & D activities ~~can be surrendered~~ **during the accounting period** for a cash rebate of up to ~~33. 35 % of qualifying expenditure incurred prior to April 1, 2023 and decreasing to~~ 18. 6 % ~~after April 1, 2023. Additionally, the U. K Government enacted further changes to the SME regime on March 4, 2024 which include the introduction~~ of ~~a new rate for R & D intensive companies of 27 % (which we may qualify for) and comes into effect for expenditures incurred after April 1, 2024. Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects for which we do not receive income. A large proportion of costs in relation to our pipeline research, clinical trials management and manufacturing development activities, all of which are being carried out by our subsidiary Autolus Limited, are eligible for inclusion within these tax credit cash rebate claims. Under the RDEC Program, tax credits for~~ qualifying R & D expenditure ~~incurred prior to April 1, 2023 are granted at a headline rate of 13 % and can generate cash rebates of up to 10~~ . ~~5 % of~~ **We do not expect to** ~~qualifying~~ --- **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.** ~~headline rate of RDEC increased to 20 % on April 1, 2023 and can generate cash rebates of up to 15 % on qualifying~~ 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 ~~incurred from this date. Amendments~~ **does not) meet the technical conditions** to **be granted tax credits (or cash rebates),** ~~the~~ **then a successful challenge or**

disallowance could have a material impact ~~current SME and RDEC programs that are contained in the Finance Bill currently proceeding through the UK Parliament will take effect from periods~~ on ~~or~~ **our cash** ~~after April 1, 2024 and will (i) (unless limited exceptions apply) introduce restrictions on the tax relief that can be claimed for expenditure incurred on sub- contracted~~ **flow and financial performance. In addition, future changes to the U. K.** R & D ~~activities or externally provided workers, where~~ **tax credit regime (including changes in HMRC practice in respect of** such **regime** ~~sub- contracted activities are not carried out in the UK or such workers are not subject to UK payroll taxes, and (ii) merge the SME Program and the RDEC Program into~~ **may mean that we no longer qualify or have** a ~~single scheme~~ **material impact on the extent to** which **we** ~~would generate net cash benefit of up to 15 % of the qualifying expenditure for profit making companies and up to 16. 2 % for loss making companies. We currently meet the conditions of the SME regime, but also~~ can make claims ~~under~~ **(or benefit from the them)** ~~RDEC regime to the extent that our projects are grant funded~~ . **We may** ~~In addition, it is~~ also **benefit** ~~expected that we will meet the conditions of the R & D intensive scheme and would be able to make claims under merged SME R & D intensive regime. We may not be able to continue~~ in the future ~~to qualify as a small or medium- sized enterprise under the SME program~~ , **when** ~~based on size criteria concerning employee headcount, turnover and gross assets. If~~ we ~~cease~~ **generate profits subject** to ~~qualify under the SME regime~~ **U. K. corporate taxation** , ~~we may make a claim under the RDEC regime for periods ending December 31, 2024 or the merged R & D regime~~ from ~~period ending December 31, 2025. It should be noted, however, that~~ the **U** ~~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)~~ . **K.** ~~We may benefit in the future from the UK~~ ' s " ~~patent~~ **Patent** ~~box~~ **Box** " regime, which allows certain profits attributable to revenues from patented products (and other qualifying income) to be taxed at an effective rate of 10 % by giving an additional tax deduction. We are the exclusive licensee or owner of one patent and several patent applications which, if issued, would cover our product candidates, and accordingly, future upfront fees, milestone fees, product revenues and royalties could be eligible for this deduction. When taken in combination with the enhanced relief available on R & D expenditures, we expect a long- term rate of corporation tax lower than statutory to apply to us. If, however, there are unexpected adverse changes to the ~~UK~~ **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. ~~To date~~ **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 ~~recovered all of~~ **reassessed and commenced restricting** the **amount of U. K.** VAT ~~incurred on its expenditure in the UK on the basis of having an intention to solely make taxable supplies. In recent months we have been working with our advisers in relation to the appropriate VAT treatment that should be applied in the UK in relation to Autolus Limited' s primary income stream. Our advisors are still finalizing their understanding of the full facts which underpin our CAR T therapy and will provide a more conclusive VAT opinion in due course but~~ it **reclaims** ~~has been mentioned during initial discussion that some products which include human blood can be exempt from a UK VAT perspective~~ . **The restriction** ~~If the conclusion~~ is ~~that this activity is exempt from a UK VAT perspective, this may result in a retrospective restriction in terms of VAT recovered on a proportion of our UK expenditure (with this restriction likely being~~ based on ~~the UK~~ **an estimate of our U. K.** market turnover as a percentage of global turnover ~~)~~ . We currently expect revenue from ~~UK~~ **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 ~~effective as of December 31, 2023~~ . The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to maintain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. As a foreign private issuer, we are permitted to and follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards applicable to public companies organized in the United States. These practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards. We are entitled to rely on a provision in Nasdaq' s corporate governance rules that allows us to follow English corporate law with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to domestic issuers listed on Nasdaq. We are not subject to Nasdaq Listing Rule 5605 (b) (2) because English law does not require that independent directors regularly have scheduled meetings at which only independent directors are present. Similarly, we have adopted a compensation committee, but English law does not require that we adopt a compensation committee or that such committee be fully independent. As a result, our practice varies from the requirements of Nasdaq Listing Rule 5605 (d), which sets forth certain requirements as to the responsibilities, composition and independence of compensation committees. English

law requires that we disclose information regarding compensation of our directors for services as a director of an undertaking that is our subsidiary undertaking and as a director of any other undertaking of which a director is appointed by virtue of our nomination (directly or indirectly) but not other third- party compensation of our directors or director nominees. As a result, our practice varies from the third- party compensation disclosure requirements of Nasdaq Listing Rule 5250 (b) (3). In addition, while we have a compensation committee, English law does not require that we adopt a compensation committee or that such committee be fully independent. Additionally, we are not subject to Nasdaq Listing Rule 5605 (e) because, under English law, director nominees are not required to be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors. Furthermore, English law does not have a regulatory regime for the solicitation of proxies applicable to us, thus our practice varies from the requirement of Nasdaq Listing Rule 5620 (b), which sets forth certain requirements regarding the solicitation of proxies. In addition, we have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity- based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice will vary from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. In addition, while we have adopted a code of business conduct and ethics, English law does not require us to publicly disclose waivers from this code that have been approved by our board within four business days. We expect to report any such waivers on our website in lieu of any SEC filing. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U. S. domestic issuer. As a result, our practice varies from the requirements for domestic issuers pursuant to Nasdaq Listing Rule 5610. In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes- Oxley Act and Rule 10A- 3 of the Exchange Act, both of which are also applicable to Nasdaq listed U. S. companies. Because we are a foreign private issuer, however, our audit committee is not subject to additional requirements applicable to Nasdaq listed U. S. companies, including an affirmative determination that all members of the audit committee are " independent, " using more stringent criteria than those applicable to us as a foreign private issuer, subject to certain phase- in requirements permitted by Rule 10A- 3 of the Exchange Act. We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses. As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer' s most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, ~~2024~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **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 ~~UK~~ **U. K.** . In addition, uncertainty exists as to whether English courts would entertain original actions brought in the ~~UK~~ **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, ~~2022~~ **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, ~~2022~~ **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, ~~2022~~ **2024** to disapply preemptive rights for a period of five years from June 28, ~~2022~~ **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.