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

Form 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

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

For the fiscal year ended December 31, 2023

OR

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

OR

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

Commission File Number: 001-40299

Achilles Therapeutics plc
(Exact name of registrant as specified in its charter)

England and Wales	2836	Not Applicable
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

Daniel C.C. Hood
Chief Legal Officer/General Counsel and Company Secretary

245 Hammersmith Road
London W6 8PW
United Kingdom
Telephone: +44 (0)20 8154 4600
Email: legal@achillestx.com

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value of £0.001 per share	ACHL	Nasdaq Global Select Market
Ordinary shares, nominal value £0.001 per share*		Nasdaq Global Select Market *

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the Annual Report:

Ordinary shares, nominal value £0.001 per share: 41,082,948 as of December 31, 2023

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

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

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

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

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

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

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒	International Financial Reporting Standards as issued by the International Accounting Standards Board ☐	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

Item 17 ☐ Item 18 ☐

If this is an Annual Report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

Auditor Name: KPMG, LLP	**Auditor Location:**	**Reading, United Kingdom**	**Auditor Firm ID:**	**1118**

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GENERAL INFORMATION

All references in this Annual Report on Form 20-F, or Annual Report, to "Achilles," "ACHL," the "company," "we," "us" and "our" refer to Achilles Therapeutics plc and its consolidated subsidiaries, except where the context otherwise requires.

We own various trademark registrations and applications, and unregistered trademarks, including ACHILLES, PELEUS, VELOS, NEOPOD, NEORANKER, CLONALX and our corporate logo. All other trade names, trademarks and service marks referred to in this Annual Report, are the property of their respective owners. Trade names, trademarks and service marks of other companies appearing in this Annual Report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report may be referred to without the ® and ™ symbols, but such references should not be construed as an indicator that their respective owners will not assert their rights thereto to the fullest extent under applicable law. We do not intend to use or display other companies' trademarks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Our audited consolidated financial statements were prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as issued by the Financial Accounting Standards Board, or FASB. Our consolidated financial statements are presented in U.S. Dollars. All references in this Annual Report to "$" are to U.S. dollars and all references to "£" and "GBP" are to pounds sterling. Unless otherwise indicated, certain pounds sterling amounts contained in this Annual Report have been translated into U.S. dollars at the rate of $1.27313 to £1.00, on December 31, 2023, the last business day of our fiscal period ended December 31, 2023. Throughout this Annual Report, references to "ADSs" mean American Depositary Shares or ordinary shares represented by American Depositary Shares, as the case may be.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 4.B "Business Overview," Part I, Item 3.D. "Risk Factors," and Part I, Item 5. "Operating and Financial Review and Prospects," but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this Annual Report are based upon information available to us as of the date of this Annual Report and, while we believe we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. All of our forward-looking statements are subject to risks and uncertainties that may cause our actual results to differ materially from our expectations. These forward-looking statements include, without limitation, statements about the following:

- the success, cost, enrollment and timing of our clinical trials;
- the success, cost and timing of our research activities;
- the timing, scope or likelihood of regulatory filings and approvals, including timing of Investigational New Drug Application and Biologics License Application filings for our current and future programs and any future product candidates, and final U.S. Food and Drug Administration, European Medicines Agency, United Kingdom Medicines and Healthcare products Regulatory Agency or other foreign regulatory authority approval of our current programs or follow-on indications and any future product candidates;
- our ability to develop and advance additional follow-on indications as well as any future product candidates into, and successfully complete, clinical studies;
- our ability to continue to innovate, improve and develop our technology platform, including continuing to develop and improve our PELEUS Artificial Intelligence, or AI-powered platform and VELOS manufacturing process and to evaluate new approaches to our manufacturing process;
- our ability to maintain, and in the future expand, our Material Acquisition Platform, or MAP, network of clinical sites;
- our ability to establish future collaborations or strategic relationships or obtain additional funding;
- the rate and degree of market acceptance and clinical utility of our current and future programs and any future product candidates we may develop;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- regulatory developments in the United States, the United Kingdom, the European Union, or the EU, and other countries and regions;
- competitive companies, technologies and our industry and the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;

- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates, if approved;
- the accuracy of our estimates of our future revenue, expenses, capital requirements and needs for additional financing;
- our estimates regarding the market opportunities for our current and future programs and any future product candidates;
- whether we are classified as a controlled foreign corporation, or CFC, and/or passive foreign investment company, or PFIC, for current and future periods; and
- our ability to overcome the challenges posed by global health concerns or pandemics, global economic uncertainty and geo-political events, including the ongoing conflict between Russia and Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the unrest in the Middle East resulting from the Israel-Hamas war, to the conduct of our business. This has led to significant increases in commodity prices, energy and fuel prices, credit and capital market instability and supply chain interruptions which have led to increasing inflation. This may in turn adversely impact our ability to deliver our goals.

In addition, even if our results, performance, financial condition and liquidity, and the development of the industry in which we operate are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are our expectations regarding risks and uncertainties related to the impact of global health concerns or pandemics, global economic uncertainty and geo-political events, including the war between Russia and Ukraine, and the unrest in the Middle East resulting from the Israel-Hamas war, on our business, operations, strategy, goals and anticipated milestones, including our ongoing and planned research activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products, and our ability to obtain and maintain requisite regulatory approvals and to enroll patients in our planned clinical trials, additional interactions with regulatory authorities and expectations regarding future regulatory filings, our reliance on collaborations with third parties, estimating the commercial potential of our development programs and other risks indicated in the risk factors included in this report and other filings with the U.S. Securities and Exchange Commission, or the SEC.

Actual results could differ materially from our forward-looking statements due to a number of factors, including the risks set forth under the section “Risk Factors” of this report and elsewhere in this Annual Report.

Any forward-looking statements that we make in this Annual Report are valid only as of the date of such statements, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events.

SUMMARY OF THE MATERIAL AND OTHER RISKS ASSOCIATED WITH OUR BUSINESS

Below is a summary of the material risks to our business, operations and the investment in our ADSs. This summary does not address all of the risks that we face. Risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Annual Report on Form 20-F in its entirety before making investment decisions regarding our ADSs.

- *Risks Related to our Financial Position and Capital Needs*
    - We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.
    - We will need substantial additional funding to achieve our goals, and a failure to raise additional capital when needed on acceptable terms, or at all, could force us to delay, reduce or eliminate our product development programs or commercialization efforts.
- *Risks Related to the Development of our Programs*
    - We are early in our development efforts. Our business is dependent on the successful development of ATL001 and future product candidates. If we are unable to advance our current programs, additional follow-on indications for ATL001 or any future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize some, any or all of the product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
    - Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our research activities and clinical trials are not sufficient to support regulatory development and approval of some, all or any of our programs for ATL001 or any future product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such program or product candidate.
    - Our business is highly dependent on the success of our product candidate, ATL001, which was developed based on our PELEUS AI-powered platform and utilizing our VELOS manufacturing process. All of our future product candidates are based, or will be based, on the same technologies and the failure of ATL001 may adversely affect their development.
    - ATL001 or any of our future product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.
- *Risks Related to our Approach to Product Development*
    - Our approach to the identification and manufacture of product candidates represents a novel approach to cancer treatment, which creates significant challenges for us. Generation of any cellular therapy, including our clonal neoantigen-reactive T cell therapy, or cNeT, that specifically targets multiple clonal neoantigens to eradicate the tumor of an individual patient requires several weeks, in part reflecting the need to generate patient-specific genomic data and perform the bioinformatic analyses prior to initiation of manufacture. During the period from procurement of tumor and blood to completion of manufacturing, patients continue to receive standard of care therapies. In cases where disease progression is rapid, clinical deterioration of a patient's condition during the manufacturing period may mean that the patient is no longer able to receive our cNeT.

- *Risks Related to Manufacturing and Supply*

    - We have no experience manufacturing ATL001 at commercial scale. Manufacturing and administering ATL001 is complex and we may encounter difficulties in production, particularly with respect to scaling up our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our cNeT for clinical trials or for commercial purposes could be delayed or stopped.
    - Our supply chain network is exposed to potentially adverse events such as physical disruptions, environmental and industrial accidents, trade restrictions, increases in the cost of raw materials or disruptions at a key supplier which could seriously harm our development efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

- *Risks Related to Sales, Marketing and Competition*

    - We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- *Risks Related to Protecting our Intellectual Property*

    - If we fail to comply with our current or future obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our current or future licensors, we could lose license rights that are important to our business.
    - If we are unable to obtain and maintain sufficient patent and other intellectual property protection for ATL001 and any future product candidates and technologies, our competitors could develop and commercialize products and technologies similar or equivalent to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.

- *Risks Related to our Business Operations and Growth*

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

PART I

Item 1. Identity of Directors, Senior Management and Advisors.

Not applicable.

Item 2. Offer Statistics and Expected Timetable.

Not applicable.

Item 3. Key Information.

A. [Reserved.]

B. Capitalization and Indebtedness.

Not applicable.

C. Reasons for the Offer and Use of Proceeds.

Not applicable.

D. Risk Factors.

Our business faces significant risks. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the SEC including the following risk factors which we face and which are faced by our industry, any of which could materially adversely affect our business, financial condition, or results of operations. The risks and uncertainties summarized and described below are not intended to be exhaustive and are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business, prospects, financial condition and results of operations. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. See also the "Cautionary Statement Regarding Forward-Looking Statements" above.

RISKS RELATED TO OUR FINANCIAL POSITION AND CAPITAL NEEDS

Risks Related to our Financial Condition

We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of ATL001 for our lead indications in advanced non-small cell lung cancer, or NSCLC, metastatic or recurrent melanoma. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to, and will for the foreseeable future, incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through private placements of our preferred shares and our initial public offering, or IPO, which we completed in April 2021.

We have incurred significant operating losses in each period since our inception in May 2016. For the years ended December 31, 2023 and 2022, we reported net losses of $69.7 million and $71.2 million, respectively. As of December 31, 2023, we had an accumulated deficit of $260.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially in connection with our ongoing activities, particularly if and as we:

- continue to develop our pipeline of discovery programs and conduct research and clinical activities for our existing programs for advanced NSCLC, metastatic or recurrent melanoma, and other solid tumors;
- continue to innovate, improve and develop our technology platform, including continuing to develop and improve our PELEUS AI-powered platform and VELOS manufacturing process and to evaluate new approaches to our manufacturing process;
- expand our MAP network to increase our network of clinical sites;
- advance the development of our current programs, additional follow-on indications and any future product candidates into additional tumor indications;
- maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals and complete any post-marketing studies, if required, for any of our product candidates that successfully complete clinical trials, if any;
- acquire or in-license additional product candidates and technologies;
- expand our infrastructure and facilities to accommodate our growing employee base and ongoing development activity;
- continue to improve our manufacturing process to create a fully closed end-to-end manufacturing process;
- expand our manufacturing infrastructure and facilities to support the manufacture of larger quantities of our product candidates for clinical development and potential commercialization globally;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs and any future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating our business, including the costs associated with operating as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional programs and product candidates and we may never generate revenue that is significant or large enough to achieve profitability. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We have not generated any revenue and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from ATL001 for any indication. We do not expect to generate significant revenue from ATL001 and any potential future product candidates unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, such product candidates. ATL001 and any other product candidates that we develop will require additional research, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our research activities and clinical trials, which may be significantly slower or cost more than we currently anticipate;
- our ability to develop ATL001 for our current pipeline of indications and additional follow-on indications as well as to identify and develop potential new product candidates;
- our ability to complete investigational new drug, or IND, enabling activities, and successfully submit IND applications or comparable applications for ATL001 in additional follow-on indications or any future product candidates;
- our successful initiation, enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials, including our ongoing Phase I/IIa clinical trials of ATL001 in advanced NSCLC and metastatic or recurrent melanoma;
- whether we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or the United Kingdom Medicines and Healthcare products Regulatory Agency, or the MHRA, or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of ATL001 in our current indications or any follow-on indications as well as any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA, the EMA, the MHRA and similar foreign regulatory authorities the safety, potency, purity, efficacy and acceptable risk to benefit profile of our current programs, additional follow-on indications for ATL001, or any future product candidates and such regulatory authorities' acceptance of our cNeT therapy-based development strategy;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our current programs, additional follow-on indications for ATL001, or future product candidates, if any;
- our ability to receive marketing approvals from the FDA, the EMA, the MHRA and similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt ATL001 or future product candidates, if approved, over alternative or more conventional approaches, such as standard tumor infiltrating lymphocyte, or TIL, therapy and other immuno-oncology therapies;
- the actual and perceived availability, cost, risk profile and safety and efficacy of our product candidates, if approved, relative to existing and future alternative immuno-oncology therapies and competitive product candidates and technologies;
- our ability to successfully increase our MAP network, including the acquisition, transportation, handling of, and management of other logistics relating to, patient tumor and other samples;
- our ability and the ability of third parties with whom we may contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP, requirements;
- our ability to successfully develop a commercial strategy and thereafter commercialize our current programs, additional follow-on indications for ATL001, or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- patient demand for our current programs, additional follow-on indications for ATL001, and any future product candidates, if approved;
- our ability to establish and enforce intellectual property rights; and
- our ability to maintain a continued acceptable safety profile in any approved product candidate.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

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 company with a limited operating history. We commenced operations in May 2016, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking research activities and clinical trials and establishing our in-house manufacturing capabilities for the manufacture of initial quantities of our product candidates and component materials. Our lead programs in advanced NSCLC and metastatic or recurrent melanoma are in Phase I/IIa clinical trials, CHIRON and THETIS, respectively. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as an early-stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and results of operations to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to our Future Cash Needs

We will need substantial additional funding to achieve our goals, and a failure to raise additional capital when needed on acceptable terms, or at all, could force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our PELEUS AI-powered platform, our VELOS manufacturing process, development of our lead programs for ATL001 and identification and development of follow-on indications for ATL001. Clinical trials and additional research and development activities will require substantial funds to complete. We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue the research and clinical development activities of our current programs, including our ongoing Phase I/IIa clinical trials of ATL001 in advanced NSCLC and metastatic or recurrent melanoma, and our ongoing and planned IND-enabling activities for ATL001 in potential follow-on indications. In addition, if we obtain marketing approval for any product candidate, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We have incurred and expect to continue to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Additionally, changing circumstances may cause us to consume capital significantly faster than

we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. If we are unable to raise capital when needed in sufficient amounts or on terms acceptable to us, we would be forced to delay, reduce or eliminate our discovery and research programs or any future commercialization efforts.

We had cash and cash equivalents of $131.5 million as of December 31, 2023. We believe that, based upon our current operating plan, our existing capital resources will be sufficient to fund our anticipated operations through 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our ongoing, planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of research activities and clinical trials for our current programs, additional follow-on indications for ATL001 and any future product candidates;
- the continued development and expansion of our PELEUS AI-powered platform;
- the continued development of and improvements to our VELOS manufacturing process;
- the extent to which we enter into collaboration arrangements with regard to product candidate development or acquire or in-license products or technologies;
- the costs, timing and outcome of regulatory review of ATL001 for our current programs and follow-on programs, and any future product candidates, including post-marketing studies that could be required by regulatory authorities;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any product candidate for which we receive marketing approval;
- the costs of continued scale-up and automation of our VELOS manufacturing processes, including developing a fully closed end-to-end system, for later stages of development and commercialization;
- the costs of expanding our manufacturing infrastructure and facilities to support the manufacture of larger quantities of our product candidates for clinical development and potential commercialization globally;
- the costs associated with maintaining, and in the future, increasing our MAP network;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, enforcing and protecting our intellectual property rights and defending intellectual property-related claims.

Identifying additional follow-on indications for ATL001 and future product candidates and conducting research activities 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 marketing approval and achieve product sales. In addition, any product candidate, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many 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.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay, or discontinue our research and development programs or any commercialization efforts; be unable to expand our operations; or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially force us to discontinue operations.

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

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of ADSs, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a shareholder.

In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our current programs, additional follow-on indications for ATL001, and any future product candidates.

If we raise additional funds through collaborations, strategic alliances, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

RISKS RELATED TO THE DEVELOPMENT OF OUR PROGRAMS

Risks Related to Research Activities and Clinical Development

We are early in our development efforts. Our business is dependent on the successful development of ATL001 and future product candidates. If we are unable to advance our current programs, additional follow-on indications for ATL001 or any future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize some, any or all of the product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

All of our programs are in early stages of development, including our clinical-stage programs for ATL001 in advanced NSCLC and metastatic or recurrent melanoma, and as such will require extensive research activities and clinical testing, as applicable. Our ability to generate product revenues, which we do not expect to occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the programs and product candidates we develop, which may never occur. Before we are able to generate any revenues from product sales, our current programs, additional follow-on indications for ATL001 or any future product candidates we develop, will require additional research activities and clinical development, management of clinical, research and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts. The success of our current programs, additional follow-on indications for ATL001 or any future product candidates will depend on several factors, including the following:

- successful completion of research activities and clinical trials;
- sufficiency of our financial and other resources to complete the necessary research activities and clinical trials;
- regulatory authority acceptance of INDs, clinical trial applications or similar applications required for us to commence our planned clinical trials or future clinical trials;
- successful patient enrollment in and completion of our ongoing and future clinical trials;
- successful data from our clinical trials that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- continued scale-up and automation of our VELOS manufacturing processes, including developing a fully closed end-to-end system, for later stages of development and commercialization;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- entry into collaborations to further the development of our product candidates, if necessary;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- the prevalence and severity of adverse events experienced with our product candidates;
- effectively competing with other cancer therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- maintaining a continued acceptable safety profile of our products following approval, if any; and
- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory approval process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to successfully commercialize ATL001 and any future product candidates we develop, which would materially harm our business.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our research activities and clinical trials are not sufficient to support regulatory development and approval of some, all or any of our programs for ATL001 or any future product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such program or product candidate.

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety, purity and potency of our product candidates. Clinical testing is expensive, time-consuming and subject to uncertainty. Clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in clinical trials nonetheless failed to obtain FDA approval or approval from foreign regulatory authorities. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results. It is impossible to predict when or if ATL001 in any of our current programs, ATL001 in any additional follow-on indications or any future product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete research activities and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for investigational drugs proceeding through clinical trials.

We may experience delays in initiating or completing research activities or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA's clearance to initiate clinical trials under future INDs, completing ongoing research activities for our other product candidates and initiating our planned clinical trials. Additionally, we cannot be certain that clinical trials will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. We may experience numerous adverse or unforeseen events during, or as a result of, research activities and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize ATL001 for any indication or any future product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- research activities or clinical trials of ATL001 or any future product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- research activities or clinical trials of ATL001 or any future product candidates may not produce differentiated or clinically significant results across cancers and we may decide not to pursue further clinical development of such product candidates accordingly;
- the number of patients required for clinical trials of ATL001 or any future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete clinical trials of ATL001 or any future product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of ATL001 or any future product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of ATL001 or any future product candidates may be greater than we anticipate;

- the quality of our product candidates or other materials necessary to conduct research activities or clinical trials of ATL001 or any future product candidates may be insufficient or inadequate, and our PELEUS AI-powered platform may not be able to accurately identify clonal neoantigens that are effective to treat solid tumors;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about ATL001 or any future product candidates;
- regulators may revise the requirements for approving ATL001 or any future product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

In addition, disruptions caused by global health concerns or pandemics, global economic uncertainty and geo-political events may increase the likelihood that we encounter difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. If we are required to conduct additional clinical trials or other testing of our current programs, additional follow-on indications for ATL001 or any future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, or IRBs, or ethics committees of the institutions in which such clinical trials are being conducted, or by the FDA or other regulatory authorities, or suspended or terminated based on recommendations by the Independent Data and Safety Monitoring Committee, or IDSMC, if any, for such clinical trial. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion, or termination, of any clinical trial for our current programs, additional follow-on indications for ATL001 or of any future product candidates, the commercial prospects of ATL001 or our any future product candidates may be harmed, and our ability to generate revenues from ATL001 or any future product candidates will be delayed or not realized at all. In addition, any delays in completing our research activities or clinical trials may increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of ATL001 or any future product candidates. If ATL001 or any future product candidates are generally observed to be ineffective, unsafe or commercially unviable, our entire pipeline may have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our business is highly dependent on the success of our product candidate, ATL001, which was developed based on our PELEUS AI-powered platform and utilizing our VELOS manufacturing process. All of our future product candidates are based, or will be based, on the same technologies and the failure of ATL001 may adversely affect their development.

A key element of our strategy is utilizing our PELEUS AI-powered platform to identify clonal neoantigens that are effective in treating solid tumors coupled with using our VELOS manufacturing process to manufacture cNeT. The therapeutic discovery activities that we are conducting may not be successful in identifying clonal neoantigens and we may not be successful in manufacturing precision TIL product candidates. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are early in our development efforts, and we only have two clinical-stage programs, ATL001 for the treatment of advanced NSCLC and metastatic

or recurrent melanoma, which are in early clinical-stage trials. In the event that our current programs for ATL001, any potential follow-on indications for ATL001, or future product candidates, encounter safety or efficacy problems, developmental delays, regulatory issues, or other problems, our development plans and business related to our other current or future product candidates could be significantly harmed. A failure of ATL001 or future product candidates may affect the ability to obtain regulatory approval to continue or conduct clinical programs for our other or future product candidates.

Our research activities and clinical trials may fail to demonstrate adequately the safety, potency and purity of ATL001 or any future product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any product candidate, including ATL001, we must demonstrate through lengthy, complex and expensive research activities and clinical trials that our product candidates are both safe and effective for use in each target indication. Research activities and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial processes, and, because ATL001 is in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

Any clinical trials that we may conduct may not demonstrate the safety, potency, purity and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical trials are inconclusive with respect to the safety, potency, purity and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety, potency or purity results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, manufacturing variances in our VELOS manufacturing process, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

Additionally, our currently ongoing Phase I/IIa clinical trials are and any additional clinical trials that we may conduct may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

ATL001 or any of our future product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities, including IRBs, to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA, the MHRA or other comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include

restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, reconsent of enrolled patients, or the monitoring of safety data by a data monitoring committee, among other strategies. FDA, the EMA, the MHRA or a comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our current product candidate and any future product candidates. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, which may stem from our therapies specifically or may be due to an illness from which the clinical trial subject is suffering. If we do observe severe side effects in our clinical trials, our ongoing clinical trials may be halted or put on clinical hold prior to completion if there is an unacceptable safety risk for patients.

If unacceptable toxicities arise in the development of ATL001 or any future product candidates, we could suspend or terminate our clinical trials or the FDA, the EMA, the MHRA or comparable foreign regulatory authorities, or local regulatory authorities such as IRBs or ethics committees, could order us to cease clinical trials. Competent national health authorities, such as the FDA or foreign equivalents, could also deny approval of our product candidates for any or all targeted indications. Even if the side effects presented do not preclude the product from obtaining or maintaining marketing approval, treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. We expect to have to train medical personnel using our product candidates to understand the adverse events associated with our treatment approach for both our planned clinical trials and upon any commercialization of any product candidates, if approved. Inadequate training in recognizing or managing the potential side effects of ATL001 or any future product candidates could result in patient harm, including deaths.

In addition to side effects and adverse events caused by any product candidates we may develop, the conditioning, administration process or related procedures that may be used in our pipeline also can cause adverse side effects and adverse events. A T-cell therapy patient is generally administered cytotoxic drugs to reduce the number of hematopoietic cells competing for growth factors and allow preferential expansion of the infused T cells. This procedure causes side effects and, among other potential risks, can transiently compromise the patient's immune system (lymphopenia), reduce neutrophil counts, (neutropenia), and reduce platelet counts (thrombocytopenia). Patients in our clinical trials receive interleukin-2, or IL-2, which is associated with toxicities such as capillary leak syndrome, hypotension, impaired kidney and liver function, and mental status changes. In the future, if we are unable to demonstrate that such adverse events were caused by the conditioning regimens used, administration process or related procedure, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we may develop for any or all target indications. Even if we are able to demonstrate that adverse events are not related to the drug product or the administration of such drug product, such occurrences could affect patient recruitment, the ability of enrolled patients to complete the clinical trial or the commercial viability of any product candidates that obtain regulatory approval.

Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we have publicly disclosed, and may in the future, publicly disclose preliminary or topline data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data

also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our ADSs.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

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 ATL001 and our future product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing ATL001 and any future product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment or patient retention due to other unforeseen factors, including impacts that have resulted from the COVID-19 pandemic or may result from future global health concerns or pandemics. We may not be able to initiate or continue clinical trials for ATL001 or any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA, the MHRA or similar foreign regulatory authorities outside the United States. The enrollment of patients further depends on many factors, including:

- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;
- the severity of the disease or condition under investigation;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the availability of competing trials, or products;
- our ability to procure sufficient tumor and blood samples from the patient to enable isolation of sufficient TILs and dendritic cells to manufacture a cNeT product candidate, identify clonal neoantigens and transport our cNeT product candidate to the trial site;
- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before the manufacturing and infusion of ATL001 or any future product candidates or clinical trial completion; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as ATL001 or any future product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. 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 will reduce the number of patients who are available for our clinical trials at such clinical trial

sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any ongoing or planned clinical trials.

On February 16, 2024, the Food and Drug Administration granted accelerated approval to lifileucel (Amtagvi, Iovance Biotherapeutics, Inc.), a tumor-derived autologous T cell immunotherapy, for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor. The success of Amtagvi may limit the number of patients available for our clinical trials and our products, if approved, that are indicated for the treatment of melanoma.

Delays in completing patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Since the number of patients that we plan to dose in our ongoing open-label Phase I/IIa clinical trials is small, the results from these clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for ATL001 or any future product candidates.

In our ongoing first-in-human, open-label Phase I/IIa clinical trials of ATL001 for our two lead tumor indications, we are evaluating the safety, tolerability and clinical activity of cNeT administered intravenously in adult patients with advanced NSCLC and metastatic or recurrent melanoma.

The results of clinical trials with smaller sample sizes, such as our ongoing Phase I/IIa clinical trials, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidate would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of ATL001, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial Phase I/IIa clinical trials.

We are conducting clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have expanded our clinical operations to the United States and Europe, in addition to conducting our clinical trials in the United Kingdom. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA, the EMA, the MHRA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless: (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In general, the patient population for any clinical trials conducted outside the United States must be representative of the population for whom we intend to label the product candidate in the United States. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, the EMA, the MHRA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, the EMA, the MHRA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which

may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Risks Related to our Approach to Product Development

Our approach to the identification and manufacture of product candidates represents a novel approach to cancer treatment, which creates significant challenges for us.

A key element of our strategy is to focus on targeting clonal neoantigens for the treatment of solid tumors, to continue innovating and developing our PELEUS AI-powered platform to further improve our clonal neoantigen prediction capability and to expand our pipeline into several additional solid tumor indications. To date, there are no approved immuno-oncology therapies based on targeting clonal neoantigens and we are not aware of any clinical evidence supporting the clinical efficacy of our approach. Although our research and development efforts to date have resulted in clinical development of ATL001 in advanced NSCLC and metastatic or recurrent melanoma, ATL001 may not be safe or effective as a cancer treatment, and we may not be able to identify any additional follow-on indications for ATL001, or identify and develop any other product candidates. Further, our approach to manufacturing cNeT on a per patient basis means that we may fail to isolate TILs from the tumor, be unable to generate the necessary amounts of dendritic cells, or at all, or not be able to identify clonal neoantigens. We may also be limited by the extent to which the peptides representing those neoantigens are presented by dendritic cells. There is high variability in sample collection between patients, which presents additional challenges of producing cNeT on a per patient basis. Generation of any cellular therapy, including our cNeT, to specifically target the mutations of an individual patient requires several weeks, in part reflecting the need to generate patient-specific genomic data and perform the bioinformatic analyses prior to initiation of manufacture. During the period from procurement of tumor and blood to completion of manufacturing, patients continue to receive standard of care therapies. In cases where disease progression is rapid, clinical deterioration of a patient's condition during the manufacturing period may mean that the patient is no longer able to receive our cNeT. The continued improvement of our PELEUS AI-powered platform also requires continued sourcing of tumor samples from the TRACKing Cancer Evolution through Therapy study, or the TRACERx Study, and our MAP network, and any interruption or termination of these programs could adversely affect our PELEUS AI-powered platform. Though we are continuing to invest in optimizing our manufacturing process, there is no guarantee that our efforts will result in a decrease of the end-to-end time for production.

Even if we are successful in expanding our pipeline of ATL001 programs and other product candidates, the follow-on programs and product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA, the EMA, the MHRA or other regulatory authorities or achieve market acceptance. We may face challenges in obtaining regulatory approval for ATL001 or any future product candidate, as the FDA, the EMA, the MHRA and other regulatory authorities may have limited experience with AI-based therapies for cancer treatment. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our commercial value.

Moreover, 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 our therapies. Based on these and other factors, health systems, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

We anticipate that ATL001 and any future product candidates may be used in combination with third-party drugs or biologics, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

ATL001 and any future product candidates have the potential to be administered in combination with approved therapeutics, such as checkpoint inhibitor immunotherapies. Our ability to develop and ultimately commercialize ATL001 and any future product candidates used in combination with checkpoint inhibitor immunotherapies or other therapeutics will depend on our ability to access such therapeutics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint inhibitor immunotherapies or other comparable therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidate and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, share price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. We may develop ATL001 and any future product candidates for use in combination with checkpoint inhibitor immunotherapies. For example, our THETIS clinical trial is currently evaluating the safety and clinical activity of ATL001 when given in combination with pembrolizumab, and our CHIRON clinical trial may evaluate the combination of ATL001 with nivolumab, which are approved anti-PD-1 antibody therapies. The FDA, the EMA, the MHRA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the combination therapy and not ATL001 and any future product candidates. Moreover, following product approval, the FDA, the EMA, the MHRA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, quality, manufacturing and supply issues, and changes to the standard of care.

In the event that any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing checkpoint inhibitor immunotherapies or other comparable therapies. Additionally, should the supply of product from any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us or our collaborators, our clinical collaborations may be delayed. In the event we are unable to source an alternative supply, or are unable to do so on commercially reasonable terms, our business, financial conditions, results of operations and prospects may be materially harmed.

We may expend our limited resources to pursue a particular follow-on indication for ATL001 or other product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on 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 discovery and research programs and product candidates for specific indications may not yield any commercially viable products.

If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we may work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization. The FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product if the FDA determines that safe and effective use of a therapeutic product depends on an *in vitro* companion diagnostic. The clearance or approval of a companion diagnostic as part of the product label will also limit the use of the product candidate to patients who have met the screening criteria tested for by the companion diagnostic.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these product candidates, or experience delays in doing so, the development of these product candidates may be adversely affected, these product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

RISKS RELATED TO MANUFACTURING AND SUPPLY

We have no experience manufacturing ATL001 at commercial scale. Manufacturing and administering ATL001 is complex and we may encounter difficulties in production, particularly with respect to scaling up our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our cNeT for clinical trials or for commercial purposes could be delayed or stopped.

ATL001 is designed to be a precision T cell therapy and the process of manufacturing it is complex, highly regulated and subject to multiple risks. As a result of these complexities, the cost to manufacture precision T cell therapies is generally higher than traditional small molecule chemical compounds or antibody therapies, and the manufacturing process for precision T cell therapies is less reliable and is more difficult to reproduce. More specifically, the manufacture of ATL001 involves procuring tumor and blood from the patient from which DNA is extracted and sequenced, using this sequencing data together with our PELEUS AI-powered platform to identify each patient's unique clonal neoantigens, isolating T cells and dendritic cells from tumor and blood, respectively, manufacturing clonal neoantigen peptides and loading them onto dendritic cells to activate and expand a sub-set of the T cells, and ultimately generating a product enriched for cNeT, which is then re-infused into the patient's body. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. Furthermore, manufacturing poses the risk of the inconsistency in product quality, which could lead to adverse events. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, 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 stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

As ATL001 or any future product candidate progresses through clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing and administration process will be altered in an effort to optimize processes and results. Any such changes may result in a clinical hold and may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates.

Developing a commercially viable process is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. Competitors have had difficulty reliably producing TIL therapies. If we experience similar challenges manufacturing product candidates to approved specifications, this may limit our product candidates' utilization and our ability to receive payment for these product candidates once approved. We may ultimately be unable to reduce the expenses associated with our product candidates to levels that will allow us to achieve a profitable return on investment.

On March 11, 2022, we entered into an agreement to reserve manufacturing capacity with a Contract Manufacturing Organization, or CMO, in King of Prussia, PA in the United States. The GMP suites and office space at the facility are designated for our exclusive use during the term of the agreement.

On October 9, 2023, we terminated a lease on premises in West London at which we had planned to construct a flexible GMP modular facility to scale our manufacturing footprint. See Note 9, "Leases," for further details.

While over time we plan to establish further or alternative other regional manufacturing facilities as needed to meet product demand, we may not be successful in scaling up our manufacturing capabilities and we may not be able to establish sufficient manufacturing facilities to meet our future needs.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products, we will need to ensure compliance with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. Our facilities are subject to inspections by the FDA, the EMA, the MHRA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of our failure to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize ATL001 and any future product candidates, including leading to significant delays in the availability of ATL001 and any future product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for ATL001 or any future product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If we use hazardous and biological materials for manufacturing in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We are, and will in future be, subject to federal, state and local laws and regulations in the United Kingdom governing the use, manufacture, storage, handling and disposal of biological and hazardous materials. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from biological or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our supply chain network is exposed to potentially adverse events such as physical disruptions, environmental and industrial accidents, trade restrictions, increases in the cost of raw materials or disruptions at a key supplier which could seriously harm our development efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

Cell-based therapies and biologics 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.

Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the materials for these products in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. We do not currently have arrangements in place for a redundant or second-source supply of certain of our product materials in the event any of our current vendors of such materials cease their operations for any reason. We are also unable to predict how changing global economic conditions, geo-political events or future global health concerns or pandemics will affect our third-party vendors. Any negative impact of such matters on our third-party

vendors may also have an adverse impact on our results of operations or financial condition. We are not certain that our single-source vendors will be able to meet our demand for their products, either because of the nature of our agreements with those vendors, our limited experience with those vendors or our relative importance as a customer to those vendors. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our vendors have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers. Establishing additional or replacement vendors for the materials used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement vendor, such replacement vendor would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such materials from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

In January 2022, Iovance Biotherapeutics Inc, or Iovance, announced that it had agreed to acquire worldwide rights to Proleukin (aldesleukin), an interleukin-2 (IL-2) product, from Clinigen Limited, or Clinigen. Proleukin is used in our manufacturing process and administered to patients at the time that they received ATL001 in accordance with the clinical protocols for both the CHIRON and THETIS trials. As a result of the acquisition, Iovance is the only manufacturer of Proleukin. We do not have a long-term supply agreement in place with Clinigen (or Iovance) and there is no guarantee that Iovance will continue to supply Proleukin to us on commercially acceptable terms, or at all. Failure to secure sufficient supplies of Proleukin in a timely manner on acceptable commercial terms could impede, delay, limit or prevent our ability to manufacture and administer ATL001 to patients, which could harm our business, results of operations, financial condition and prospects.

We plan to establish our own commercial-scale manufacturing facilities and infrastructure in lieu of relying on third parties for the manufacture of ATL001 and any future product candidates, which will be costly, time-consuming, and which may not be successful.

We have established manufacturing capacity for our clinical trials at our Royal Free Hospital and Call and Gene Therapy Catapult sites in the United Kingdom and we plan to establish our own commercial manufacturing facility in the future. The establishment of our own commercial manufacturing facility would be a costly and time-consuming process that we expect to require additional capital to fund and take several years before becoming operational. For example, we plan to develop a fully closed end-to-end manufacturing process, which is challenging, time-consuming and will require significant resources. We may experience unexpected delays or costs as we continue to improve our VELOS manufacturing process and may ultimately be unsuccessful in obtaining manufacturing scale capabilities. Furthermore, as we scale up the VELOS manufacturing process, we may be required to make changes to the process which can affect the composition of ATL001 and any future product candidates.

We have no experience as a company in setting up, building or managing a commercial-scale manufacturing facility, and may never be successful in developing our own commercial-scale manufacturing facility. We will need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, and eventual commercialization, if approved, of our product candidates. If we fail to recruit the required personnel and generally manage our growth effectively or fail to select the correct location, the development and production of our product candidates could be curtailed or delayed. Even if we are successful in establishing a commercial-scale manufacturing facility, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the FDA, the EMA, the MHRA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA, the MHRA or other foreign regulatory authorities may require that

we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

RISKS RELATED TO SALES, MARKETING AND COMPETITION

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

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

Even if we obtain regulatory approval of ATL001 or any future product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of precision cNeT product candidates as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community, even if approved by the appropriate regulatory authorities for marketing and sale. If we obtain regulatory approval for ATL001 in any of our current programs or additional follow-on indications or any future product candidates and such product candidates do not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Various factors will influence whether our product candidates, if approved, are accepted in the market, including:

- the efficacy of ATL001 in the applicable indication or any future product candidates as demonstrated in clinical trials, and, if required by any applicable authority in connection with the approval for the applicable indications, the ability of ATL001 or any future product candidates to provide patients with incremental health benefits, as compared with other available therapies;
- potential product liability claims;
- the clinical indications for which ATL001 or any future product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering ATL001 or any future product candidates as a safe and effective treatment;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the potential and perceived advantages of ATL001 or any future product candidates over alternative treatments;
- the prevalence and severity of any side effects of ATL001 or any future product candidates;
- the prevalence and severity of any side effects for other cancer immuno-therapeutics and public perception of other cancer immune-therapeutics;
- product labeling or product insert requirements of the FDA or other comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other comparable foreign regulatory authorities;
- any distribution and use restrictions imposed by the FDA or other comparable foreign regulatory authorities or to which we agree as part of a mandatory risk evaluation and mitigation strategy, or REMS or voluntary risk management plan;
- the timing of market introduction of ATL001 or any future product candidates as well as competitive products;
- the cost of treatment in relation to current and future alternative treatments;
- the need to dose our product candidates in combination with other therapeutic agents and related costs;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to current and future alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although ATL001 differs in certain ways from other cancer immuno-therapies, advanced T cell therapies and neoantigen directed cell or vaccine approaches, serious adverse events or deaths in other clinical trials involving cancer immuno-therapies, advanced T cell therapies or neoantigen directed cell or vaccine approaches, even if not ultimately attributable to our product or product candidates, could negatively impact our business. For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T cell malignancies following BCMA-directed or CD19-directed autologous chimeric antigen receptor, or CAR, T cell immunotherapies following reports of T cell lymphoma in patients receiving these therapies. In January 2024, the FDA determined that

new safety information related to T cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD-19-directed genetically modified autologous T cell immunotherapies. While ATL001 is designed to utilize a different mechanism of action, FDA's investigation into CAR-T therapies and other similar actions could result in increased government regulation, unfavorable public perception and publicity, potential impacts on enrollment in our clinical trials, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates.

Even if our product candidates, if approved, 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.

The market opportunities for ATL001 or any future product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized by line of therapy (first line, second line, third line, fourth line, etc.) and the FDA often approves new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of ATL001 in most indications at least as a second or third line therapy, such as for use in patients with advanced unresectable or metastatic NSCLC and/or recurrent or metastatic malignant melanoma. Subsequently, for those indications in which ATL001 proves to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that ATL001, even if approved as a second or third line of therapy for any indications, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. Consequently, the potentially addressable patient population for ATL001 or any future product candidates may be extremely limited or may not be amenable to treatment with our product candidates.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with ATL001 or future product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, commissioned reports, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if ATL001 or any product candidates are approved for a second or third line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our differentiated product, scientific knowledge, platform technology and development expertise in the field of immuno-oncology therapy provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing,

regulatory approvals and product marketing than we do. Our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, potency, purity, tolerability, reliability, convenience of use, price and reimbursement.

Specifically, advanced T cell therapies are under evaluation in solid tumors by multiple biotechnology and pharmaceutical companies, including Kite Pharma Inc. (a Gilead company), Iovance, Adaptimmune Therapeutics PLC, Autolus Therapeutics PLC, Instil Bio, Inc., or Instil, Neogene Therapeutics, B.V. (acquired by AstraZeneca), BioNTech SE, Turnstone Biologics Corp., Immatics N.V., Obsidian Therapeutics and KSQ Therapeutics, Inc.

We anticipate that we will face intense and increasing competition as new products and therapies enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, delivery, price and the availability of reimbursement from government and other third-party payers.

On February 16, 2024, the Food and Drug Administration granted accelerated approval to lifileucel (Amtagvi, Iovance Biotherapeutics, Inc.), a tumor-derived autologous T cell immunotherapy, for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor. The success of Amtagvi may limit the number of patients available for our clinical trials and our products, if approved, that are indicated for the treatment of melanoma.

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

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates, if approved. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Item 4.B. Business Overview—Competition."

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of ATL001 and any future product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws and regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

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

We face an inherent risk of product liability as a result of the clinical testing of ATL001 or any future product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if a product candidate causes or is perceived to cause injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for ATL001 or any future product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigation, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and

- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In the future, we may be unable to maintain this insurance coverage, or we may not be able to obtain additional or replacement coverage at a reasonable cost, if at all. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

RISKS RELATED TO GOVERNMENT REGULATION

Risks Related to Regulatory Review and Approval of Product Candidates

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of ATL001 and any future product candidates.

We have not previously submitted a Biologics License Application, or BLA, to the FDA or similar marketing applications to similar foreign regulatory authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining approval at each clinical trial site by an IRB or ethics committee;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and including current good tissue practices, or cGTPs, requirements and applying them on a subject-by-subject basis for use in clinical trials.

Securing regulatory approval also requires the submission of information about the biologic manufacturing process and inspection of manufacturing facilities by the relevant regulatory authority. The FDA, the EMA, the MHRA or similar foreign regulatory authorities may fail to approve our manufacturing processes or facilities, whether run by us or our CMOs. In addition, if we make changes to our manufacturing process for ATL001 or any future product candidates in the future, including adding a new CMO, we may need to conduct additional research or clinical trials to bridge our modified product candidates to earlier versions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of ATL001 and any future product candidates.

Regulatory authorities in the United States, United Kingdom and EU have limited experience in reviewing and approving cell therapy products, which could affect the time and data required to obtain marketing authorization of any of our product candidates.

Our future success depends in part on our successful development of viable cell therapy product candidates utilizing our PELEUS AI-powered platform. We may experience problems or delays in developing such product candidates and any such problems or delays may result in unanticipated costs and time to develop our product candidates and/or may not be resolved in a satisfactory manner.

The regulatory approval process and clinical trial requirements for novel product candidates can be more expensive and take longer than for other, better known or more extensively studied product candidates, and we cannot predict how long it will take or how much it will cost to complete clinical developments and obtain regulatory approvals for a cell therapy product candidate in either the United States, the EU or the United Kingdom or how long it will take to commercialize a cell therapy product candidate, if and when approved. Regulatory requirements governing cell therapy products have changed frequently and may continue to change in the future. For example, in 2016, the FDA established the Office of Tissues and Advanced Therapies, or OTAT, within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of cell therapies and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products, or OTP, and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions.

A similar framework is in place in the EU. The EMA has a Committee for Advanced Therapies, or CAT, that is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. Advanced-therapy medical products include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines, which must be centrally authorized in the EU. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a cell therapy medicinal candidate that is submitted to the EMA. In the EU, the development and evaluation of a cell therapy medicinal product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for somatic cell therapy medicinal products and require that we comply with these new guidelines. Similarly, complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. As a result, there may be additional procedures and standards with which we will have to comply with respect to the development of our product candidates.

The clinical trial requirements of the FDA, the EMA, the MHRA and other regulatory authorities and the criteria these regulators use to evaluate the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. Since we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA, the MHRA or comparable regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of cell therapy products in a timely manner or under technically or commercially feasible conditions.

Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Additionally, adverse developments in clinical trials conducted by others of cell therapy products or products created using similar technology, or adverse public perception of the field of cell therapies, may cause the FDA, the EMA, the MHRA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing technologies such as ours, either of which could materially harm our business.

As we advance our product candidates, we will be required to consult with various regulatory authorities, and we must comply with applicable laws, rules, and regulations, which may change from time to time including during the course of development of our product candidates. If we fail to do so, we may be required to delay or discontinue the clinical development of certain of our product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Even if we comply with applicable laws, rules, and regulations, and even if we maintain close coordination with the applicable regulatory authorities with oversight over our product candidates, our development programs may fail to succeed. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market would materially and adversely affect our business, financial condition, results of operations and prospects.

We may in the future seek orphan drug designation for ATL001 and any future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or more in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product candidate that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for ATL001 in the indications we are currently targeting or any follow-on indications as well as for any future product candidates in additional orphan indications in which there is a plausible basis for the evaluation of these product candidates. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a later product for the same condition if the FDA

concludes that the later product is clinically superior in that it is safer, more effective, or makes a major contribution to patient care.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where the FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. The FDA may further re-evaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A breakthrough therapy designation or accelerated approval by the FDA, even if granted for ATL001 or any of our future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek breakthrough therapy designation for ATL001 in the indications we are currently targeting or any follow-on indications as well as for any future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors of product candidates that have been designated as breakthrough therapies are eligible to receive more intensive FDA guidance on developing an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review. A product candidate is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA must review an application in six months compared to ten months for a standard review.

Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval. A product candidate may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of accelerated approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence, and under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. In addition, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials be submitted to the agency for review, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval, and, even if we do, we may not experience a faster development, review or approval process. In addition, receiving accelerated approval does not provide assurance that the product's accelerated approval will eventually be converted to a traditional approval. FDORA also gives the FDA increased authority to withdraw the approval of a product granted accelerated approval on an expedited basis if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek breakthrough therapy designation for certain of our current and future product candidates for the treatment of various cancers, there can be no assurance that we will receive Breakthrough Therapy Designation.

A fast track or regenerative medicine advanced therapy, or RMAT, designation by the FDA, even if granted for ATL001 or any future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug or biologic is intended for the treatment of a serious or life-threatening disease or condition and the product candidate demonstrates the potential to address unmet medical needs for such disease or condition, the sponsor may apply for FDA Fast Track designation for a particular indication. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. Fast Track designation does not, however, guarantee that the application will be designated for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A company may request RMAT designation of its product candidate, and FDA may granted such designation if the product meets the following criteria: (i) it is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and potential eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion of trials to additional sites.

The FDA has broad discretion whether or not to grant fast track or RMAT designation, so even if we believe a particular product candidate is eligible for such designations, there can be no assurance that the FDA would decide to grant it. Even if we do receive fast track or RMAT designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a fast track or RMAT designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program.

We may seek approval of ATL001 or any future product candidates using FDA's Real-Time Oncology Review program. This program may not lead to a faster regulatory review or approval process and does not increase the likelihood that our product candidate will receive marketing approval.

Participation in FDA's Real-Time Oncology Review, or RTOR, program is voluntary. Our acceptance into RTOR, should we apply, does not guarantee or influence approval of a marketing application for ATL001 or any future product candidates, which would be subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application even if it is selected by FDA for RTOR. If at any time the FDA

determines our participation in RTOR, if selected, is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

Even if we obtain FDA, EMA or MHRA approval for ATL001 in the indications we are currently targeting or any follow-on indications or any future product candidates that we may identify and pursue in the United States, Europe or the United Kingdom, we may never obtain approval to commercialize any such product candidates outside of those jurisdictions, which would limit our ability to realize their full market potential.

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, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional research or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a 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.

Seeking foreign regulatory approval could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our current or future product candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA, EMA or MHRA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets for our current or future product candidates. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our current or future product candidates will be harmed.

RISKS RELATED TO ONGOING REGULATORY OBLIGATIONS

Even if we receive regulatory approval of ATL001 in the indications we are currently targeting or any follow-on indications or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, cGTPs, good laboratory practice, or GLP, regulations and good clinical practice, or GCP, regulations, for any clinical trials that we conduct post-approval. Manufacturers and manufacturers' facilities are also required to comply with applicable product tracking and tracing requirements. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS which may include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved.

Physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

If ATL001 or any future product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies, as reflected in the product's approved labeling. If such regulatory agencies find that we have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use of their products and has enjoined several companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required companies to enter into consent decrees or corporate integrity agreements, or imposed permanent injunctions under which specified promotional conduct must be changed or curtailed.

In the United States, engaging in the impermissible promotion of any products, following approval, for off-label uses can also subject us to false claim actions and other litigation under federal and state statutes. These statutes include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, suspension and debarment from government contracts and refusal of orders under existing government contracts. False Claims Act lawsuits brought by federal and state enforcement agencies against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If, after ATL001 or any of our future product candidates obtains marketing approval, the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities, and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

The success of current programs, additional follow-on indications for ATL001 and any future product candidates, if approved, will depend significantly on our ability to obtain adequate coverage and reimbursement of, or the willingness of patients to pay for, our product candidates.

In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for our product candidates, and the extent to which patients will be willing to pay out-of-pocket for such products. For further discussion on coverage and reimbursement, see the section entitled "Business Overview–Government Regulation–Coverage and Reimbursement" in this Annual Report.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

There can be no assurance that any of our product candidates, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary and/or cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, even if they are approved for sale.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to 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. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product 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. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Healthcare legislative or regulatory reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in applicable laws, rules, and regulations or the interpretation of existing laws, rules, and regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For further discussion on healthcare reform, see the section entitled "Business Overview–Government Regulation–Healthcare Reform" in this Annual Report.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

· the demand for any of our product candidates, if approved;
· the ability to set a price that we believe is fair for any of our product candidates, if approved;
· our ability to generate revenues and achieve or maintain profitability;
· the level of taxes that we are required to pay; and
· the availability of capital.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product candidate. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs, and could have a material adverse effect on our business, financial condition, and results of operations.

Our business activities are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

As we engage in and expand our business activities outside of the United States, including our clinical trial efforts, we are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other foreign jurisdictions, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity and variability of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Inadequate funding for the FDA, the SEC and other government agencies caused by funding shortages, government shut downs or other disruptions to these agencies' operations, 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 from performing normal business 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 the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example,

over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other 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. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable, and could impact review of our public filings, to the extent such review is necessary, and our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to U.S. federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, other healthcare laws and regulations and other foreign privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any therapies on the market, our current and future operations may be directly, or indirectly through our relationships with investigators, health care professionals, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any therapies for which we may obtain marketing approval. These laws impact, among other things, our research activities and proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved therapies, and other parties through which we market, sell and distribute our therapies for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. For further discussion on healthcare laws and other compliance requirements, see the section entitled “Business Overview–Government Regulation–Other Healthcare Laws and Compliance Requirements” in this Annual Report.

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 recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices including compensation of physicians with stock or stock options, could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and

expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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 have a material adverse effect on the success of 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 and flammable 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.

Although we maintain workers' compensation 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, hazardous or radioactive materials.

Failure to comply with current or future national, supranational, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security, including restrictive European regulations, could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our collaborators and third-party providers are subject to national, supranational, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security. This includes the EU General Data Protection Regulation, or EU GDPR, and the United Kingdom (or UK) equivalent of the same (the UK GDPR, together with the EU GDPR, referred to as the GDPR) as well as other national data protection legislation in force in relevant EU and EEA member states and the UK (including the UK Data Protection Act 2018), which governs the collection, use, storage, disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials): (i) regarding individuals in the EU, EEA and UK; and/or (ii) carried out in the context of the activities of our establishment in any EU and EEA member state or the UK. Currently, the EU GDPR and UK GDPR remain largely aligned.

The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, disclosures to individuals regarding data processing activities, safeguards to protect the security and confidentiality of personal data, mandatory data breach notification requirements in certain circumstances, and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR defines personal data to include coded data and imposes high thresholds for informed consent and detailed notices for clinical trial subjects and investigators. The GDPR provides individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection. EU and UK data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to €20 million (£17.5 million) or 4% of annual global revenue, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

The GDPR imposes strict rules on the transfer of personal data to countries outside the EEA, Switzerland or the UK, including the United States to other countries in respect of which the European Commission or the UK government

has not issued a so-called "adequacy decision" or " adequacy regulation" (known as "third countries"), unless a derogation exists or the parties to the transfer have implemented specific safeguards to protect the transferred personal data. This includes putting in place the European Commission's Standard Contractual Clauses, or SCCs, for transfers outside of the EEA and a similar transfer mechanism for transfers of personal data outside of the UK, the International Data Transfer Agreement or Addendum (IDTA). Under both the EU GDPR and the UK GDPR, exporters are also required to assess the risk of the data transfer on a case-by-case basis, including conducting an analysis of the laws in the destination country. The SCCs are required to be in place now, whereas the IDTA had to be used for all new contracts from September 21, 2022, and must be implemented in all existing contracts (entered into prior to September 21, 2022) by March 21, 2024. Finalizing the implementation of the updated UK IDTA, and conducting the required risk assessments, may continue to necessitate significant contractual overhaul of our data transfer arrangements with customers, sub-processors and vendors. On June 28, 2021, the European Commission published its decision recognizing the UK as having adequate laws to the protect the rights and freedoms of data subjects such that personal data may transfer to from the EU to the UK without an approved transfer mechanism. The decision is effective for four years and its continuing effect is dependent on UK law and regulation on data privacy not diverging materially from the GDPR. The UK Government also confirmed that data transfers to the EU remain free flowing.

The UK Government has introduced a Data Protection and Digital Information Bill, or Data Reform Bill, into the UK legislative process to reform the UK's data protection regime, and if passed, the final version of the Data Reform Bill may have the effect of further altering the similarities between the UK and EEA data protection regimes and threaten the UK Adequacy Decision from the European Commission, which may lead to additional compliance costs for us and could increase our overall risk. It is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR. In addition, EEA Member States have adopted national laws to supplement the EU GDPR, which may partially deviate from the EU GDPR, and the competent authorities in the EEA Member States may interpret EU GDPR obligations slightly differently from country to country, such that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance programs could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA.

The GDPR increases our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR. While we have taken steps to comply with the GDPR, and implementing legislation in the UK and applicable EEA member states, including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing our security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful. Given the breadth and depth of data protection obligations, complying with the GDPR and similar laws, requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. For example, California enacted the California Consumer Privacy Act, or the CCPA, which became effective on January 1, 2020 and established a comprehensive privacy framework which provided California consumers certain privacy rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provided civil penalties for violations, as well as a private right of action for certain data breaches that is expected to increase data breach litigation. Additionally, the California Privacy Rights Act, or the CPRA, amended the CCPA in significant ways, including to impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the CPRA's provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the United States, states are constantly amending existing laws, requiring attention to frequently changing regulatory requirements.

Similar comprehensive privacy laws have been passed and proposed in numerous other states. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

Many international laws, including the GDPR, require businesses to notify regulators and data subjects in the event of a cybersecurity incident. Meanwhile, in the United States, all 50 states of the United States require businesses to provide notice to customers whose personal data has been disclosed as a result of a cybersecurity incident. These laws are not consistent, and compliance in the event of a widespread cybersecurity incident is costly.

In many jurisdictions, enforcement actions and consequences for non-compliance with protection, privacy and information security laws and regulations are rising. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non-compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws. In the United States, possible consequences for non-compliance include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our CROs', collaborators', service providers' and other contractors' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects.

Any failure, or perceived failure by us or our collaborators and third-party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The use of new and evolving technologies, such as artificial intelligence, in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

We have built and integrated, and may in the future build and integrate artificial intelligence into our development and manufacturing processes and our offerings, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act ("AI Act") — the world's first comprehensive AI law — is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their own offerings, and the providers of these

artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

Risks Related to Protecting our Intellectual Property

If we fail to comply with our current or future obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.

We currently are, and in the future may continue to be, party to license or collaboration agreements with third parties to advance our research or allow commercialization of ATL001 or any future product candidates. In particular, we are party to a license agreement, or the CRT Agreement, with Cancer Research Technology Limited, or CRT, to obtain exclusive and non-exclusive licenses under certain patents, know-how, data, and information relating to a multi-institution study known as the TRACERx Study, focused on advanced NSCLC. We rely on this license for the development of ATL001 and may rely on it for future product candidates, and we rely on the data from TRACERx to continue to improve our PELEUS AI-powered platform. The CRT Agreement and other future agreements may impose, and may continue to impose, numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize approved products, in order to maintain the licenses. Despite our best efforts, our current and future licensors might conclude that we have materially breached our future license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of the CRT Agreement or future licenses, or if the underlying patents or applications fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize ATL001 and any future product candidates and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

- 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, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- 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 right to claim priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we license intellectual property or technology from third parties, and which we may continue to license in the future, are and may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase

what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license in the future prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

In addition to the protection afforded by patents we may own or in-license in the future, we seek to rely on trade secret protection, in particular in relation to our proprietary VELOS manufacturing process and PELEUS AI-powered platform, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets, in particular those relating to our proprietary VELOS manufacturing process or PELEUS AI-powered platform. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our

employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations may be costly and time-consuming and may prevent or delay our product discovery and development efforts.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop or manufacture our current product candidate in the indications we are currently targeting or any follow-on indications as well as any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that ATL001 or future product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court order prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our product candidates or processes so they do not infringe, misappropriate or violate third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- 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.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue, and some patent applications in the United States may be maintained in secrecy until the patents are issued. Since patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined

to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license in the future is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

If we are unable to obtain and maintain sufficient patent and other intellectual property protection for ATL001 and any future product candidates and technologies, our competitors could develop and commercialize products and technologies similar or equivalent to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop.

Our success depends in significant part on our ability and the ability of our current or future collaborators and licensors to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to ATL001 and any future product candidates and technology and to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights of others. If we and our current or future collaborators and licensors are unable to obtain and maintain sufficient intellectual property protection for ATL001 or other future product candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize product candidates similar or equivalent to ours, and our ability to successfully commercialize our product candidates and other product candidates that we may pursue may be impaired.

Further, we may not be successful in obtaining or maintain necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses. Presently we have rights to certain intellectual property, through licenses from third parties and under patent applications that we own or will own, related to use of data and materials from the TRACERx study, the use of clonal neoantigens and T cells in cell therapy, certain processes and devices used in our proprietary VELOS manufacturing process, aspects of our proprietary PELEUS AI-powered platform and ATL001. Because any future product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

ATL001 and any future product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to

develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that may in the future be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we sometimes collaborate with academic institutions to accelerate our research activities or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program and allowing third parties to compete with us. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business, results of operations, financial condition and prospects could suffer.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent are due to be paid to the USPTO and foreign patent agencies 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 and following the issuance of a patent. While an inadvertent lapse can in some 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. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions or carry out the required acts within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or equivalent products or platforms, which could have a material adverse effect on our business prospects and financial condition.

If we do not obtain patent term extension and data exclusivity for ATL001 or any future product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates we may develop, one or more U.S. patents we may own or in-license in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the

Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following expiration of any patents that issue from our patent applications, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is at least partially dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. Any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce any rights we may have in our patent applications or any patents we may own or in-license in the future.

Recent or future patent reform legislation could also increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we may own or in-license in the future. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law, which includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, establish a new post-grant review system and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either: (i) file any patent application related to our product candidates or other technologies; or (ii) invent any of the inventions claimed in our patent applications or any patents we may own or in-license. These changes also allow third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products 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. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents we may own or in-license in the future, all of which could have a material adverse effect on our business and financial condition.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license in the future may not lead to issued patents;
- patents, should they issue, that we may own or in-license in the future, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license in the future, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;

- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Intellectual Property Litigation

We may be involved in lawsuits to protect or enforce our intellectual property rights, including any patents we may own or in-license in the future, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents we may own or in-license in the future. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license in the future is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license in the future do not cover the technology in question or that such third party's activities do not infringe our patent applications or any patents we may own or in-license in the future. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license in the future at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license in the future. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in foreign patent offices, where our foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs.

We may not be able to detect infringement of any patents we may own or in-license in the future. Even if we detect infringement by a third party of any patents we may own or in-license in the future, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third party.

Any issued patents we may own or in-license in the future covering ATL001 or any future product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

If we or our future licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering ATL001 or any future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in the future in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license in the future, allow third parties to commercialize our product candidates or other technologies 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. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or equivalent technology and products, or limit the duration of the patent protection of our product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on

commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or equivalent technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims challenging the inventorship or ownership of any intellectual property, including any patents we may own or in-license in the future.

We may be subject to claims that former employees, collaborators or other third parties have an interest in any patents we may own or in-license in the future, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing ATL001 or any future product candidates or other technologies. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. Litigation may be necessary to defend against these and other claims challenging inventorship of any patents we may own or in-license in the future, trade secrets or other intellectual property. If we were unsuccessful, in addition to paying monetary damages, we could lose valuable rights in intellectual property that we regard as our own, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We have received confidential and proprietary information from third parties. In addition, as is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information or trade secrets of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims and possible aftermath could result in substantial cost and be a distraction to our management and employees. Any litigation or the threat thereof may adversely affect our ability to hire employees.

A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition. 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 the ADSs. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such

litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property-related proceedings could adversely affect our ability to compete in the marketplace.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

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

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support certain of our research activities and clinical trials under agreements with us.

We expect to have to continue to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our research activities and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these research activities and clinical trials and the management of data developed through research activities and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, supplies of our product candidates used in our clinical trials must be manufactured under good manufacturing practices, or cGMP, regulations. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties performing services or otherwise acting on our behalf violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

Switching or adding third parties to conduct our research, clinical trials or manufacturing activities involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. If we engage directly with third-party CROs and CMOs, we may incur additional costs

or experience delays. If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

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

We may form or seek additional 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. 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.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for ATL001, VELOS, PELEUS and any future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving ATL001, VELOS, PELEUS and any future product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license ATL001, VELOS, PELEUS or any future product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to ATL001, VELOS, PELEUS or any future product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

RISKS RELATED TO EMPLOYEE MATTERS, MANAGING OUR GROWTH AND OTHER RISKS

Risks Related to our Employee Matters

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience in our therapies and related technologies.

The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

To encourage valuable employees to remain at our company, in addition to salary, bonus scheme and our benefits package, we have provided shares for some UK based employees and share options for U.S. and some UK based employees that vest over time. The value to employees of shares and share options that vest over time may be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. 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. To date, this success has been geared towards building an attractive employee value proposition which puts culture at the heart of how we engage our people. This focus on soft retention elements has worked well to date and we are now exploring wider incentive mechanisms to be in-line with the market. Notwithstanding our current and future development of incentive mechanisms, we may be exposed to increases in wage inflation that have an adverse impact on our financial position and on our ability to attract, hire and retain key employees.

Risks Related to our Business Operations and Growth

Insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, travel, property, cyber, umbrella, and directors' and officers' insurance.

Insurance coverage is expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that operating as a public company has made it, and will continue to make it, more difficult and more expensive for us to obtain director and officer liability insurance than had we remained as a private limited company, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory bodies, provide true, complete and accurate information to the FDA and other comparable foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 or regulations.

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

As of December 31, 2023, we had 204 full-time employees and 11 part-time employees. As our development and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to commercialize ATL001 and any future 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 expand our organization by hiring new employees, consultants and/or contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize ATL001 and any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Risks Related to our International Operations

A variety of risks associated with operating our business internationally could materially adversely affect our business.

We plan to seek regulatory approval of ATL001 and any future product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA, Office of Foreign Assets Control Anti-Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

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 internationally. Accordingly, our future results could be harmed by a variety of factors, including the following:

- economic weakness, including inflation, political instability in particular in foreign economies and markets, and future global health concerns or pandemics;
- differing regulatory requirements for drug approvals;
- differing jurisdictions potentially presenting 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 regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates of the pound sterling, euro, U.S. dollar and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States, United Kingdom and EU;
- 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 geo-political actions, including war, such as the ongoing conflict between Russia and Ukraine, and the unrest in the Middle East resulting from the Israel-Hamas war, terrorism, pandemics, or natural disasters including earthquakes, typhoons, floods and fires.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of England and Wales. Most of the members of our senior management and certain members of our board of directors are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the U.S. federal securities laws.

The United States and the UK do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the UK. In addition, uncertainty exists as to whether the courts of England and Wales would entertain original actions brought in the UK against us or our directors or senior management predicated upon securities laws of the U.S. 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 the courts of England and Wales 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 an issue for the court making such decision. If the courts of England and Wales give a 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 courts of England and Wales 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.

Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may increase the risk of holding our ADSs and may materially affect our results of operations and financial condition.

Our ADSs trade on Nasdaq in U.S. dollars. Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the U.S. dollar, the pound sterling and the euro. Our reporting currency is denominated in U.S. dollars and our functional currency is the pound sterling (except that the functional currency of our U.S. subsidiaries is the U.S. dollar) and the majority of our operating expenses are paid in pound sterling. We also regularly acquire services, consumables and materials in U.S. dollars and the euro. Further potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates between the pound sterling and these other currencies, which may also have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place. See Note 2 to our annual financial statements appearing elsewhere in this Annual Report for a description of foreign exchange risks.

The possible abandonment of the euro by one or more members of the EU, could materially affect our business in the future. Despite measures taken by the EU to provide funding to certain EU member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the EU. The effects on our business of a potential dissolution of the EU, the exit of one or more EU member states from the EU or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

In addition, since the Brexit referendum in 2016, there has been a significant increase in the volatility of the exchange rate between the pound sterling and the U.S. dollar and an overall weakening of the pound sterling. As a result of fluctuations in the exchange rate between the U.S. dollar and the pound sterling, the U.S. dollar equivalent of the proceeds that a holder of ADSs would receive upon the sale in the UK of any ordinary shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in pounds sterling on our ordinary shares represented by ADSs could also decline.

RISKS RELATED TO OWNERSHIP OF OUR ADSs

Certain significant shareholders own a substantial number of our ordinary shares and as a result (together with low attendance in recent shareholders meetings), may be able to exercise control over us, including the outcome of shareholder votes. These shareholders may have different interests from us or your interests.

We have a number of significant shareholders. For an overview of our current significant shareholders, please see “Item 7.A. Major Shareholders.”

Currently, we are not aware that any of our existing shareholders have entered or will enter into a shareholders’ agreement with respect to the exercise of their voting rights. Nevertheless, depending on the level of attendance at our general meetings of shareholders, or the General Meeting, these significant shareholders could, alone or together, have the ability to determine the outcome of decisions taken at any such General Meeting. Any such voting by these shareholders may not be in accordance with our interests or those of our other shareholders. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our ADSs or ordinary shares.

If securities or industry analysts cease coverage of us, or publish inaccurate or unfavorable research about our business, the price of our ADSs and our trading volume could decline.

The trading market for our ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. Securities or industry analysts may elect not to provide research coverage of our ADSs, and such lack of research coverage may negatively impact the market price of our ADSs. If one or more of the analysts who cover us downgrade our ADSs or publish inaccurate or unfavorable research about our business, the price of the ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which might cause the price of our ADSs and trading volume to decline.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies make our ADSs less attractive to investors.

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies. However, we may early adopt these standards.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

We may take advantage of these exemptions until we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of: (1) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (2) December 31, 2026, which is the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions.

We qualify as a foreign private issuer and, as a result, are not subject to U.S. proxy rules. We are subject to reporting obligations under the Exchange Act that, to some extent, permit less detailed and frequent reporting than that of a U.S. domestic public company.

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including: (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the Securities and Exchange Commission, or SEC, of quarterly reports on Form 10-Q

containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their Annual Report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are large accelerated filers are required to file their Annual Report on Form 10-K within 60 days after the end of each fiscal year end and accelerated filers are required to file their Annual Report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers, some investors may find our ADSs less attractive, and there may be a less active trading market for our ADSs.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are entitled to rely on a provision in Nasdaq's corporate governance rules that allows us to follow English corporate law and the UK Companies Act 2006, or the Companies Act 2006, with regard to certain aspects of corporate governance, known as home country governance practices. Following our home country governance practices allows us to follow English corporate law and the Companies Act 2006 with regard to certain corporate governance matters as opposed to the requirements that would otherwise apply to U.S. companies listed on Nasdaq and may provide less protection to our shareholders than what is accorded to investors under the Nasdaq rules applicable to domestic U.S. issuers.

As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements. Our officers, directors and principal shareholders are also exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we are exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we are not required to comply with Regulation Fair Disclosure, which restricts the selective disclosure of material information. These exemptions and leniencies 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.

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. Because we are a foreign private issuer, however, our audit committee is not subject to additional Nasdaq requirements applicable to 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. Furthermore, Nasdaq's corporate governance rules require listed U.S. companies to, among other things, seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares, which we are not required to follow as a foreign private issuer. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

While we currently qualify as a foreign private issuer, 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.

In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of the members of our executive committee or members of our board of directors are residents or citizens of the United States, we could lose our foreign private issuer status.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

We may not meet the continued listing requirements of the Nasdaq Global Select Market, which could result in a delisting of our ADSs.

Our ADSs are listed on the Nasdaq Global Select Market. On September 20, 2023, we received a deficiency letter from the Nasdaq Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market LLC, or Nasdaq, notifying us that, for the last 30 consecutive business days, the closing bid price for our ADSs had been below the minimum $1.00 per ADS required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5550(a)(2). The Nasdaq deficiency letter had no immediate effect on the listing of our ADSs. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were given 180 calendar days, or until March 18, 2024, to regain compliance with Nasdaq Listing Rule 5550(a)(2). On March 4, 2024 the Staff notified us that the closing bid price of our ADSs had been at least $1.00 per ADS for the required 10 consecutive business days, that we had therefore re-established price compliance and the Nasdaq deficiency letter was no longer effective.

There can be no assurance that we will be able to maintain compliance with Nasdaq Listing Rule 5550(a)(2) or, if we were to receive a Nasdaq deficiency letter in future, that we would be able to regain compliance during the applicable compliance period. If Nasdaq delists ADSs from trading on its exchange for failure to meet the listing standards, an investor would likely find it significantly more difficult to dispose of or obtain ADSs, and our ability to raise future capital through the sale of ADSs could be severely limited. We additionally may not be able to list ADSs on another national securities exchange, which could result in our securities being quoted on an over-the-counter market. If this were to occur, our shareholders could face significant material adverse consequences, including limited availability of market quotations for ADSs and reduced liquidity for the trading of our securities. In addition, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

We have incurred and will continue to incur significant costs as a result of operating as a company listed in the U.S., and our board of directors have been and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a company listed in the U.S., and particularly after we no longer qualify as an emerging growth company, we have and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, 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 foreign reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors, management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations have made it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our board of directors on our internal control over financial reporting. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal controls over financial reporting, which is both costly and challenging. In this regard, we have needed to and will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that in the future we will not be able to conclude, within the prescribed timeframe, that our internal controls over financial reporting are effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

The depositary for our ADSs has agreed to pay to you 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. You would receive these distributions in proportion to the number of our ordinary shares your 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 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 our ADSs. This means that you 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 your ADSs.

We have not paid, and do not intend to pay, dividends on our ADSs, so any future returns will be limited to the value of our ordinary shares.

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which include other terms prohibiting or limiting the amount of dividends that may be declared or paid on the ADSs. Furthermore, under the Companies Act 2006, a company's accumulated realized profits, so far as not previously utilized by distribution or capitalization, must exceed its accumulated realized losses so far as not previously written off in a reduction or reorganization of capital duly made (on a non-consolidated basis), before dividends can be paid. In the future, were our dividend policy to change, a dividend or distribution may still be restricted from being declared and paid. For these reasons, any return to shareholders may therefore be limited to the appreciation of their shares, which may never occur.

Holders of our ADSs do not have the same voting rights as the holders of our ordinary shares, and may not receive voting materials or any other documents that would need to be provided to our shareholders pursuant to English corporate law, including the Companies Act 2006, in time to be able to exercise their right to vote.

Except as described elsewhere in this Annual Report and the deposit agreement, holders of our ADSs are not able to exercise voting rights attaching to the ordinary shares represented by our ADSs. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon our request, the depositary shall distribute to the holders as of the record date: (i) the notice of the meeting or solicitation of consent or proxy sent by us; and (ii) a statement as to the manner in which instructions may be given by the holders. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs.

Otherwise, ADS holders are not able to exercise their right to vote, unless they cancel the ADSs and withdraw the ordinary shares underlying the ADSs they hold. However, ADS holders may not know about the meeting far enough in advance to cancel the ADSs and withdraw those ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. As a result, ADS holders may not be able to exercise their right to vote, and there may be nothing they can do if the ordinary shares underlying their ADSs are not voted as they requested or if their shares cannot be voted.

Holders of ADSs may not be able to participate in equity offerings we may conduct from time to time.

Certain shareholders and holders of ADSs, including those in the United States, may, even in the case where preferential subscription rights have not been cancelled or limited, not be entitled to exercise such rights, unless the offering is registered or the ordinary shares are qualified for sale under the relevant regulatory framework. As a result, there is the risk that investors may suffer dilution of their holdings should they not be permitted to participate in preference right equity or other offerings that we may conduct in the future.

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying ordinary shares.

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders meeting or we are paying a dividend on our ordinary shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities. See "Item 12.D. American Depositary Shares."

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing our ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, owners and holders of ADSs irrevocably waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ADSs or the deposit agreement.

If this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. Any person or entity purchasing or otherwise acquiring any of the ADSs, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

ADS holders have limited choice of forum, which could limit your ability to obtain a favorable judicial forum for complaints against us, the depositary or our respective directors, officers or employees.

The deposit agreement governing the ADSs provides that: (i) the deposit agreement and the ADSs will be interpreted in accordance with the laws of the State of New York; and (ii) as an owner of ADSs, you irrevocably agree that any legal action arising out of the deposit agreement and the ADSs involving us or the depositary may only be instituted in a state or federal court in the city of New York. Any person or entity purchasing or otherwise acquiring any ADSs, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions. This choice of forum provision may increase your cost and limit your ability to bring a claim in a judicial forum that you find favorable for disputes with us, the depositary or our and the depositary's respective directors, officers or employees, which may discourage such lawsuits against us, the depositary and our and the depositary's respective directors, officers or employees. However, it is possible that a court could find such choice of forum provisions to be inapplicable or unenforceable. The enforceability of similar choice of forum provisions has been challenged in legal proceedings.

To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, actions by our ADS holders to enforce any duty or liability created by the Exchange Act, the Securities Act or the respective rules and regulations thereunder must be brought in a federal court in the city of New York. Our ADS holders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

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

English law provides that a board of directors may only allot shares (or grant rights to subscribe for or to convert any security into shares) with the prior authorization of shareholders, either pursuant to an ordinary resolution or as set out in the articles of association adopted from time to time with the approval of our shareholders. This authorization must state the aggregate nominal amount of shares that it covers, can be valid up to a maximum period of five years and can be varied, renewed or revoked by shareholders. Such authority from our shareholders to allot additional shares for a period of five years from March 15, 2021 was included in the ordinary resolution passed by our shareholders on March 15, 2021, 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, 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, if the disapplication is contained in the Articles, but not longer than the duration of the authority to allot shares to which this disapplication relates 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). Such authority from our shareholders to disapply preemptive rights for a period of five years was included in the special resolution passed by our shareholders on March 15, 2021, 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 its shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, and other formalities. Such approval may be provided for a maximum period of up to five years.

GENERAL RISK FACTORS

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer cybersecurity incidents, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. The risk of a cybersecurity incident or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure or cybersecurity incident to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, such as the loss of clinical trial data from completed or future clinical trials. Such loss could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we may rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Any cybersecurity incident relating to our information technology systems could lead to the unauthorized access, disclosure and use of non-public information, including information from our patient registry or other patient information, which is protected by data privacy and security laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our product candidates could be delayed.

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

Our operations, and those of our CROs, CMOs and other contractors and consultants, 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 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.

Unstable global economic conditions and global geo-political events could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. In addition, recent geo-political events, including the ongoing conflict between Russia and Ukraine,

the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the unrest in the Middle East resulting from the Israel-Hamas war, have created global economic uncertainty in general. We continue to monitor the adverse impact generally, and on our business and operations and on the business and operations of our suppliers and other third parties with which we conduct business, caused by these geo-political events. For example, these events have led to significant increases in commodity prices, energy and fuel prices, credit and capital market instability and supply chain interruptions which have led to increasing inflation. This may in turn adversely impact our ability to deliver our goals. A severe or prolonged economic downturn, including due to the impact of future global health concerns or pandemics and geo-political events, could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our third-party suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business may be adversely affected by a pandemic, epidemic or outbreak of an infectious disease

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third-party contract manufacturers and contract research organizations upon whom we rely, as well as our ability to recruit patients for our clinical trials. For example, the COVID-19 pandemic has had a significant impact on global societies, economies, financial markets, and business practices around the world. We experienced some temporary delays or disruptions due to the coronavirus pandemic, including pauses in and delays to patient dosing, limited or reduced patient access to beds, hospitals and healthcare resources generally, delayed initiation of new clinical trial sites and limited on-site personnel support at various trial sites. In addition, certain of our third-party manufacturers and suppliers paused their operations in the early stages of the pandemic, and some paused their operations again as a result of additional variants of the COVID-19 virus. The extent to which future pandemics may impact our business, results of operations and future growth prospects will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope and severity of, and how governments respond to, the pandemic.

We may be unable to adequately protect our information systems from cyber-attacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyber-attack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyber-attack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyber-attacks are a threat, and there can be no assurance that our efforts will prevent cybersecurity incidents that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate cybersecurity incidents or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international (e.g., the GDPR) law and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, the computer systems of various third parties on which we rely, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, ransomware attacks, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate cybersecurity incidents or improper access to or disclosure of such information could have similarly adverse consequences for us.

The GDPR, United States state laws and other international laws to which we may be subject require businesses to notify regulators and data subjects in the event of a cybersecurity incident. If we are unable to prevent or mitigate the impact of such cybersecurity or data privacy incidents, we could be exposed to litigation and governmental investigations, which could lead to fines, damages, reputational damage and a potential disruption to our business.

Environmental, social and governance matters may impact our business and reputation.

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While we strive to meet all legal and regulatory requirements in relation to ESG and aim over time to continually improve our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects.

We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea-level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future

product development. These risks could disrupt our operations and its supply chain, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and, if approved, sales of our product candidates. These upfront and milestone payments may vary significantly from period to period and any variance could cause a significant fluctuation in our operating results from one period to the next.

Further, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current programs, additional follow-on indications for ATL001, and any future product candidates, which will change from time to time;
- the timing and outcomes of clinical trials for our current programs, additional follow-on indications for ATL001, and any future product candidates;
- the cost of manufacturing ATL001 and any of our future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- our ability to adequately support our future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and geo-political environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our ADSs could decline substantially. The price of our ADSs could decline even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

Shareholder protections found in provisions under the United Kingdom City Code on Takeovers and Mergers, or the Takeover Code, will not apply if our place of central management and control remains outside of the United Kingdom (or the Channel Islands or the Isle of Man).

We believe that, as of the date of this Annual Report, our place of central management and control is not in the United Kingdom (or the Channel Islands or the Isle of Man) for the purposes of the jurisdictional criteria of the Takeover Code. Accordingly, we believe that we are not currently subject to the Takeover Code and, as a result, our shareholders are not currently entitled to the benefit of certain takeover offer protections provided under the Takeover Code, including the rules regarding mandatory takeover bids.

In the event that this changes, or if the interpretation and application of the Takeover Code by the Panel on Takeovers and Mergers, or Takeover Panel, changes (including changes to the way in which the Takeover Panel assesses the application of the Takeover Code to English companies whose shares are listed outside of the United Kingdom), the Takeover Code may apply to us in the future.

The Takeover Code provides a framework within which takeovers of companies which are subject to the Takeover Code are regulated and conducted. The following is a brief summary of some of the most important rules of the Takeover Code:

- When any person acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares already held by that person and an interest in shares held or acquired by persons acting in concert with him or her) carry 30% or more of the voting rights of a company that is subject to the Takeover Code, that person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights in that company to acquire the balance of their interests in the company.
- When any person who, together with persons acting in concert with him or her, is interested in shares representing not less than 30% but does not hold more than 50% of the voting rights of a company that is subject to the Takeover Code, and such person, or any person acting in concert with him or her, acquires an additional interest in shares which increases the percentage of shares carrying voting rights in which he or she is interested, then such person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights of that company to acquire the balance of their interests in the company.
- A mandatory offer triggered in the circumstances described in the two paragraphs above must be in cash (or be accompanied by a cash alternative) and at not less than the highest price paid within the preceding 12 months to acquire any interest in shares in the company by the person required to make the offer or any person acting in concert with him or her.
- In relation to a voluntary offer (i.e., any offer which is not a mandatory offer), when interests in shares representing 10% or more of the shares of a class have been acquired for cash by an offeror (i.e., a bidder) and any person acting in concert with it in the offer period and the previous 12 months, the offer must be in cash or include a cash alternative for all shareholders of that class at not less than the highest price paid for any interest in shares of that class by the offeror and by any person acting in concert with it in that period. Further, if an offeror acquires for cash any interest in shares during the offer period, a cash alternative must be made available at not less than the highest price paid for any interest in the shares of that class.
- If, after making an offer for a company, the offeror or any person acting in concert with them acquires an interest in shares in an offeree company (i.e., a target) at a price higher than the value of the offer, the offer must be increased to not less than the highest price paid for the interest in shares so acquired.
- An offeree company must appoint a competent independent advisor whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company.
- Special or favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial advisor to the offeree.
- All shareholders must be given the same information.

- Each document published in connection with an offer by or on behalf of the offeror or offeree must state that the directors of the offeror or the offeree, as the case may be, accept responsibility for the information contained therein.
- Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisors.
- Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately.
- Actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group.
- Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities.
- Employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website.

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

We are incorporated under the laws of England and Wales. The rights of holders of our ordinary shares and Class A ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by the laws of England and Wales, including the provisions of the Companies Act 2006, and by our Articles of Association, or Articles. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

The principal differences include the following:

- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or Class A ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares or Class A ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.
- Under English law and our Articles, certain matters require the approval of 75% of shareholders representing 75% of the ordinary shares voting (in person or by proxy), including amendments to the Articles. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.
- In the United Kingdom, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a "squeeze out" to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares (including those represented by ADSs) will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75% of the ordinary shares (including those represented by ADSs) voting at the meeting for approval.
- Under English law and our Articles, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.

Our Articles 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 or the Exchange Act, and that the United States 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 provide that, unless we consent by ordinary resolution to the selection of an alternative forum, the courts of England and Wales shall, to the fullest extent permitted by law, be the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us; (iii) any action or proceeding asserting a claim arising out of any provision of the Companies Act 2006 or our Articles (as may be amended from time to time); or (iv) any action or proceeding asserting a claim or otherwise related to our affairs, or the England and Wales Forum Provision. The England and Wales Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our Articles further provide that unless we consent by ordinary resolution to the selection of an alternative forum, the United States District Court for the Southern District of New York shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act, or the U.S. Federal Forum Provision. In addition, our Articles provide that any person or entity purchasing or otherwise acquiring any interest in our shares is deemed to have notice of and consented to the England and Wales Forum Provision and the U.S. Federal Forum Provision; provided, however, that our shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The England and Wales Forum Provision and the U.S. Federal Forum Provision in our Articles may impose additional litigation costs on our shareholders in pursuing any such claims. Additionally, the forum selection clauses in our Articles may limit the ability of our shareholders to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts, including the courts of England and Wales and other courts within the U.S., will enforce our U.S. Federal Forum Provision. If the U.S. Federal Forum Provision is found 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. The U.S. Federal Forum Provision may also impose additional litigation costs on our shareholders who assert that the provision is not enforceable or invalid. The courts of England and Wales and the United States District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

If we were classified as a passive foreign investment company, there could be material adverse U.S. federal income tax consequences to U.S. Holders.

Under the Internal Revenue Code of 1986, as amended, or the Code, we are a passive foreign investment company, or PFIC, for any taxable year in which (i) 75% or more of our gross income consists of passive income, or the income test, or (ii) 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, or the asset test. 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 holding and receiving directly its proportionate share of assets and income of such corporation. If we are a PFIC for any taxable year during which a U.S. Holder (as defined below under "Item 10.E. Taxation—U.S. Taxation") holds our ordinary shares or ADSs, the U.S. Holder may be subject to material 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.

We believe that we were classified as a PFIC for our taxable year ended December 31, 2023. Based on the current and expected composition of our income and assets and the value of our assets, we expect to be a PFIC for the current taxable year ending December 31, 2024. However, no assurances regarding our PFIC status can be provided for any past, current or future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Subject to certain exceptions, for purposes of the asset test, if we are treated as a non-publicly traded "controlled foreign corporation," or a CFC (as discussed below), for the year being tested for purposes of the PFIC rules, the value of our assets will be measured by the adjusted tax basis of our assets. If we are a publicly traded CFC or not a CFC for such year, the value of our assets generally will be determined by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. The income test depends on the nature and composition of our income. The composition of our income and assets is also affected by how fast we spend the cash we raise in any offering.

For further discussion of the PFIC rules and adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see the section titled "Item 10.E. Taxation—U.S. Taxation" in this Annual Report. Each U.S. Holder should consult its own tax advisors with respect to the potential adverse U.S. tax consequences to it if we are or were to become a PFIC.

If we are a "controlled foreign corporation," or CFC, there could be adverse U.S. federal income tax consequences to certain U.S. Holders.

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a CFC for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income," "global intangible low-taxed income" and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a United States person (as defined by the Code) who owns or is considered to own (directly, indirectly or constructively) 10% or more of the value of all classes of stock or total combined voting power of all classes of stock entitled to vote of such corporation. In addition, if a non-U.S. corporation owns at least one U.S. subsidiary, even if such non-U.S. corporation is not a CFC, under current law, any current non-U.S. subsidiaries and any future newly formed or acquired non-U.S. subsidiaries of the non-U.S. corporation will be treated as CFCs. Subpart F income generally includes dividends, interest, rents, royalties, gains from the sale of securities and income from certain transactions with related parties. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain.

We believe that we were not classified as a CFC for the year ended December 31, 2023. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. An individual that is a Ten Percent Shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a Ten Percent Shareholder that is a U.S. corporation. Failure to comply with CFC reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any Ten Percent Shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the CFC rules of the Code. U.S. Holders should consult their own tax advisors with respect to the potential adverse U.S. tax consequences of becoming a Ten Percent Shareholder in a CFC.

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

As a UK incorporated and tax resident entity, we are subject to UK corporate taxation on tax-adjusted trading profits. Due to the nature of our business, we have generated losses since inception and therefore have not paid any UK corporation tax. As of December 31, 2023, we had cumulative United Kingdom carryforward tax losses of $121.7 million. Subject to any relevant 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 of our ordinary shares 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.

As a company that carries out extensive R&D activities, the Company benefits from the UK research and development tax credit regime under the scheme for small or medium-sized enterprises ("SME"). Under the current SME regime, the Company can surrender some of its trading losses that arise from qualifying R&D activities for a cash rebate of 33.35% of qualifying R&D expenditure incurred prior to April 1, 2023 (after taking into account the enhanced rate of deduction) and decreasing to 18.6% of qualifying R&D expenditure after April 1, 2023 (after taking into account the enhanced rate of deduction). Additionally, the UK Government has enacted further changes to the SME regime in February 2024, which include the introduction of a new rate for R&D intensive companies of 26.97% (which the Company is expected to qualify for) and comes into effect for qualifying R&D expenditures incurred after April 1, 2023.

Additional changes to the R&D tax relief legislation, which take effect from April 2024, introduced restrictions on relief that may be claimed for expenditure on sub-contracted R&D activity, broadly requiring either that workers carrying on such activity are subject to UK PAYE or, where work is undertaken outside the UK, that this must be due to geographical, environmental or social conditions not replicable in the UK. These restrictions may impact the quantum of R&D relief that we are able to claim in the future.

It should also be noted that there is a cap on R&D claims to a multiple of payroll taxes (broadly, to a maximum payable credit equal to £20,000 plus three times the total PAYE and National Insurance contributions, or NICs, liability of the company) subject to an exception which prevents the cap from applying. That exception requires the Company to be creating, taking steps to create or managing intellectual property, as well as having qualifying R&D expenditure in respect of connected parties which does not exceed 15% of the total claimed. If such exception does not apply, this could restrict the amount of payable credit that we are able to claim.

We may benefit in the future from the United Kingdom's "patent box" regime, which allows certain profits attributable to revenue from patented products (and other qualifying income) to be taxed at an effective rate of 10% by giving an additional tax deduction. When taken in combination with the enhanced relief available on our R&D expenditure, we expect a long-term effective rate of corporation tax lower than the statutory rate to apply to us (even after the announced changes to the SME Program and RDEC Program described above). If, however, there are further adverse changes to the UK R&D tax credit regime or the "patent box" regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments then our business, results of operations and financial condition may be adversely affected. This may impact our ongoing requirement for investment and the timeframes within which additional investment is required.

For completeness, it should be noted that the UK tax authority, His Majesty's Revenue & Customs, or HMRC, currently has an increased focus on claims for R&D tax credits and so the Company may be subject to increased scrutiny in respect of any claims it makes. In addition, the legislation on the UK R&D tax credits regime is updated and changed frequently, so there can be no guarantee of our ability to make use of such credits as we might currently expect to in future.

Changes and uncertainties in the tax system in the countries in which we have operations could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders.

We conduct business globally and file tax returns in the UK and the U.S. The tax treatment of the company or any of the group companies could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration (such as those related to the Organization for Economic Co-operation and Development's, or OCED, Base Erosion and Profit Shifting, or BEPS, Project, the European Commission's state aid investigations and other initiatives); the practices of tax authorities in jurisdictions in which we operate (the UK and the U.S.); and the resolution of issues arising from tax audits or examinations and any related interest or penalties. 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.

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 in jurisdictions in which we operate, could affect our financial position, future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders and increase the complexity, burden and cost of tax compliance.

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

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, HMRC, the Internal Revenue Service, or IRS, or another tax authority could challenge our allocation of income among various jurisdictions and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies. 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 tax liabilities, interest and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, 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, or result in other liabilities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We continue the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires annual management assessment of the effectiveness of our internal control over financial reporting. We will look to recruit additional finance and accounting personnel with certain skill sets that we need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm the price of our ADSs and make it more difficult for us to effectively market and sell our products to new and existing customers.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our business and operations may be negatively impacted by the United Kingdom's withdrawal from the EU.

The UK formally left the EU on January 31, 2020 (commonly referred to as Brexit), and the EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of Good Manufacturing Practice, or GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework currently continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in the most part with EU medicines regulations, however it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation.

For instance, the EU Clinical Trials Regulation which became effective on January 31, 2022 and provides for a streamlined clinical trial application and assessment procedure covering multiple EU Member States has not been implemented into UK law, and a separate application must therefore be submitted for clinical trial authorization in the UK. In addition, Great Britain is no longer covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland) until January 1, 2025; following which a single UK-wide marketing authorization will be required to market a medicinal product throughout the UK in accordance with the Windsor Framework outlined in the section below titled *Brexit and the Regulatory Framework in the UK*). Notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, the MHRA put in place a new framework on January 1, 2024, whereby the MHRA may take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators)

when considering an application for a Great Britain marketing authorization. Any new regulations in the future could add time and expense to the conduct of our business in both the UK and EU, as well as the process by which our drug candidates receive regulatory approval in the UK, the EU and elsewhere.

In addition, as we are headquartered in the UK, it is possible that the continued effects of Brexit may impact some or all of our current operations. For example, since the transition period ended, Brexit has restricted our ability to freely move employees from our headquarters in the UK to other locations in Europe and the ability of European healthcare practitioners to move freely to the UK in order to complete part of their training or work on our clinical trials there. In addition, we intend to continue to manufacture our cNeT product candidates at our two UK manufacturing sites, the Royal Free Hospital and the Cell and Gene Therapy Catapult. Manufacturing product candidates in the UK may affect the clearance or timing of the release of our clinical trial materials out of the UK. Any such delays could result in our clinical trial sites outside of the UK not having sufficient clinical trial materials and could adversely affect the timing and completion of our clinical trials.

Item 4. Information on the Company.

A. History and Development of the Company

Achilles Therapeutics plc (formerly Achilles TX Limited) and subsidiaries, or the Company, is a biopharmaceutical company developing AI-powered precision T cell therapies targeting clonal neoantigens to treat solid tumors. The Company is focused on advancing immuno-oncology therapeutics by exploiting its pioneering work in the field of tumor evolution and clonal neoantigens.

The Company is a public limited company originally incorporated pursuant to the laws of England and Wales in November 2020 as a private limited company named Achilles TX Limited, with nominal assets and liabilities, for the purposes of becoming the ultimate holding company for Achilles Therapeutics UK Limited (formerly Achilles Therapeutics Limited). Achilles Therapeutics UK Limited was incorporated in May 2016 under the laws of England and Wales. Achilles TX Limited and Achilles Therapeutics Holdings Limited (a wholly owned direct subsidiary of Achilles TX Limited formed in November 2020 for the purpose of becoming the direct holding company of Achilles Therapeutics UK Limited and Achilles Therapeutics US, Inc.) have not conducted any operations prior to the corporate reorganization other than activities incidental to their formation. In April 2021, following the completion of our U.S. initial public offering, our American Depositary Shares began trading on the Nasdaq, under the symbol “ACHL”. Our agent for service of process in the United States is Cogency Global Inc.

Our registered office is located at 245 Hammersmith Road, London, W6 8PW, United Kingdom, and our telephone number is +44 (0)20 8154 4600. Our website address is www.achillestx.com. The information contained on, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this Annual Report. We have included our website address as an inactive textual reference only.

Our capital expenditures for the years ended December 31, 2023, 2022 and 2021 amounted to $1.1 million, $7.5 million and $7.6 million, respectively. Capital expenditures primarily consisted of purchases of property and equipment and leasehold improvements, which largely consisted of operating and lab equipment.

The SEC maintains an internet site at http://www.sec.gov that contains reports, information statements, and other information regarding issuers that file electronically with the SEC.

B. Business Overview

We are a clinical stage immuno-oncology biopharmaceutical company developing precision T cell therapies to treat multiple types of solid tumors. We are focused on advancing cancer therapies through our pioneering work in the field of tumor evolution and our belief that clonal neoantigens represent the most specific class of cancer cell targets and address a long standing and fundamental issue in oncology drug development, how to target tumor cells and spare

healthy tissue. Our platform enables us to identify mutations formed early in the development of a cancer that give rise to antigens that are expressed by all of a patient's cancer cells but are absent from healthy tissue, something that has not been possible until now. We refer to this novel class of solid tumor targets as clonal neoantigens. To identify clonal neoantigens in a patient, we have developed a proprietary AI-powered bioinformatics platform called PELEUS, which is based on the patented ClonalX module. This platform employs advanced computational methods with AI and machine learning and is not limited to *in-silico* prediction but has been validated with real world patient tumor genetic data derived from our exclusive commercial license to data from the TRACERx study, which aims to analyze tumor samples from 814 non-small cell lung cancer, or NSCLC, patients. Once we have identified the clonal neoantigens, our proprietary manufacturing process, VELOS, uses the patient's T cells and blood-derived dendritic cells to create a clonal neoantigen-reactive T cell, or cNeT, therapy that specifically targets multiple clonal neoantigens to eradicate the tumor or tumors. Furthermore, the clonal neoantigens identified by PELEUS can be targeted with a number of different therapeutic modalities beyond cNeT from our current VELOS process, including mRNA-based vaccines, TCR-T, and clonally activated T cells sourced from patients' blood.

We are currently conducting two open-label Phase I/IIa trials to evaluate our cNeT product candidate, ATL001, in advanced NSCLC and metastatic or recurrent melanoma and expect to report additional patient data from these trials through 2024. We are also using our Material Acquisition Platform, or MAP, network, which consists of a network of participating hospitals, with the ability to collect patient tissue samples from a range of tumor types to further develop and enhance both our PELEUS AI-powered platform to identify clonal neoantigens in these tumor types as well our VELOS manufacturing process.

Cancers originate from mutations in the DNA of individual cells. Some of these mutations promote uncontrolled proliferation, metastasis and evasion of the immune system. Tumors within any given patient evolve in a Darwinian branched manner, where the mutations present at the point of a cell becoming cancerous will be carried to all future cells and are therefore present in every future tumor cell of the patient. Additional mutations continue to arise in response to environmental pressures, carcinogens and genomic instability. These additional mutations increase the intra-tumor genomic variation and are present in some tumor cells but not others.

Mutations can give rise to neoantigens expressed in the tumor cells. The neoantigens arising from the early mutations present at the time of cell transformation are referred to as clonal neoantigens while those that arise later in tumor development are referred to as subclonal neoantigens. As a result of this branched evolution, clonal neoantigens are expressed in every tumor cell, while subclonal neoantigens are expressed only by a fraction of tumor cells. Despite the recent advances in cancer therapy, no therapy to date has been able to specifically identify and target only the clonal neoantigens found throughout the tumor. We believe this is a key reason for limitations in efficacy and durability of many of today's cancer therapies.

In the last decade, numerous clinical trials have validated the therapeutic potential of the immune system in the fight against cancer. Immunotherapy approaches include checkpoint inhibitors, or CPIs, which inhibit the downregulation of endogenous T cell activity, mRNA vaccines that target neoantigens and adoptive cell therapies, or ACTs, that expand a patient's own tumor-targeting T cells in vitro followed by their transfer back into the patient. There are different types of ACTs, primarily differentiated by the approach used to target the T cells to the tumor, including chimeric antigen receptor therapy, or CAR-T, T cell receptor therapy, or TCR-T, and tumor-infiltrating lymphocytes, or TIL, therapy. These approaches are based on harnessing T cells to attack tumor antigens. Despite the clinical successes of CPI and ACT therapies, we believe their clinical benefit has generally been limited by an inability to specifically target the antigens that are uniformly expressed by solid tumors and not expressed on healthy tissue. This has resulted in a lack of durable response, off target activity and toxicity concerns.

Our VELOS process uses a TIL therapeutic approach, which is based on the observation that tumor reactive T cells are found in a patient's tumor at higher frequencies than in other tissues. In standard TIL therapy, T cells are extracted from a patient's tumor, activated and expanded to large numbers before being reinfused back into the patient. Despite the impressive results of standard TIL therapies, we believe their clinical benefit has been limited by their inability to specifically target clonal neoantigens. This lack of specificity is a result of the inability of standard TIL therapies to control selection of targeted antigens; instead, all T cells within the patient's tumor sample are expanded and the resulting composition of the T cell therapy is not known or controlled. In addition, manufacturing processes for standard TIL therapies employ non-physiological T cell expansion methods, which we believe result in less functionally fit T cells in the final TIL product. We believe that this lack of control over T cell specificity and T cell

fitness limits the potential of standard TIL therapies and provides an opportunity to develop a precision TIL therapy. In contrast, we have demonstrated the ability to detect, quantify, and track patient-specific clonal neoantigen-reactive T cells, or cNeT. The ability to reliably detect and quantify our active component is a key differentiator of our technology, which we believe is unique in the field and critical for the successful development of TIL-based therapies.

OUR APPROACH—TRACKABLE PRECISION T-CELL BASED THERAPIES TARGETING MULTIPLE CLONAL NEOANTIGENS IN SOLID TUMORS

We believe that targeting clonal neoantigens is the key to unlocking immunotherapy in solid tumors and have developed our platform to specifically address these targets. By targeting multiple clonal neoantigens, we have the potential to reduce the likelihood of immune escape by tumor cells, thereby enhancing long-term tumor control, while also reducing the potential for off-target toxicity. We utilize our AI-powered platform, PELEUS, to identify clonal neoantigens in patients and combine these targets with our VELOS manufacturing process, which utilizes a physiological, antigen driven expansion process to create a functionally fitter T cell product. We believe the resulting cNeT product candidates can overcome many of the challenges faced by existing immunotherapies for the treatment of solid tumors.

The foundation of our approach is the PELEUS AI-powered platform which is designed to identify each patient's tumor-specific clonal neoantigens by comparing DNA sequencing information from healthy tissue and tumor. PELEUS combines data from the TRACERx study with sophisticated proprietary statistical models together with AI and machine learning to: (i) distinguish which mutations in a patient's tumor are clonal or subclonal; (ii) determine how immunogenic each neoantigen is; and (iii) assess the extent of immune evasion mechanism in the tumor. TRACERx is a study which aims to analyze tumor samples from 814 NSCLC patients and has collected over 4,300 tumor region samples. We have exclusive commercial rights to the TRACERx database of multi-region samples from primary tumor and metastases and whole exome sequencing data for each individual patient for development of neoantigen-targeting cell therapies. The PELEUS AI-powered platform is continuously updated, trained, and improved with this reference data that gives us what we believe is a unique approach to enable identification of clonal neoantigens.

To create our cNeT product candidates, we first procure tumor tissue and blood samples from the patient. We then extract, sequence and analyze the tumor DNA using PELEUS to identify the patient's unique clonal neoantigens. Using this information, we manufacture clonal neoantigen peptides, load them onto dendritic cells extracted from the patient's blood, and co-culture them with TILs extracted from the patient's tumor to activate and expand a subset of the T cells — we call this proprietary manufacturing process VELOS. This process creates a cNeT product candidate significantly enriched for T cells designed to recognize and specifically target multiple clonal neoantigens across all of the patient's tumor cells. We are continuing to develop an automated, fully-closed system for cell manufacturing, which we believe will be scalable for commercial supply.

OUR PIPELINE

We believe our cNeT technology is uniquely positioned to overcome the challenges faced by existing immunotherapies for the treatment of solid tumors. We have worldwide rights to our cNeT programs and are currently conducting a Phase I/IIa, open-label, proof-of-concept trial in advanced NSCLC, referred to as CHIRON, and metastatic or recurrent melanoma, referred to as THETIS. We have prioritized the tumor types that we are seeking to address based on criteria we believe will maximize the potential of our programs to demonstrate a clinical benefit, including clonal neoantigen burden, TIL infiltration, tumor accessibility, as well as commercial factors such as high unmet medical need. Our Phase I/IIa trials are evaluating safety and tolerability of cNeT and assessing clinical efficacy based primarily on the change from baseline in tumor size, response rate and duration of response. An interim data update from 32 patients that received cNeT monotherapy (n=29) and cNeT PD-1 combination therapy (n=1) was presented in April 2024 and we expect to generate additional patient data across both clinical trials through 2024.

Depending on the results of our Phase I/II trials, we plan to engage with the appropriate regulatory authorities to discuss potential pathways to registration.

We believe the principles of tumor evolution to be common across many tumor types enabling our cNeT approach to be broadly applicable. As such, we have built up our MAP network to allow us to acquire and analyze tumor samples from multiple different indications to facilitate the development of follow-on indications for our cNeT technology.

OUR TEAM

Our management team has a strong track record of delivery including expertise in cancer immunology, oncology drug development, cell therapy process development, manufacturing and supply chain management. We are led by Dr. Iraj Ali, our Chief Executive Officer. Dr. Ali was formerly a Managing Partner of Syncona, where he served as an Investment Director at Nightstar Therapeutics (acquired by Biogen) and Blue Earth Diagnostics (acquired by Bracco Imaging), and was previously an Associate-Principal at McKinsey & Co. Our Chief Scientific Officer and co-founder is Professor Sergio Quezada, who is a recognized leader in the field of immune regulation and cancer immunology and was a founder of TUSK Therapeutics, an immuno-oncology company acquired by Roche. Our Chief Medical Officer and co-founder is Professor Karl Peggs, who was formerly a Professor of Transplant Science and Cancer Immunotherapy at University College London. Professor Peggs has significant experience in the clinical translation of T cell therapies and is the Director of the Cellular Immunotherapy Unit at University College London Hospitals NHS Trust, or UCLH. Our Scientific Advisory Board also includes Dr. Scott Antonia, Dr. Ben Creelan, Dr. Alena Gros, Dr. Elizabeth Jaffee, Dr. Christopher Klebanoff, Dr. Markwin Velders and Dr. Cassian Yee.

TUMOR EVOLUTION AND THE IMMUNE SYSTEM

The Genetic Basis of Cancer

Cancers originate from mutations in the DNA of individual cells that promote uncontrolled proliferation, metastasis and evasion of the immune system. Tumors evolve in a Darwinian branched manner, whereby the mutations that are present in a cell before it becomes cancerous will be carried by all daughter cells of the growing cancer. These mutations are called clonal neoantigens, represented as the red “trunk” in the figure below. After the cell becomes cancerous, additional mutations may continue to arise in some cancer cells in response to genomic instability or environmental challenge. These additional mutations are called subclonal neoantigens – represented as the “branches” in the figure below. Clonal neoantigens are expressed in every tumor cell, while subclonal neoantigens are expressed by only a fraction of tumor cells. Since subclonal neoantigens are not present in all cancer cells, therapies that only target subclonal neoantigens only address a subset of the cancer cells and therefore allow the non-targeted cancer cells to continue to evolve and evade immune attack.

DEPICTION of DARWINIAN TUMOR EVOLUTION

Red = clonal neoantigens
Purple, Green and Orange = subclonal neoantigens

Cancer and the Immune System

A key line of defense of the immune system's response to tumors are T cells, which are white blood cells that mature mainly in the thymus. One of the primary functions of T cells is to detect and eliminate abnormal or "non-self" cells. T cells can be classified into two major subsets, CD4+ T "helper" cells and CD8+ T "effector" cells. CD8+ T cells can directly attack and kill cells that they recognize as abnormal or "non-self." CD4+ T cells provide help to the immune response by secreting cytokines that enhance the activation, expansion, migration and effector functions of other types of immune cells in response to "non-self" cells. In addition, they can also directly kill tumor cells. Central and peripheral tolerance mechanisms prevent T cells from reacting to self-antigens, enabling them to differentiate between human leukocyte antigens, or HLA-peptide complexes that are "self" and those that are "foreign" or "non-self."

When the DNA of tumor cells mutates, it results in the expression of "non-self" peptides. These peptides are then displayed on the cell surface as an HLA-peptide complex, which can be recognized and targeted by T cells, leading to subsequent destruction of the cell expressing them. Cancerous cells evolve as they divide and develop mechanisms to avoid the immune response. For example, tumor cells are able to activate immune checkpoint proteins on the surface of T cells that act to down-regulate the immune response to tumors. This also results in the recruitment of immunosuppressive cells to the tumor microenvironment, or TME, production of immune-suppressive factors, and reduced antigen presenting capacity, which reduces the ability of T cells to recognize cancerous cells as foreign. As a result, endogenous tumor reactive T cells are present in insufficient quantities and with inadequate levels of activity against the tumor.

Overview of Current Therapies and their Limitations

Immuno-oncology is an emerging field of cancer therapy that is designed to activate the immune system to enhance and/or create anti-cancer immune responses, as well as to overcome immunosuppressive mechanisms that cancer cells have developed. In the last decade, clinical trials have demonstrated the utility of the immune system in the fight against cancer, including some studies that have demonstrated impressive clinical responses against late-stage metastatic disease. Immuno-oncology therapies approved or in development include vaccines and checkpoint inhibitors, which are designed to re-activate the immune response to cancer, and genetically engineered immune cells, such as CAR-T and TCR-T therapies, which are designed to recognize and attack cancerous cells. While these existing immuno-oncology therapies have shown some impressive results in treating cancer, they each have limitations. An alternative approach, known as TIL therapy, aims to extract T cells from the patient's tumor, expand them outside the body and reinfuse the expanded cells back into the patient.

***Checkpoint inhibitors*:** Immune checkpoints mediate peripheral tolerance by down-regulating T cell activity and have been targeted with CPI therapies to block their inhibitory function. Despite showing great potential in treating solid tumors, there are several shortcomings to CPIs. Most importantly, CPIs are designed to overcome the immunosuppressive TME by activating T cells regardless of their specificity, leaving their activity dependent on the

presence of tumor reactive T cells. As a result, only a fraction of patients treated with CPIs respond to the therapy. Furthermore, they can promote systemic activation of self-reactive T cells, resulting in immune-related adverse events.

Vaccine approaches: Vaccines are able to promote the activation and expansion of tumor reactive T cells in vivo, both in mouse models of cancer, as well as in cancer patients. In the last five years, the vaccine field has been revolutionized by progress in the field of messenger mRNA, as mRNA have proven efficacious vectors for vaccination in the context of viral infections and more recently encouraging clinical results from vaccines targeting neoantigens in early (adjuvant) stage melanoma. Whereas mRNA vaccines are considered simpler than cell therapy in terms of manufacturability, one potential limitation is the limited number of tumor targets that can be included in each vaccine and the need to prioritize the most potent antigens.

***Adoptive cell therapies*:** Adoptive cell therapies, or ACTs, are based on the *in vitro* expansion of tumor-targeting T cells followed by their transfer into the patient. This process allows for the expansion of large numbers of T cells *ex vivo* away from the immunosuppressive nature of the TME. ACTs are primarily differentiated by the approach used to direct the T cells to target tumor cells and include:

- *CAR-T therapy:* T cells are genetically engineered to target a molecule expressed on the surface of a tumor cell, such as CD19, a molecule present on the surface of hematological cancers. CAR-Ts have demonstrated significant response rates in hematological cancers but remain of limited use in non-hematological cancers due to the lack of sufficiently specific surface targets, as most potential common solid tumor target candidates are also expressed by normal tissue, which increases the chances of serious off-tumor effects.
- *TCR-T therapy:* TCR-T cell therapies engineer T cells to target a selected tumor antigen in the context of the patient's own HLA molecules. Tumor targets can include tumor associated antigens, or TAAs, which are endogenous antigens expressed preferentially, but not exclusively, by tumor cells. The selected TAA can be expressed by normal tissue, which leads to a lack of specificity and off-target toxicity concerns. In addition, they are not uniformly expressed by tumor cells which leads to the potential for tumor escape. An alternative antigen type that can be targeted by this form of therapy are tumor neoantigens. These can be shared by a fraction of patients (for example, common driver mutations such as KRAS G12D) or be unique to a patient's tumor. While there have been clinical successes in solid tumors, each TCR-T cell therapy can only be developed for a specific HLA type, limiting its applicability to the population of patients with that specific HLA type.

- *Standard TIL approaches:* In standard TIL approaches, T cells are extracted from a patient's tumor, activated, and expanded to large numbers before being reinfused into the patient. These therapies are limited due to the lack of understanding and control over the specificity of the T cells in the infused product, their fitness of the T cells and toxicity profile.

Background on Standard TIL Therapy

Standard TIL therapy has demonstrated some of the most impressive results in treating solid tumors to date, which culminated in the recent February 2024 FDA approval of the first TIL based therapy, AMTAGVI™, for use in metastatic melanoma. These therapies have been observed to induce significant response rates as well as including some complete responses, or CRs, in clinical trials for melanoma, cervical carcinoma and NSCLC. Despite the clinical benefits provided by standard TIL therapy, we believe the technology has been limited by several factors, including:

- *Specificity and durability*—Standard TIL therapy does not have control over the specific reactivity of the T cells infused into a patient. In this therapy, all T cells within a patient's tumor sample are expanded in an antigen-specific manner and the resulting target specificity of the T cell therapy is not known or controlled. Such an expanded standard TIL product may include a mixture of bystander T cells that are unable to identify and target the tumor, and T cells that recognize clonal or subclonal neoantigens. We believe that this lack of control over T cell specificity, without specifically targeting clonal neoantigens, contributes to the observed lack of a durable response to standard TIL therapy in a proportion of patients.

- *T cell fitness*—Standard TIL expansion uses non-antigen specific methods to induce T cell proliferation with high doses of IL-2 throughout the end-to-end manufacturing process. These artificial methods for T cell

expansion, coupled with chronic stimulation in the absence of dendritic cell-driven co-stimulation can lead to terminal differentiation and exhaustion of the T cell product. These exhausted or terminally differentiated T cells are considered less functionally fit to attack tumors due to their reduced capacity to proliferate and release cytokines *in vivo* after being dosed back into the patient.

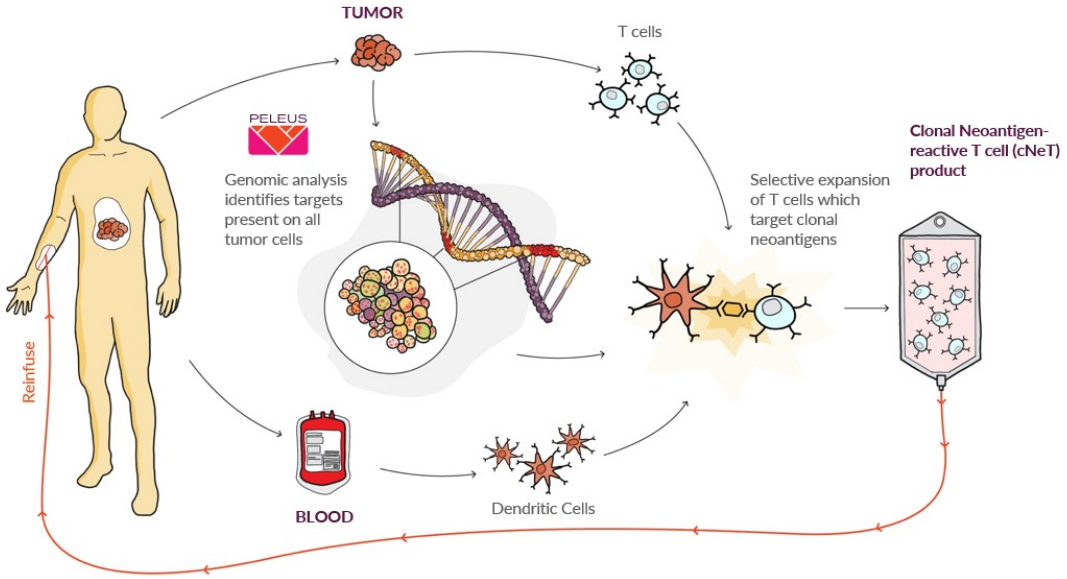
OUR SOLUTION

Our strategy uses a trackable precision T cell-based therapy to target what we believe to be the most specific tumor antigens, clonal neoantigens, in solid tumors. We believe that tumor clonal neoantigens represent optimal tumor targets because they are recognized by the immune system as foreign antigens and are absent in normal, healthy tissue but present in all of a patient's tumor cells.

We believe that our approach of selectively targeting clonal neoantigens to elicit a robust and durable clinical response is supported by third party studies. These studies have observed that neoantigens were relevant in producing anti-tumor activity, since patients with a high number of neoantigens showed improved progression free survival and overall survival when treated with CPIs and TIL therapies. Furthermore, clinical case studies have observed that adoptive transfer of neoantigen reactive T cells to cancer patients have shown impressive tumor control supporting the hypothesis that neoantigen-targeting T cells are the active component of TIL therapy. While these studies support the development of standard TIL therapies and other immuno-therapies that target neoantigens, third party studies have further observed that clonal neoantigens contributed more than subclonal neoantigens to patient survival. In one study of treatment of naïve lung cancer patients, it was observed that high numbers of clonal neoantigens in the tumors correlated with disease-free survival, while this relationship was not evident with subclonal neoantigens.

To address the limitations of current immuno-oncology approaches, we developed cNeT. As outlined in the figure below, the first step of our process involves the procurement of tumor and blood samples from the patient. Once the tumor and blood are procured, we extract and sequence DNA. These sequencing data are fed into our PELEUS AI-powered platform to identify the patient's unique clonal neoantigens. In parallel, we expand CD4+ and CD8+ T cells and generate dendritic cells from the tumor and blood, respectively. After PELEUS identifies the sequences of clonal neoantigens from the tumor genome, we manufacture clonal neoantigen peptides, load them onto dendritic cells and co-culture the dendritic cells with TILs to activate and expand a subset of the T cells. This process is designed to create a cNeT product candidate that is enriched with T cells designed to recognize and specifically target multiple clonal neoantigens in all of the patient's tumor cells. Our goal for the VELOS end-to-end manufacturing process time is approximately eight to nine weeks for commercial supply.

Our cNeT Approach



Our cNeT is designed to be:

- *Specific and durable*—We are able to design our cNeT to specifically target multiple clonal neoantigens present in a patient's tumor. We believe this specificity for multiple targets will reduce the likelihood of tumor escape and increase the rates of durable complete response.

- *Functionally fit*—The use of dendritic cells to drive physiological, antigen-driven T cell expansion reduces the need for non-physiological IL-2 driven expansion and allows the production of fit T cell populations of CD4+ and CD8+ T cells capable of significant expansion and persistence in the patient.

- *Well-tolerated*—Clonal neoantigens are absent from healthy tissue, which we believe minimizes the risk of off-tumor toxicity.

- *Designed to be cost effectively manufactured at scale*—The manufacturing process for cNeT has been designed, from its inception, to be compatible with industrialization and scalability while considering cost of goods. We are developing our manufacturing process to be automated in a closed end-to-end system, in order to decrease cost and maximize yield.

- *Measurable and quantifiable*—With our platform we can quantify the cNeT component as a percentage of the total T cells (cNeT reactivity) and calculate the expected cNeT dose of each product. cNeT reactivity can be used as both a release criterion and potency measure. We believe that cNeT is the active component of TIL and will correlate with anti-tumor effect. Further phenotypic and functional characteristics of cNeT can be measured to develop potency assays.

Our approach also allows us to determine the dose of active cNeT cells in each patient's cNeT therapy. We use a flow cytometric assay to detect which T cells may be able to produce inflammatory cytokines in each patient in response to the clonal neoantigen peptides which allows us to calculate the fraction of cNeT present in the total CD3+ T cell dose. We believe this information will allow us to investigate potential relationships between cNeT dose, cNeT persistence and clinical response. We plan to use these correlations to further develop our understanding of the cellular mechanism of TIL therapy and support the design and the evaluation of next-generation processes for cNeT manufacture.

OUR PELEUS AI-POWERED PLATFORM – A UNIQUE, PROPRIETARY TOOL FOR IDENTIFYING CLONAL NEOANTIGENS

The identification of clonal neoantigens is computationally complex, requiring the interrogation of an extremely large DNA data set and a statistical framework to predict clonality. In an independent study of over 40 different academic and commercial groups with neoantigen prediction capability, less than 20% concordance was observed in the identified neoantigens across the groups (cf. Wells et al – Cell October 29, 2020; 183(3):818-834.e13). We believe this demonstrates the diversity and lack of concordance in approaches that have been developed to address this challenge. The patent protected Achilles approach is unique in being validated on real-world patient data from the TRACERx study and we believe has enabled the reliable and accurate identification of clonal neoantigens.

Our platform, PELEUS is designed to identify each patient's tumor-specific neoantigens by comparing DNA sequencing information from healthy tissue and tumor. PELEUS' advanced computational and statistical models distinguish which of these neoantigens are clonal and subclonal and our proprietary AI modules increase the confidence of prediction by identifying mutational signatures associated with clonality. Furthermore, leveraging our extensive real-world data and experience of over 5,000 predicted neoantigens, PELEUS is able to rank the neoantigens by those most likely to elicit a potent immune response, features that are critical in the composition of each patient's product. PELEUS is designed to prioritize antigens not impacted by immune evasion mechanisms (i.e., loss of HLA heterozygosity). In addition, PELEUS is able to identify the most immunogenic targets using our proprietary and validated neoRanker AI-technology, which can identify greater than 70 percent of all T cell reactivities in just 30 antigens.

We have exclusive commercial access to data, for use in fields including neoantigen cell therapies, from TRACERx, which is a UK national study, funded by Cancer Research UK, to collect NSCLC samples from patients at diagnosis and relapse. The program has been running for more than eight years and has enrolled 814 NSCLC patients to date and collected over 4,300 tumor region samples. TRACERx collects multi-region samples from primary tumor and metastases (where available) over multiple points in time, generating whole exome sequencing data for each sample to understand each patient's tumor genomic evolution in detail. By searching for the overlap of coding mutations across multiple tumor regions across hundreds of patients, we have used TRACERx to identify the fundamental features that define clonal neoantigens. Our PELEUS algorithm is based on this reference data and is continuously updated, trained and improved as additional patients are recruited to the study. While TRACERx is focused on patients with lung cancer, we believe the principles of tumor evolution utilized by PELEUS are broadly applicable across multiple tumor types. We are using our MAP network to expand the tumor database of PELEUS with additional samples from other tumor types. We plan to further grow our network as we develop and advance our current and future cNeT programs in the future.

PELEUS identifies clonal neoantigens for each individual patient in a multi-step process. First, tumor and blood samples are collected from the patient and sequenced, using whole exome sequencing and RNA sequencing. The genetic profile of the tumor is compared to that of healthy tissue using blood to identify mutations specific to the tumor. The resulting sequence information is then processed by PELEUS in a three-step process.

- **Step 1:** ***Identify tumor mutations***—PELEUS utilizes a state-of-the-art ensemble approach that combines multiple different algorithms to identify tumor-specific mutations. The sequencing data obtained from the tumor samples originate from a combination of tumor cells and healthy tissues that dilute the tumor signal. The challenge of identifying cancer-specific mutations is further compounded by sequencing errors, as well as non-cancer-specific mutations in the tissue surrounding the tumor. This creates a significant amount of "noise" in each data sample. The unique scale of the TRACERx data has allowed us to develop highly sophisticated proprietary algorithms to improve the signal-to-noise ratio and allow us to reliably identify true cancer-specific mutations from real-world patient samples.

- **Step 2:** ***Identify clonal mutations***—PELEUS assesses the evidence for whether each mutation is present in all tumor cells in order to determine clonal versus subclonal status. This is achieved using a proprietary Bayesian statistical model which combines multiple lines of evidence.

- **Step 3:** ***Identify expressed mutations and predict immunogenicity*****—**PELEUS evaluates factors which influence the likelihood of each clonal neoantigen generating an immune response, such as neoantigen expression and predicted binding affinity. This enables us to prioritize clonal neoantigen targets for inclusion in our VELOS manufacturing process to selectively expand both CD4+ and CD8+ T cell reactivity.

OUR VELOS MANUFACTURING PROCESS

The viability of a personalized cell therapy product depends critically on manufacturing success and ability to scale sufficiently to address patient demand in a cost-effective manner.

The emergence of high throughput next generation DNA sequencing has enabled the rapid and cost-effective genetic characterization of tumor samples on a per patient basis. We are leveraging these advances, combined with our understanding of tumor evolution, to build upon the initial success of standard TIL therapy and deliver highly precise and functionally fitter T cells that are designed to target multiple clonal neoantigens.

Our VELOS manufacturing process has been designed from the outset to be suitable for scaled commercial use. This approach is in contrast to many other cell therapy processes in development today that have been transferred out of academia. Our process benefits from learnings over years of experience in ACT and is designed with a focus on GMP compliance and the use of closed systems.

Background and Challenges of Cell Therapy Manufacturing

Developing a reliable and robust manufacturing process for personalized cell therapies that can ensure adequate product safety, potency, and consistency at an economically viable cost of goods has been one of the most significant challenges in the field of cell and gene therapy. Key challenges include:

- **Academic manufacturing processes**—Historically, cell therapy manufacturing processes have been developed in academic institutions for early-stage clinical trials treating a small number of patients. These are often open processes that require the highest-grade cleanroom environment to protect from contamination. Operating and facility costs to maintain these manufacturing environments are substantial, requiring a large footprint and high numbers of staff.

- **Manual processing leads to challenges at commercial scale**—Traditional academic approaches to cell therapy manufacturing have been both time consuming and labor intensive due to the high number of operator-dependent manual processes involved. Reverse engineering these academic processes to be suitable for late phase clinical trials and commercialization is both time consuming and cost intensive, introduces risk to overall development timelines, and challenges in maintaining product characteristics.

- **Human clinical trial material is variable**—Patient-to-patient variability in clinical trial material is inherent in autologous therapies. Validation of manufacturing processes are often performed with surrogate healthy volunteer donor material or cell lines due to lack of commercially available patient material.

- **Supply chain and logistics are complex and time consuming**—The shipment of tumor and blood samples direct from surgery to manufacturing hubs requires a complex temperature controlled and sterile supply chain network to maintain cell and tissue viability.

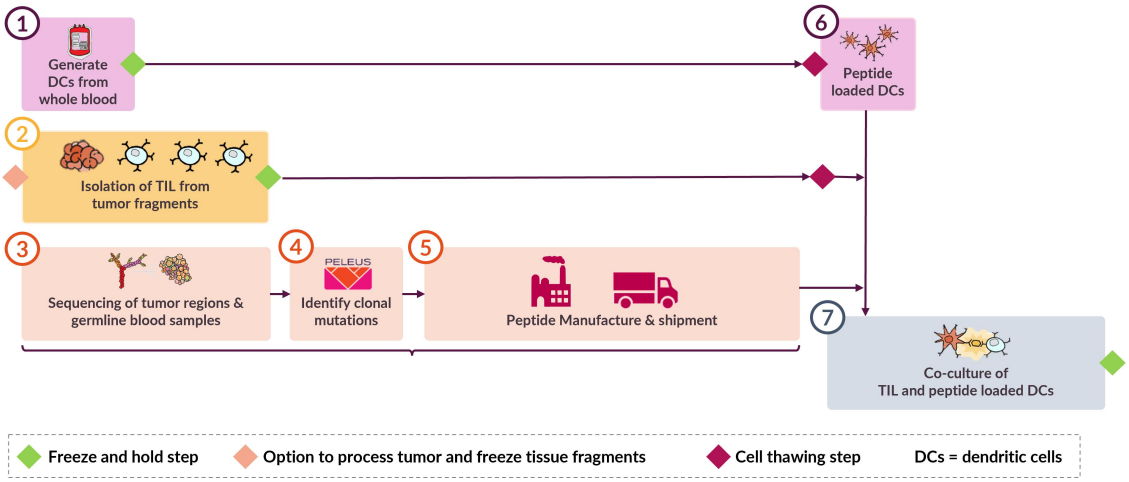
Our Manufacturing Solution

We have invested in our manufacturing process from the outset with the goal of producing our cNeT at a commercial scale, which we believe will allow us to address the challenges faced by traditional methods of cell therapy manufacture. Our approach is to design a closed, end-to-end manufacturing system with integrated automation. We believe this will enable lower operating costs by reducing the number of labor-intensive manual operator steps and eliminate the requirement for the higher-grade manufacturing environment needed for open processing. We believe that this approach is essential for industrial scale-up, as it drives a reduction in process variability between operators, minimizes failure rates, and improves reproducibility. Our approach has been to invest in developing new technology,

both in-house and with partners, to deliver an automated and standardized platform that permits rapid scale-up while controlling commercial cost of goods. Our proprietary process benefits from the deep experience of our management team and founders in the field of ACT, combined with a core focus on GMP compliance and the use of closed systems.

Key Steps in our VELOS Process

Our Current VELOS Manufacturing Process



The key steps in our manufacturing process include:

1. **Generation of dendritic cells from whole blood**—Monocytes are isolated from the patient's whole blood using a process of immunomagnetic selection and subsequently differentiated into dendritic cells in culture. The harvested dendritic cells are then cryopreserved for later use.

2. **Isolation of TIL from tumor**—Tumor samples are cleaned, dissected into small fragments, and placed into culture with cytokines. TILs are isolated from the fragments, harvested in a closed system automated device, and cryopreserved for later use.

3. **Sequencing of tumor regions**—Following dissection of the patient's tumor sample, multiple fragments are selected and sent for DNA and RNA sequencing.

4. **Selection of clonal neoantigens**—DNA data from each patient are analyzed by PELEUS to identify a unique set of clonal neoantigens. In some cases, RNA sequencing data are used to further select the best clonal neoantigens based on expression levels.

5. **Manufacture of patient specific peptides**—Each patient's clonal neoantigens are used to manufacture a personalized set of clonal neoantigen peptides.

6. **Peptide loading of dendritic cells**—Following receipt of the clonal neoantigen peptides, the patient's dendritic cells are removed from storage, thawed and put back into cell culture and loaded with the peptides.

7. **Co-culture of TIL and peptide-loaded dendritic cells**—The thawed TIL intermediate is co-cultured with the dendritic cells that have been loaded with the patient's clonal neoantigen peptides resulting in the selective expansion and enrichment of cNeT, that is followed by a polyclonal T cell boost step to further expand the final cNet dose, prior to final formulation and cryopreservation to enable flexibility for shipping to clinical sites as required for patient treatment.

OUR PIPELINE

We believe our cNeT technology is uniquely positioned to overcome many of the challenges faced by existing therapies for solid tumors. We have prioritized the tumor types that we are seeking to address based on criteria that we believe will maximize the potential of our programs to demonstrate a clinical benefit, including expected clonal neoantigen burden, TIL infiltration and tumor accessibility, as well as high unmet medical need and future commercial potential.

We are currently conducting two open-label Phase I/IIa trials, CHIRON and THETIS, to evaluate our cNeT programs in advanced NSCLC and metastatic or recurrent melanoma, respectively. Our Phase I/IIa trials are evaluating safety and tolerability of cNeT and assessing clinical efficacy based primarily on the change from baseline in tumor size, response rate and duration of response. An interim data update from 32 patients that received cNeT monotherapy (n=29) and cNeT in combination with PD-1 (n=1) were presented in April 2024 and we expect to generate additional patient data across both clinical trials through 2024.

We believe the principles of tumor evolution to be common across many tumor types, which could enable our cNeT approach to be broadly applicable. As such, we have built up our MAP network to acquire and analyze tumor samples from multiple different indications to facilitate the development of follow-on indications for our cNeT.

We have identified these initial tumor indications using the following criteria:

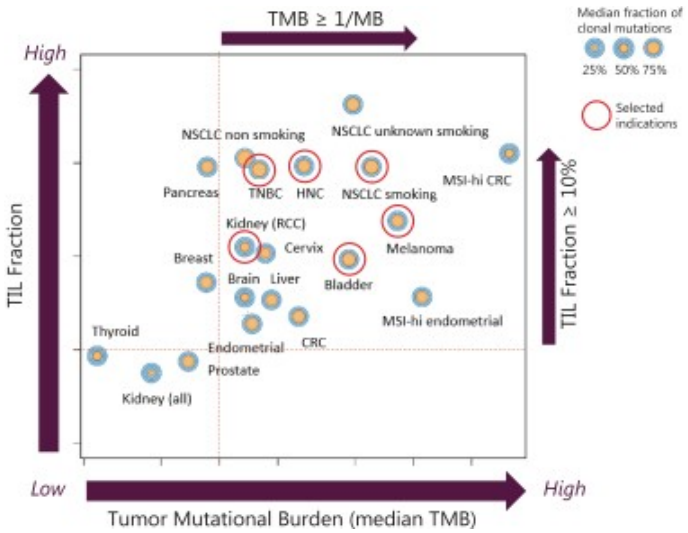
- **Tumor mutational burden**—Tumor mutational burden is a measure of the number of mutations in the coding region of tumor DNA as compared to healthy tissue DNA. This mutational burden will generally increase over time as new mutations accumulate through exposure to environmental carcinogens (e.g., smoking, sunlight) and this is also generally associated with an increase in neoantigen and clonal neoantigen frequency. These clonal neoantigens are the target for our cNeT product candidates.

- **The extent of T cell infiltration into the tumor**—Tumors will typically be targeted and infiltrated by varying numbers of T cells that are able to recognize tumor neoantigens. We have prioritized tumors that typically demonstrate high levels of T cell infiltration for our initial indications since tumor infiltrating T cells are the starting material for our cNeT.

- **The accessibility of tumor tissue**—In order to extract the tumor infiltrating T cells that are required as our starting material, the ability to safely procure adequate primary or metastatic tumor tissue through a surgical procedure is critical for manufacture. We have therefore prioritized indications where tumors are typically present in sufficient volumes and in locations that can be readily accessed to extract the tumor sample without compromising its quality.

- **Unmet need and commercial opportunity**—In order to maximize the beneficial impact for cancer patients, we have sought to address indications with the highest addressable market potential, as defined by various factors including unmet medical need, typical co-morbidities and outcomes with current and likely future treatment options.

The figure below compares the amount of T cell infiltration into a tumor and the corresponding tumor mutational burden for various cancer types. The area shaded orange in each circle reflects the median fraction of clonal mutations for that tumor type. As depicted below, the indications we are targeting in both our lead and follow-on indications typically have high levels of tumor mutational burden, clonal mutational burden and TIL infiltration as compared to other solid tumors.



OUR PROGRAMS

cNeT (ATL001) for Non-Small Cell Lung Cancer and Melanoma

Our lead cNeT programs (product candidate ATL001) are currently in two ongoing Phase I/IIa clinical trials for the treatment of advanced NSCLC and metastatic or recurrent melanoma. Our Phase I/IIa clinical trials will evaluate safety and tolerability of these programs as a monotherapy with the option for investigation of cNeT in combination with a PD-1 inhibitor. In addition, the trials are evaluating the impact of intensity of host conditioning on cNeT engraftment, persistence and efficacy. The trials will also evaluate, among other measures, change from baseline in tumor size, response rate and duration of response. We expect to receive further patient data from both clinical trials through 2024.

Clinical Trial Designs for NSCLC and Melanoma

We are currently conducting two open-label, proof-of-concept clinical trials in advanced NSCLC and metastatic or recurrent melanoma:

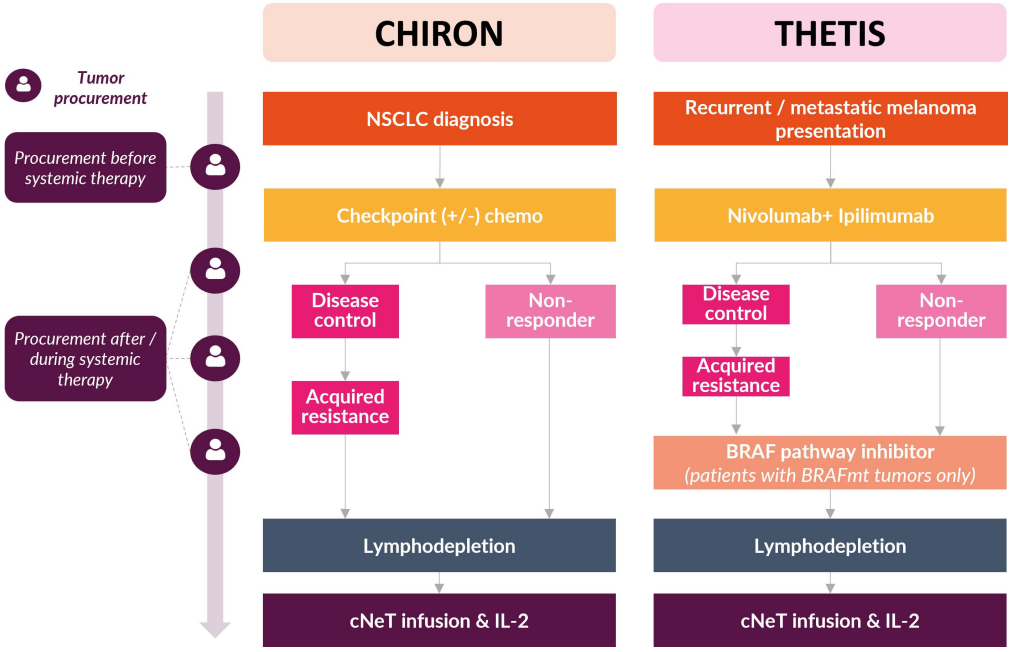
- **CHIRON**—a Phase I/IIa clinical trial to evaluate the safety, tolerability and clinical activity of cNeT in up to 40 patients with advanced NSCLC, ongoing at sites in the UK, US and Europe.

- **THETIS**—a Phase I/IIa clinical trial to evaluate the safety, tolerability and clinical activity of cNeT in up to 40 patients with metastatic or recurrent melanoma. We are currently conducting this trial at sites in the UK and Europe.

Our trial protocol allows us the option to include an additional cohort for each of CHIRON and THETIS to evaluate cNeT in combination with a PD-1 inhibitor (pembrolizumab in CHIRON and nivolumab in THETIS) and to evaluate an enhanced lymphodepletion and IL-2 regimen (Cohort C). We dosed the first patient from the THETIS Cohort B in the fourth quarter of 2022 and the first patients in THETIS and CHIRON Cohort C in October 2023 and February 2024, respectively.

As the first step in each of these trials, enrolled patients undergo procurement of tumor and blood samples to allow genetic characterization of the tumor and manufacture of the cNeT product candidate. Tissue procurement can occur prior to, during and after completion of standard systemic therapy, as depicted in the diagrams below. During the period between tissue procurement and final cNeT manufacture, patients can continue to be treated with standard-of-care therapy for their specific cancer. Once manufacture of the patient's specific cNeT is complete, it can be cryopreserved until required for administration.

cNeT treatment paradigm



Our dosing regimen is based on experience across dosing of standard TIL, genetically modified T cell therapies and both anti-viral and anti-cancer therapies generated using dendritic cell co-culture systems. Compared to standard TIL therapy, we use lower doses of cyclophosphamide and IL-2, with more recent evaluation of escalating doses of lymphodepletion and IL-2 dosing in line with those employed with standard TIL. The ongoing Phase I/IIa clinical trials do not use a standard dose escalation design since, as a personalized cell therapy product, cNeT yields will vary from patient to patient. Instead, the maximum number of cNeT manufactured will be administered to each patient, within a current dose range of 5 x 10^7 to 1 x 10^{10} cNeT.

Patients in both trials receive non-myeloablative lymphodepletion, which was initially with a regimen of cyclophosphamide (300mg/ m2/day) and fludarabine (30mg/m2/day) for 3 days, after which they received their dose of cNeT, followed by ten daily subcutaneous injections of IL-2 (1M IU/m^2/day). Subsequent trial amendments in CHIRON have increased lymphodepletion to evaluate cyclophosphamide 30-60mg/kg x 2 doses and fludarabine 25mg/m^2 x 5 doses and to evaluate a higher dose of IL-2 (600,000IU/kg 8-12 hourly for up to 6 doses) in Cohort C, aligned to the dose in Cohort C of THETIS. Patients receive scans to assess tumor size every six weeks for the first six months, followed by scans every three months for the duration of the trial.

The primary endpoint of both trials is safety and tolerability. The secondary endpoints include change in tumor size from baseline, overall survival and objective response rate, disease control rate, time to response and progression-free survival based on RECIST criteria. Depending on the results of our Phase I/II monotherapy trials, we plan to engage with the appropriate regulatory authorities to discuss potential pathways to registration. If we advance ATL001 for NSCLC or metastatic or recurrent melanoma in combination with a PD-1 inhibitor, we expect to conduct additional Phase II clinical trials before advancing to a Phase III registrational trial. Other exploratory translational science

analyses will aid interpretation of the observed clinical data, addressing such questions as how dose, phenotype, functionality and engraftment kinetics may affect clinical outcomes.

Clinical Data for NSCLC and Melanoma

In April 2024, we presented interim data from 32 patients in the CHIRON and THETIS clinical trials, consisting of 20 patients with NSCLC and 12 patients with melanoma. All had progressive disease at the time of lymphodepletion prior to cNeT infusion and each patient has completed their first scheduled scan six weeks post-cNeT infusion to assess tumor size. Ten patients received cNeT doses of >100 million in keeping with improvements implemented to our VELOS manufacturing process through 2022 and 2023. Within THETIS, 10 patients received low dose lymphodepletion and IL-2 with cNeT monotherapy, and 1 patient identical conditioning but with the addition of nivolumab post dosing. To date, 1 patient in THETIS has received the higher doses of IL-2. In CHIRON, 16 patients received low dose lymphodepletion and IL-2 with cNeT monotherapy, and 2 have received enhanced lymphodepletion and higher dose IL-2.

cNeT Tolerability

Overall, the safety and tolerability observations of cNeT compare favorably to standard tumor infiltrating lymphocytes, or TIL due to less IL-2 related toxicity in those receiving low dose IL-2. Lymphopenia and neutropenia were the most common adverse events, which are principally associated with the conditioning regimen, and no dose limiting high-grade toxicities associated with IL-2 were reported. The higher doses of IL-2 were associated with expected toxicities (fever, hypoxia, hypotension) with full resolution. There have been no suspected unexpected serious adverse reactions, or SUSARs reported since the previous update on the first 14 patients in 2022.

Overall, in the whole cohort treated to date with ATL001, there were three reportable events of cytokine release syndrome and two reportable events of immune effector cell-associated neurotoxicity syndrome, or ICANS, event deemed to be related/possibly related to cNeT treatment. A previously disclosed case of encephalopathy was subsequently deemed unlikely related to cNeT treatment following an Independent Data and Safety Monitoring Committee, or IDSMC, review.

cNeT Activity

It has been observed in prior studies of CAR-T cell therapies that engraftment and expansion of tumor-reactive T cells post infusion is correlated to clinical response. This correlation has not been evaluable with standard TIL therapies due to the lack of routine characterization of the active component of the infused cells, and the associated inability to track the active component post dosing. Since we characterize our cell product candidates at the level of individual cNeT reactivities, we are able to determine engraftment, peak expansion, and durability of persistence of clonal neoantigen-reactive T cells.

In CHIRON, we observed a best overall response (OR) of partial response (PR, 56% tumor reduction maintained at week 36) in one patient, stable disease (SD) in 10 patients and progressive disease (PD) in 5 patients treated with low dose host conditioning and IL-2. Twelve patients received cNeT doses <100 million and 4 doses >100 million. cNeT detection was observed early following infusion, but persistence was limited in the majority of patients regardless of infused dose. The patient with a partial response had more durable detection of cNeT beyond 4 weeks. As a result, we increased doses of both lymphodepletion (Cohorts A and C) and IL-2 (Cohort C) for subsequent patients. Two patients were treated in Cohort C.

In THETIS, we observed a best OR of SD in 5 patients and PD in 7 patients. The patient treated in Cohort C (high dose IL-2) demonstrated evidence of improved cNeT persistence, though extensive prior treatment with checkpoint inhibitors had likely driven immune evasion associated with the loss of HLA to which the cNeT responses were restricted (i.e. the cNeT were unable to recognize the tumor).

We will continue to assess these features and any associations with clinical outcomes and in particular the impact of increased doses of lymphodepletion and Il-2 in subsequent patients that we treat through 2024 and will continue to optimize both PELEUS and VELOS to deliver product features that have been shown to deliver clinical activity.

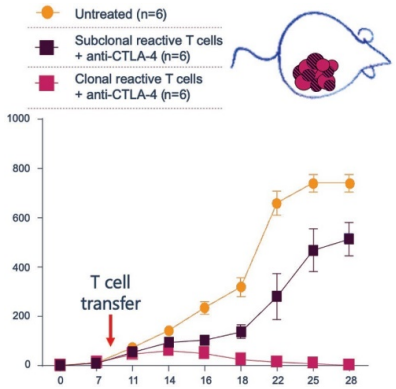
Next Steps

Based on the interim data announced in April 2024, we plan to continue to recruit and treat patients in the CHIRON and THETIS clinical trials using the enhanced host conditioning strategy in order to improve engraftment and persistence of cNeT and expect to report further clinical and translational science data through 2024.

OUR PRECLINICAL STUDIES SUPPORTING THE SPECIFICITY AND FITNESS OF OUR cNeT PRODUCT CANDIDATES

To evaluate whether T cells targeting clonal neoantigens could generate a more complete and durable response than T cells targeting subclonal neoantigens, we used a melanoma mouse tumor model containing clonal and subclonal neoantigens. After tumor growth was visible, the mice were either left untreated or treated with T cells targeting the clonal or the subclonal neoantigen. We observed that the transfer of T cells targeting a subclonal neoantigen resulted in partial control of, or delayed, tumor growth with eventual relapse and tumor growth in all treated mice. In contrast, we observed that mice treated with T cells targeting a clonal neoantigen experienced a complete and durable response through to the completion of the study at day 28.

Clonal Neoantigen Targeting T Cell Therapies Led to Durable Complete Responses in Mouse Models of Cancer



Our goal is to deliver a cNeT product candidate with greater specificity to clonal neoantigens as well as higher functional T cell fitness as compared to standard TIL, in order to maximize tumor control. We have compared the specificity of standard TILs with cNeT derived from the same patient, and demonstrated the potential of cNeT to better recognize and target clonal neoantigens compared to CD8+ and CD4+ T cells generated with the standard TIL. We observed that more than 80% of cNeT recognized the clonal neoantigens from the patient's tumor while less than 30% of CD8+ TILs recognized those same antigens. Importantly, approximately 60% of the CD4+ cNeT recognized clonal neoantigens while none of the standard TIL CD4+ T cells recognized these same clonal neoantigens. We believe these data support the potential of our process to generate a product candidate that is enriched for CD8+ and CD4+ T cells that recognize clonal neoantigens as compared to standard TIL.

cNeT Process Delivered Higher Clonal Reactivity than Standard TIL Therapy

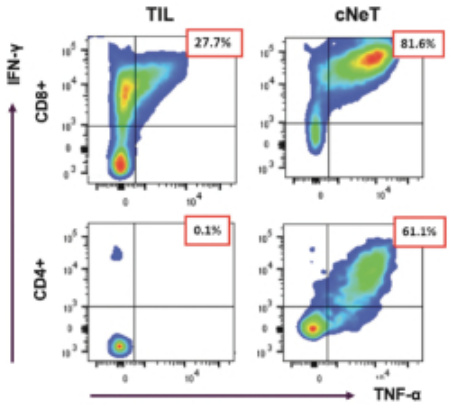


FIGURE A

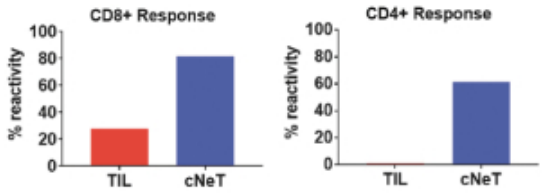


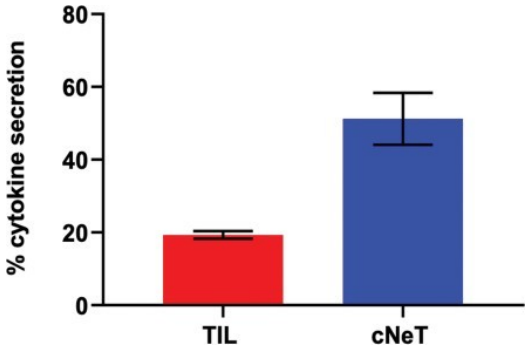
FIGURE B

Figure A is a flow cytometric analysis depicting the ability of cNeT to produce IFN-g and TNF-a, which are accepted T cell activation markers. Figure B represents the percentage of IFN-g and TNF-a produced by CD8+ and CD4+ T cells.

Separately, we assessed T cell fitness using T cell receptor independent polyclonal stimulation of the cNeT and standard expanded TIL product candidate. By stimulating T cells with anti-CD3, all the T cells in the assay were tested for their maximal capacity to produce effector cytokines, regardless of their reactivity. This assay is widely used by academics and industry to test overall activity of T cells.

The data below depicts the potential of cNeT to outperform standard TIL cells in the production of effector cytokines, which we believe supports our belief that cNeT show improved fitness compared with standard TIL.

cNeT Produced Higher Amounts of Effector Cytokines than Standard TILs



Material Acquisition Platform

Our MAP network is our proprietary network for collection of donor tumor tissue and blood from cancer patients. We created our MAP network as a strategic asset to secure continued access to patient tumor and blood samples which are procured from patients undergoing standard-of-care cancer surgery across multiple solid tumor indications. The samples accessed through our MAP network are used in the development of our VELOS process and the expansion of the PELEUS AI-powered platform. In addition, our MAP network provides access to patient samples from our lead indications with demonstrated capability to expand into multiple additional tumor types that can inform the basis of our future pipeline development. Our MAP network has also allowed us to improve our supply chain operations with

respect to interventional studies, by identifying and building non-standard site pathways for patient access and transportation pathways from procurement centers to our manufacturing facilities and back to patients.

Our network of MAP sites also provides a platform for opportunity to procure and archive cancer samples from patients earlier in their treatment pathway, for example when surgery is undertaken for curative treatment in patients determined to be at high risk of future relapse. Archived tumor samples and TIL intermediates have the potential to be partially processed and then stored until the patient experiences disease progression, at which point cNeT manufacture could be completed and the final therapy supplied. This potentially provides an additional pathway to shorten the effective supply time of our cNeT, and would offer patients a more rapidly available, customized treatment option. Furthermore, by procuring tumor samples earlier in the patient treatment pathway and prior to exposure to multiple lines of therapy, we believe these samples have the potential to yield T cells of both higher fitness and quantity. The ability to collect tumor samples earlier in the treatment paradigm also allows us to explore the potential for cNeT in earlier lines of therapy in future.

OUR CURRENT MANUFACTURING CAPACITY AND EXPANSION PLANS

Recognizing the strategic importance of manufacturing to the development and commercial success of our personalized cell therapy approach, we continue to take steps to scale-up and expand our capabilities in this regard.

We have secured dedicated manufacturing capacity to support our clinical trials at two UK sites: The Royal Free Hospital and the Cell and Gene Therapy Catapult. The Royal Free Hospital (Centre for Cell, Gene and Tissue Therapeutics) is an MHRA-licensed facility for the manufacture of investigational medicinal products and holds a Human Tissue Authority license for the import and storage of cells and tissues. The manufacturing agreement provides services that include quality management systems, qualified persons for product release, quality control labs and GMP storage. In September 2020, we entered into agreements with UCL for office and lab space on the Royal Free Campus to support both GMP development and translational science operations.

In March 2020, we entered into a collaboration agreement with Cell Therapy Catapult Limited, or Catapult, pursuant to which we lease a manufacturing space from Catapult at the Cell and Gene Therapy Catapult Manufacturing Centre in Stevenage and pay Catapult to support GMP operations at the manufacturing facility. The term of this agreement was extended in February 2024. We received an MHRA GMP license for the facility to support clinical manufacturing in April 2022 and a Human Tissue Authority license for the import of cells and tissues in June 2022. We have subsequently brought on-line additional GMP quality control labs at Sycamore House in Stevenage, which achieved MHRA licensing in September 2023.

In March 2022, we entered into an agreement to reserve manufacturing capacity with a CMO in King of Prussia, PA, in the U.S. Phase 1 of technology transfer was completed during 2022 and as of December 31, 2023, the Company is reviewing the timing for implementation of Phase 2.

Future Strategy for Automation

Automation will enable improvements to our manufacturing success rate, a reduction in operator dependencies and related costs and will support the industrial scale-up of GMP operations. Additionally, the custom devices that support a fully-closed process, while further reducing high operating costs associated with open processes, enable the potential for new intellectual property and security of the manufacturing process and know-how. We have developed a roadmap for automation by focusing on several key areas across the end-to-end manufacturing process to drive the future commercial delivery of cNeT. Some of the key initiatives in our automation strategy include:

- **Tumor collection and processing device:** We are developing a closed system to process patient tumor samples. This system is designed to be utilized for procurement of the tumor sample at the time of surgery and delivered to the manufacturing site. We believe this will increase sample throughput and minimize operator variability, while decreasing the time required to process samples. Additionally, this closed system approach allows manufacturing in a simpler and lower cost cleanroom environment.

- **Automation for co-culture:** We are evaluating different fully closed bioreactor systems to be used in the industrial manufacturing process of our cNeT. These bioreactors will enable us to reduce costs through higher output and fewer manual operations. Our goal is to utilize these bioreactors to increase cell yield through optimized cell feeding methods enabled through real time monitoring of cell cultures.

We continue to assess and evaluate several strategic partnerships to support the development of automation and devices to deliver an industrial manufacturing process.

TRANSLATIONAL SCIENCE PROGRAM

We believe that by prospectively targeting identified clonal neoantigens, we have a unique opportunity to more fully characterize cNeT at the product and single cell level, providing a detailed understanding of their kinetics and function in patients and potential association to clinical responses. We have built a Translational Science Program, or TSP, that is run in parallel with our clinical studies and is designed to allow us to better understand specific features of our cNeT and their mechanism of action.

We collect samples to analyze each patient's TME prior to cNeT manufacturing, as well as the manufactured cNeT including dose, number of reactivities, immune phenotype and specific T cell receptor sequences. Upon administration into the patient, we track cNeT engraftment, expansion, phenotype, activity and transcriptional profile. In parallel to tracking cNeT, we also evaluate circulating tumor DNA as a liquid biomarker of tumor burden.

The increasingly detailed molecular understanding of cNeT and their mechanism of action in patients will further inform and control the development of next generations of our VELOS manufacturing process by focusing on functional fitness, anti-cancer activity and safety as well as alternative starting material for cNeT manufacture (e.g., blood). By using blood as a starting material, we would aim to provide patient optionality and broaden patient access and supply for those patients where tumor collection by surgery may not always be possible.

COMMERCIALIZATION

At our current stage of development, we have not yet established a commercial organization or distribution capabilities. We are developing our clinical-stage programs for the treatment of patients with late-stage solid tumors, most of whom are treated in specialized treatment centers or hospitals. We aim to use selected centers to pilot and establish systems necessary for product delivery by the time of launch. By focusing on these centers, we can begin to build our commercialization capabilities with limited resources.

We have worldwide commercial rights for our potential products. We currently plan to build our global commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. We may selectively pursue strategic collaborations with third parties in order to maximize the commercial potential of our product candidates. We generally expect to launch any of our products that receive regulatory approval in the United States first, followed by the EU, and then in other major markets.

COMPETITION

There is significant investment across the biotechnology and pharmaceutical industries in developing novel and proprietary therapies for the treatment of cancer. While we believe that our differentiated, precision and scientific expertise in the field of cancer immunotherapy provides us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions. We anticipate that we will face intense and increasing competition as new drugs and therapies enter the market and advanced technologies become available.

Advanced T cell therapies are under evaluation in solid tumors by multiple biotechnology and pharmaceutical companies, including Kite Pharma Inc. (a Gilead company), Iovance, Adaptimmune Therapeutics PLC, Autolus

Therapeutics PLC, Instil Bio, Inc., or Instil, Neogene Therapeutics (acquired by AstraZeneca), BioNTech SE, Turnstone Biologics Corp., Immatics N.V., Obsidian Therapeutics, Inc. and KSQ Therapeutics, Inc.

We cannot predict whether new types of immunotherapies including novel checkpoint inhibitors may be enhanced and show greater efficacy, and we may have direct and substantial competition from such immunotherapies in the future. In addition, more effective small molecules, cancer vaccines and other approaches may be developed and used as first line or second line treatments, which would reduce the opportunity for our T cell therapies.

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 and may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new products and therapies enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, delivery, price and the availability of reimbursement from government and other third-party payers.

On February 16, 2024, the Food and Drug Administration granted accelerated approval to lifileucel (Amtagvi, Iovance Biotherapeutics, Inc.), a tumor-derived autologous T cell immunotherapy, for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor. The success of Amtagvi may limit the number of patients available for our clinical trials and our products, if approved, that are indicated for the treatment of melanoma.

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

INTELLECTUAL PROPERTY

Our success depends, in part, on our ability to obtain and maintain intellectual property protection for our product candidates, technology and know-how, to defend and enforce our intellectual property rights, in particular, our patent rights, to preserve the confidentiality of our know-how and trade secrets, and to operate without infringing the proprietary rights of others. We seek to protect our product candidates and technologies by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing of third-party intellectual property to develop and maintain our proprietary position. We, or our collaborators and licensors, file patent applications directed to our key product candidates in an effort to establish intellectual property positions to protect our product candidates as well as processes for producing our product candidates and uses of our product candidates for the prevention and/or treatment of diseases.

With regard to ATL001, we own a family of pending patent applications and granted patents with claims directed to: (i) a method of treating cancer, including non-small cell lung cancer and melanoma; (ii) claims directed to a T cell composition comprising a TCR-T that binds a clonal neoantigen; and (iii) claims directed to a vaccine comprising clonal neoantigen peptides or proteins, or mRNA or DNA encoding a clonal neoantigen. This patent family includes two pending U.S. patent applications, one granted EP patent, one granted patent in each of Australia, Chile, China, Hong Kong, Israel, Japan, Malaysia, New Zealand, Singapore and South Africa, and other foreign patent applications

pending in various jurisdictions, including Canada, and South Korea. Patent applications in this family, if issued, are expected to expire in 2036 without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

With regards to ATL001, we own a family of pending patent applications with claims directed to treatment regimens for using T cell therapy in combination with a low dose of IL-2 in the treatment of cancer. This patent family includes a pending U.S. patent application and foreign patent applications pending in China, Europe and Japan. Patent applications in this family, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

With regards to ATL001, we own a granted U.S. patent with claims directed to the treatment of patients with an immunotherapy targeting clonal neoantigens that have been identified using the ClonalX bioinformatics tool, which is expected to expire in 2042, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. This patent family includes a pending U.S. patent application and pending foreign patent applications in various jurisdictions, namely Australia, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea and Singapore, with claims directed to a method of determining whether a tumor-specific mutation is likely to be clonal in a subject. Patent applications in this family, if issued, are expected to expire in 2042, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We in-license from CRT a granted U.S. patent with claims directed to a method for determining the loss of an HLA allele in a tumor, and methods of treating cancer by targeting neoantigens that are predicted to be presented by an HLA molecule that has not been lost from the tumor. This tool is referred to as the "LOHHLA" bioinformatics tool, which enables prediction of neoantigens that are presented by an HLA molecule that has not been lost by the tumor, and hence are still available for targeting by immunotherapy. This patent family includes a granted Japanese patent and foreign patent applications pending in various jurisdictions, namely Australia, Canada, China and Europe. Patent applications in this family, if issued, are expected to expire in 2038 without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a family of pending patent applications with claims directed to a method for obtaining tumor nucleic acid for sequencing from medium containing tumor cells shed from a solid tumor sample, which family includes a pending U.S. patent application and foreign patent applications pending in Australia, Canada, China, Europe, Hong Kong, Japan, South Korea and Singapore. Patent applications in this family, if issued, are expected to expire in 2040 without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a family of pending patent applications with claims directed to a tumor sample collection and disaggregation device, which family includes a pending U.S. patent application and foreign patent applications pending in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea and Singapore. Patent applications in this family, if issued, are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a pending U.S. patent application and a pending European patent application with claims directed to a batch release assay for a pharmaceutical product comprising T cells. If a patent were to issue from the U.S. application or the European patent application, such a patent would be expected to expire in 2042, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a family of pending patent applications with claims directed to a method of producing a population of T cells which comprises antigen-specific T cells., which family includes a pending U.S. patent application and foreign patent applications pending in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea and Singapore. Patent applications in this family are expected to expire in 2042, without giving effect to any potential patent term

extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a pending international patent application filed at the European Patent Office, or EPO, with claims directed to a method of predicting peptide manufacturability. If a patent were to issue from a national/regional patent application derived from this international patent application, such a patent would be expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a pending international patent application filed at the EPO with claims directed to a method of determining whether a tumor-specific mutation is likely to be clonal in a subject, the method comprising combining evidence from sequence data obtained from the subject and an indication of whether the mutation is associated with one or more predetermined mutational signatures. If a patent were to issue from a national/regional patent application derived from this international patent application, such a patent would be expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a pending international patent application filed at the EPO with claims directed to a method for analyzing the expected tumor reactivity of the T cell population within a sample of T cells, which can be used to characterize suitability of T cell products for use in T cell therapy, or to determine suitability of tumor samples for derivation of reactive TIL products or suitability for treatment with immune therapies. If a patent were to issue from a national/regional patent application derived from this international patent application, such a patent would be expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

We own a pending international patent application filed at the EPO with claims directed to a tool for calculating the likelihood of a mutated allele being expressed based on tumor RNA data, which is referred to as the "Achilles Likelihood of Expression of an Allele (ALExA)" tool. This tool can be used to prioritize neoantigens for inclusion in the product that are expressed in the patient's tumor. If a patent were to issue from a national/regional patent application derived from this international patent application, such a patent would be expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

GOVERNMENT REGULATION

The FDA and other U.S. regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biological product candidates such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Biological Products Development Process

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FDC Act, the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. The process required by the FDA before a biological product candidate may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with FDA's good laboratory practice, or GLP, requirements and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an application for an IND which must become effective before human clinical trials may begin;
- approval of the protocol and related documentation by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each study may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's good clinical practice, or GCP, requirements and any additional requirements for the protection of human research subjects and their health information, to establish the safety, purity, and potency of the proposed biological product candidate for its intended use;
- preparation and submission to the FDA of a biologic license application, or BLA, after completion of all pivotal clinical trials that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA pre-license inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or cGTPs, for the use of human cellular and tissue products;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within sixty (60) days of its receipt of a BLA to file the application for review;
- potential FDA audit of selected nonclinical study and clinical trial sites that generated the data in support of the BLA to assess compliance with GLP or GCP, as applicable;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product biological characteristics, chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. An IND is a request for authorization from the FDA to ship an unapproved, investigational product in interstate commerce and to administer it to humans, and must become effective before clinical trials may begin.

The IND automatically becomes effective thirty (30) days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that thirty (30)-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA also may impose clinical holds on a biological product candidate at any time before or during clinical trials due to, among other considerations, unreasonable or significant safety concerns, inability to assess safety concerns, lack of qualified investigators, a misleading or materially incomplete investigator brochure, study design deficiencies, interference with the conduct or completion of an a study designed to be adequate and well-controlled for the same or another investigational product, insufficient quantities of investigational product, lack of effectiveness, or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial and its related documentation must be reviewed and approved by an Institutional Review Board, or IRB, at or servicing each site at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the biological product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2. The biological product candidate is evaluated in a limited patient population with a specific disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3. The biological product candidate is administered to an expanded patient population to further evaluate dosage, clinical efficacy, potency, and safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for approval and product labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a biological product is approved to gain more information about the product. These post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may also be made a condition to approval of the BLA. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

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

During all phases of clinical development, the FDA requires extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety

report within fifteen (15) calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as an Independent Data Safety and Monitoring Committee, or IDSMC, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information.

Within sixty (60) days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived under certain circumstances. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. Therefore, the BLA review process typically takes twelve (12) months from the date the application is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification. For example, the review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

During the BLA review process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the biological product candidate. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

For a cell therapy product that includes human cells, tissues or tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient, the FDA also will not approve the product if the manufacturer is not in compliance with cGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps. The primary intent of the cGTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through appropriate screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, cGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers for PREA requirements. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the FDA decides not to approve the BLA in its present form, the FDA will issue a Complete Response Letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the Complete Response Letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings precautions or interactions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Orphan Drug Designation

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

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity, or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Competitors, however,

may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA offers various programs, including fast track designation, breakthrough therapy designation, accelerated approval, priority review and regenerative medicine advanced therapy, or RMAT, designation, that are intended to expedite or simplify the process for the development and FDA review of biological products that are intended for the treatment of serious or life-threatening diseases or conditions. To be eligible for fast track designation, biological product candidates must be intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a biological product candidate may request the FDA to designate the biologic as a fast track product at any time during the clinical development of the product. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Under the FDA's breakthrough therapy program, a biological product candidate may be eligible for breakthrough therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all the features of fast track designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

In 2017, the FDA established a new RMAT designation as part of its implementation of the 21st Century Cures Act. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any biological product that meets the following criteria: (i) the biological product qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the biological product is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the biological product has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites.

Any marketing application for a biological product submitted to the FDA for approval, including a product candidate with a fast track designation breakthrough therapy designation and/or RMAT designation may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. Any product candidate is eligible for priority review if it is designed to treat a serious or

life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a biological product candidate designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application within six months of the 60-day filing date, compared to ten months for a standard review.

With respect to oncology products, the FDA may review applications under Real-Time Oncology Review, or RTOR, program established by the FDA's Oncology Center of Excellence. RTOR, which allows an applicant to pre-submit components of the application to allow the FDA to review clinical data before the complete filing is submitted, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Products considered for review under RTOR must, among other things, be likely to demonstrate substantial improvements on a clinically relevant endpoint(s) over available therapy, and must have easily interpreted endpoints. In addition, no aspect of the application should be likely to require a longer review time, such as, for example, a requirement for a REMS. To determine eligibility for RTOR, the FDA requires top-line efficacy and safety results from an applicant's pivotal clinical trial(s), as well as completion of database lock for the clinical trial(s). The FDA will generally make a decision regarding acceptance into RTOR within twenty (20) business days of receipt of the request from the applicant. If an applicant is not accepted into RTOR, the applicant will follow routine application submission procedures.

Additionally, FDA may grant accelerated approval to a product candidate intended to treat a serious or life- threatening disease or condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, 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. As a condition of approval, the FDA may require that a sponsor of a biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit which must be conducted with due diligence and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specified time period after the date accelerated approval was granted. Under FDORA, the FDA also has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval if, for example, the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, RMAT designation, priority review, TROR, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP that may affect the identity, potency, purity, or safety of a marketed product, and FDA also imposes reporting requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Following approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA

review and approval. There also are continuing, annual program fees for any marketed products. Other post-approval requirements applicable to biological products, include, among other things, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements.

In addition, after a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds, warning or untitled letters, product recalls, product seizures, safety alerts, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors or other stakeholders, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of biological products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our biological product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of fourteen (14) years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

The Affordable Care Act, or ACA, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-approved reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been

previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted four and twelve (12) year exclusivity periods from the time of first licensure of the product. FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve (12) years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was approved in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously approved product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the biological product. . This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, implementation and the ultimate impact of the BPCIA is subject to significant uncertainty.

U.S. Regulation of Companion Diagnostics

If the safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel candidates, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. Once cleared or approved, the companion diagnostic must adhere to post-marketing requirements including the requirements of FDA's quality system regulation, medical device reporting, recalls and corrections along with product marketing requirements and limitations. Companion diagnostic manufacturers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities. To date, the FDA has required premarket approval for nearly all companion diagnostics for cancer therapies. In January 2024, FDA announced its intention to initiate the reclassification process for most *in vitro* diagnostics, including companion diagnostics. Further, the FDA indicated that in addition to the reclassification process, the FDA will continue taking a risk-based approach in the initial classification of individual *in vitro* diagnostics to determine whether a new test may be classified into class II through the de novo classification process. In so doing, the FDA indicated that it may regulate most future companion diagnostics as class II devices.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic

Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products as well as authorization and approval of our products.

Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product approval, and pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

EU Clinical Trials Regulation

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries.

In the EU, the Clinical Trials Regulation (EU) No 536/2014, which replaced the former Clinical Trials Directive 2001/20/EC, has been in effect since January 31, 2022. It overhauled the previous system of approvals for clinical trials in the EU. Specifically, the Regulation, which is directly applicable in all Member States (meaning that no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. The main characteristics of the Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Concerned Member States) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Concerned Member State. Strict deadlines have also been established for the assessment of clinical trial applications.

EU Drug Review and Approval

In the EU, medicinal products, including advanced therapy medicinal products, or ATMPs, are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. Under Article 2(1) of Regulation (EC) No 1394/2007, or the "ATMP Regulation," ATMPs include somatic cell therapy products, which are cells that have undergone substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, where such cells are to be administered to human beings in order to cure, diagnose or prevent disease. Our current development products are somatic cell therapy medical products which would be regulated as ATMPs in the EU.

To obtain regulatory approval of an ATMP under the EU regulatory system, we must submit a marketing authorization application, or MAA, under the centralized procedure administered by the EMA. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid across all of the EEA (which is made up of all the EU Member States, as well as Iceland, Norway and Liechtenstein). As provided for in the ATMP Regulation, the scientific evaluation of MAAs for ATMPs is primarily performed by a specialized scientific committee called the Committee for Advanced Therapies, or CAT. The CAT prepares a draft opinion on the quality, safety and efficacy of the ATMP which is the subject of the MAA, which is sent for final approval to the Committee for Medicinal Products for Human Use, or CHMP. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. The maximum timeframe for the evaluation of an MAA for an ATMP is 210 days from receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CAT and/or CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the point of view of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

The application used to submit the BLA in the United States is similar to that required in the EU, with the exception of, among other things, certain specific requirements set out in the ATMP Regulation, for example certain particulars to be contained in the summary of product characteristics.

In the EU, if human tissues and cells are used as starting materials in an ATMP, the donation, procurement and testing of the cells are covered by the Tissues and Cells Directive (2004/23/EC), or Human Tissue Directive. The competent authority in the UK under the Human Tissue Act 2004 is the Human Tissue Authority, or HTA, which is responsible for licensing certain activities in the UK related to the donation, procurement and testing of cells used for the manufacture of ATMPs under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The processing, storage and distribution of the ATMP itself is governed by the medicines regulations and marketing authorization process set out above, however a separate license from the HTA may be needed for the initial procurement, processing, testing and storage (if for more than 48 hours) of the human cells which are to be subsequently used in the ATMP manufacture. Any organization involved in these activities in the UK will require an HTA license.

Data and Marketing Exclusivity in the EU

The EU also provides opportunities for market exclusivity. Upon receiving marketing authorization in the EU, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Designation and Exclusivity in the EU

Products receiving orphan designation in the EU can receive ten years of market exclusivity, during which time no "similar medicinal product" for the same indication may be placed on the market. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity where an agreed Pediatric Investigation Plan for pediatric studies has been complied with. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if it meets the following criteria: (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; and (ii) either the prevalence of such condition must not be more than five (5) in ten thousand (10,000) persons in the EU when the application is made; or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the EU to justify the investment needed for its development; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers made available by the EU and its Member States to support research into, and the development and availability of, orphan products. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten (10)-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Otherwise, orphan medicine marketing exclusivity may be revoked only in very select cases, such as if:

- it is established that a similar medicinal product is safer, more effective or otherwise clinically superior;
- the marketing authorization holder for the authorized orphan product consents to the second medicinal product authorization; or
- the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product.

Pediatric Development in the EU

In the EU, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless the EMA has granted a product-specific waiver, a class waiver applies, (e.g., because the relevant disease or condition occurs only in adults), or a deferral for one or more of the measures included in the PIP. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product for which a marketing authorization is being sought. The MAA for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization with the results of pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate, or SPC, (provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to 2 years before the SPC expires) even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market

exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Post-Approval Controls

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include the following:

- The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

- All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post- authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

- All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the UK and EU. In the EU, although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

EU Medical Devices Regulation

Some of our devices used to collect blood and tissue used in the manufacture of our medicinal products may be considered a class IIa medical device under the EU Medical Devices Regulations 2017/745, or EU MDR. The EU MDR became fully applicable in all EU Member States from May 26, 2021 (therefore not including the UK). All medical devices require a CE mark to be placed on the market in the EU. In order to obtain a CE mark, a notified body must conduct a conformity assessment of the device to confirm whether it complies with the general safety and performance requirements in the EU MDR. Such requirements will differ depending on the class of the device. The conformity assessment usually involves an audit of the manufacturer's quality system and a review of the technical documentation from the manufacturer on the safety and performance of the device. If the notified body considers that the device is in conformity with the EU MDR, it will issue a conformity assessment certificate and the manufacturer of the device can place a CE mark on the device, allowing it to be marketed in any EU Member State. The EU MDR introduced more stringent requirements than the previous EU Medical Devices Directive 93/42/EEC, EU MDD. In accordance with the transitional provisions in the EU MDR, class IIa medical devices placed on the EU market prior to May 26, 2021 in accordance with the EU MDD may continue to be supplied until December 31, 2028, subject to certain conditions (including requirements for market surveillance, quality management systems, and engagement with notified bodies). After such date, class IIa medical devices must be certified under the EU MDR in order to be marketed in the EU. However, the "sell-off" date has been removed from the EU MDR (i.e. the date after which devices already on the market but not yet with the final user).

As stated above, our product candidates may require use of an *in vitro* diagnostic to identify appropriate patient populations. As in the U.S., these diagnostics, referred to as companion diagnostics, are regulated as medical devices in the EU and will be governed by the In-Vitro Diagnostic Devices Regulation (EU) 2017/746, or EU IVDR. The EU IVDR became fully applicable in all EU Member States on May 26, 2022 (therefore not including the UK). The EU IVDR introduced more stringent requirements than the current EU In Vitro Diagnostics Directive 98/79/EC, EU IVDD. In accordance with the transitional provisions in the EU IVDR, devices placed on the EU market prior to May 26, 2022 in accordance with the EU IVDD may continue to be supplied until a certain date (ranging from May 2025 to May 2027) which will depend on the risk class of the device, provided that manufacturers comply with the EU

IVDR requirements relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and devices. After such date, all devices must be certified under the EU IVDR in order to be marketed in the EU. However, the "sell-off" date has been removed from the EU IVDR (i.e. the date after which devices already on the market but not yet with the final user. In January 2024, the European Commission published a proposal for a further extension to the transitional periods until December 2027 to December 2029, depending on the risk class of the device and subject to certain requirements (e.g., for devices requiring notified body assessment, the manufacturer must submit an application to a notified body to transfer the device to the IVDR by a certain date (ranging from May 2025 to May 2027), depending on the risk class of the device). The proposal will now be put forward to the European Parliament and European Council for adoption.

Before a notified body can issue a CE certificate for a companion diagnostic, it must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized marketing authorization procedure.

The aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the EU

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval. In October 2023, the European Parliament published draft reports proposing amendments to the legislative proposals, which will be debated by the European Parliament. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

Brexit and the Regulatory Framework in the UK

The UK left the EU on January 31, 2020 and the EU and the UK have since concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework currently continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore largely aligns with current EU medicines regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. For example, the Clinical Trials Regulation which became effective in the EU on January 31, 2022 has not been implemented into UK law, and a separate application will need to be submitted for a clinical trial authorization in the UK. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new international recognition framework mentioned below which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law.On June 9, 2 023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products. The MHRA put in place a new international recognition framework on January 1, 2024, under which the MHRA may have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators when determining an application for a new Great Britain marketing authorization. There is now no pre-marketing authorization orphan designation in Great Britain. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the Great Britain market, i.e., the prevalence of the condition in Great Britain (rather than the EU) must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in Great Britain.

As the EU MDR and EU IVDR became fully applicable after January 1, 2021, they do not apply in Great Britain. Instead, the Medical Devices Regulations 2002, or UK MDR, applies. As updated to apply since Brexit, the UK MDR has introduced several changes including (but not limited to) replacing the CE mark with a UKCA mark, requiring manufacturers outside of the UK to appoint a "UK Responsible Person" if they place devices on the Great Britain market and more wide-ranging device registration requirements. However, on June, 30 2023, the UK government introduced legislation, confirming that, subject to certain conditions, general medical devices compliant with the EU MDD with a valid declaration and CE mark can be placed on the Great Britain market up until the sooner of the expiry of the CE certificate or June 30, 2028. It was also confirmed that, subject to certain conditions, in vitro diagnostic medical devices compliant with the EU IVDD with a valid declaration and CE mark can be placed on the Great Britain market up until the sooner of the expiry of the CE certificate or June 30, 2030.

Following a public consultation on proposed changes to the UK's medical device regulations, the response to which was published on June 26, 2022, the MHRA confirmed that it would bring about changes to the current regulations applicable in Great Britain. It is anticipated that the core aspects of the future regime will now apply from July 1, 2025.

Other Healthcare Laws and Compliance Requirements

In addition to FDA restrictions on the marketing of pharmaceutical products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. Healthcare providers, physicians, and third party payors play a primary role in the recommendation and prescription of drug products for which we obtain marketing approval. Arrangements with third party payors, healthcare providers and physicians, in connection with the clinical research, sales, marketing and promotion of products, once approved, and related activities, may expose a pharmaceutical manufacturer to broadly applicable fraud and abuse and other healthcare laws and regulations. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below:

- the federal Anti-Kickback Statute, or AKS, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward, referrals including the purchase recommendation, order or prescription of a particular drug for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities

for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the civil monetary penalties law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the federal Health Insurance Portability and Accountability Act of 1996, or 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 the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created 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 federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biological products and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, or CMS, under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring 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 may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that a pharmaceutical manufacturer's business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If a pharmaceutical manufacturer's operations, including its arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, are found to be in violation of any of such laws or any other governmental regulations that apply, governmental and enforcement authorities may institute action. If the pharmaceutical manufacturer is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion or suspension from participation in Medicare, Medicaid and other federal healthcare programs, integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the financial results of operations. Additionally, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states against a pharmaceutical manufacturer. The approval and commercialization of a pharmaceutical manufacturer's product candidates outside the United States will also likely subject it to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Lastly, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

The risk of our being found in violation of these laws is increased by the fact that many of these laws have not been fully interpreted by the regulatory authorities or the courts, their provisions are open to a variety of interpretations, and are currently the subject of legal challenge. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial cost.

Healthcare Reform

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system. In particular, in 2010 the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the

Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. The U.S. Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. Subsequent legislation extended the 2% reduction which remains in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care

programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and result in reduced demand for our current product candidates and any future product candidates or additional pricing pressures.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Further, legislative and regulatory proposals, and enactment of laws, at the foreign, federal and state levels, directed at containing or lowering the cost of healthcare, will continue into the future.

Coverage and Reimbursement

The availability of insurance coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and novel pharmaceutical products such as our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. One payor's determination to provide coverage for a drug or biological product does not assure that other payors will also provide coverage for the same product. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. It is difficult to predict what the Centers for Medicare & Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program, will decide with respect to reimbursement for fundamentally novel products such as ours. Factors payors consider in determining reimbursement are based on whether the product is:

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

Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services.

Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians

may be unlikely to offer procedures for such treatment if they are not covered or are inadequately covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

Increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may, nonetheless, not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional upcoming and anticipated legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to our product candidates under any foreign reimbursement system. To that end, reimbursement agencies in the UK and EU may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in the UK and/or certain European countries.

C. Organizational Structure.

As of December 31, 2023, we had three subsidiaries. The following table sets out for our principal subsidiaries, country of incorporation and percentage ownership and voting interest held by us (directly or indirectly through subsidiaries).

Company	Country of incorporation	Percentage ownership and voting interest
Achilles Therapeutics Holdings Limited	England and Wales	100.00%
Achilles Therapeutics UK Limited	England and Wales	100.00%
Achilles Therapeutics US, Inc.	United States	100.00%

D. Property, Plant and Equipment.

Our corporate headquarters are located in Hammersmith Road, London in the UK, where we currently lease a facility containing our research and development, laboratory and office space, which consists of approximately 25,000 square feet. Our lease expires in 2030 with a break clause in 2025.

We lease a facility in Philadelphia, United States containing research and development, laboratory and office space, which consists of approximately 7,000 square feet. Our lease expires in 2025.

We have other leases that are primarily used for office and laboratory space. See Note 9, "Leases," to our financial statements appearing at the end of this Annual Report, for further discussion.

We believe that our current facilities are adequate for our current needs and that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Item 4A. Unresolved Staff Comments.

None.

Item 5. Operating and Financial Review and Prospects.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and our expectations with respect to liquidity and capital resources, includes forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, those risks and uncertainties described in Item 3.D. "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in this Annual Report. Our actual results could differ materially from the results described in or implied by these forward- looking statements.

We maintain our books and records in pounds sterling, our results are subsequently converted to U.S. dollars and we prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as issued by the Financial Accounting Standards Board, or FASB. All references in this Report to "$" are to U.S. dollars and all references to "£" are to pounds sterling. Unless otherwise indicated, certain U.S. dollar amounts contained in this Report have been translated into pounds sterling at the rate of £1.00 to $1.27313 on December 31, 2023. These translations should not be considered representations that any such amounts have been, could have been or could be converted into pounds sterling at that or any other exchange rate as of that or any other date.

We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

A. Operating Results.

Overview

We are a clinical immuno-oncology biopharmaceutical stage company developing AI-powered precision T cell therapies to treat multiple types of solid tumors. We are focused on advancing cancer therapies through our pioneering work in the field of tumor evolution and our belief that clonal neoantigens represent the most specific class of cancer cell targets. Our platform enables us to identify mutations formed early in the development of a cancer that give rise to antigens that are expressed by all of a patient's cancer cells but are absent from healthy tissue. We refer to this novel class of solid tumor targets as clonal neoantigens. To identify clonal neoantigens in a patient, we have developed a proprietary AI-powered platform called PELEUS. This platform employs advanced computational methods with AI and machine learning and is validated on real world patient tumor genetic data derived from our exclusive license to data from the TRACERx study, which aims to analyze tumor samples from 814 non-small cell lung cancer, or NSCLC, patients. Once we have identified the clonal neoantigens, our proprietary manufacturing process, VELOS, uses the patient's T cells and blood-derived dendritic cells to create a clonal neoantigen-reactive T cell therapy, or cNeT, that specifically targets multiple clonal neoantigens to eradicate the tumor.

Since our inception in 2016, we have devoted substantially all of our resources to conducting research activities and clinical trials, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. We have initially focused on two solid tumor types: advanced NSCLC and metastatic or recurrent melanoma as well as expanding into a range of additional indications. We do not have any products approved for sale and have not generated any revenue from product sales. We have principally raised capital through the issuance and

sale of our convertible preferred shares to outside investors and sales of ADSs through our IPO. Through December 31, 2023, we had received net cash proceeds of $230.9 million from investors in our preferred shares financings and $160.6 million from sales of ADS through our IPO.

We have incurred significant operating losses since inception. We incurred total net losses of $69.7 million, $71.2 million and $61.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. As of December 31, 2023, we had an accumulated deficit of $260.0 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect that our expenditure will increase substantially in connection with our ongoing activities, particularly as we:

- continue to develop our pipeline of discovery programs and conduct research and clinical activities for our existing programs for advanced NSCLC, metastatic or recurrent melanoma and other solid tumors;
- continue to innovate, improve and develop our technology platform, including continuing to develop and improve our PELEUS AI-powered platform and VELOS manufacturing process and to evaluate new approaches to our manufacturing process;
- maintain, and in future expand our MAP network to increase our network of clinical sites;
- advance the development of our current programs, additional follow-on indications and any future product candidates into additional solid tumor indications;
- maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals and complete any post-marketing studies, if required, for any of our product candidates that successfully complete clinical trials, if any;
- acquire or in-license additional product candidates and technologies;
- expand our infrastructure and facilities to accommodate our growing employee base and ongoing development activity;
- continue to improve our manufacturing process to create a fully closed end-to-end manufacturing process;
- expand our manufacturing infrastructure and facilities to support the manufacture of larger quantities of our product candidates for clinical development and potential commercialization globally;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our operations as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for ATL001 or any future product candidates. If we obtain regulatory approval for ATL001 or any product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

As of December 31, 2023, we had cash and cash equivalents of $131.5 million. We believe our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2025. See "—Liquidity and Capital Resources—Funding Requirements" below.

Impacts of Global Political and Economic Events on Our Business

Geopolitical events and disruptions of global financial markets, including as a result of the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, the unrest in the Middle East resulting from the Israel-Hamas war and other global macroeconomic factors such as inflation, increases in commodity prices, energy and fuel prices, credit and capital markets instability and supply chain interruptions could reduce our ability to access capital, which could, in the future, negatively affect our business and

the value of our common shares. We believe our financial results for the years ended December 31, 2023, 2022 and 2021 were not significantly impacted by these conditions.

CRT License

In May 2016, we entered into the CRT Agreement with CRT pursuant to which we obtained access rights to intellectual property and know-how from the TRACERx Study. Under the CRT Agreement, we are granted an exclusive, sublicensable license to the TRACERx patents and bioinformatic data for use in: (i) the therapeutic field of neoantigen cell therapies and adoptive cell transfer; and (ii) the neoantigen diagnostic field, for use in research and the potential development of products for commercialization. We are further granted, during the vaccine option period, an exclusive license to the TRACERx patents and the bioinformatic data in the private neoantigen therapeutic vaccine field for research and development but not in the development of products for commercial sale, and a non-exclusive license to the same in the public neoantigen therapeutic vaccine field. We also obtained a non-exclusive license to the TRACERx bioinformatic pipeline, patient sequencing and medical data, know-how, and materials.

CRT additionally granted us certain rights to new patent applications filed by the Founding Institutions in respect of inventions resulting from the TRACERx study through February 2023, including automatic exclusive licenses to patent rights relating to non-severable improvements of technology covered by the original TRACERx patents and non-exclusive rights to severable improvements.

In July 2017, we obtained a non-exclusive license to the LOHHLA patent under the CRT Agreement. In October 2018, we obtained an exclusive license to the LOHHLA patent under an addendum to the CRT Agreement.

Under the CRT Agreement, we hold an option to exploit products in the therapeutic vaccine field (the "Vaccine Option"). In March 2021, we extended the Vaccine Option from May 2021 to May 2023 with a payment of less than £0.1 million or $0.1 million. We exercised the Vaccine Option on May 4, 2023.

Upon execution of the CRT Agreement, we granted CRT 396,125 B ordinary shares and 67,793 C ordinary shares. The C ordinary shares granted to CRT were forfeited and transferred to the deferred shares during the year ended December 31, 2019, as the applicable performance conditions were not met. The B ordinary shares granted to CRT were converted into ordinary shares upon our IPO. We recorded $0.3 million of IP research and development expense in 2016. We are obligated to pay CRT milestone success payments up to an aggregate of £6.5 million for therapeutic products, and milestone success payments up to an aggregate £0.8 million for non-therapeutic products, as well as sub-single digit to low-single digit percentage royalty on net sales of products that utilize the licensed intellectual property, subject to certain customary reductions. The royalty obligations continue on a product-by-product and country-by-country basis until the later of: (i) the date there ceases to be a valid patent claim covering such product in the country in which it is sold; or (ii) with respect to contribution royalty products, ten years from the first commercial sale of the product, and with respect to a patent royalty product, five years from the first commercial sale of the product. On a product-by-product basis, we may also elect to provide other cash consideration at fair market value and forgo the milestone or royalty payment.

Unless terminated earlier, the term of the agreement continues until the later of the expiration of the royalty term in each country and such time as no further milestone payments are due, and upon such termination, the licenses granted shall become fully-paid, royalty-free, irrevocable, and perpetual. We have the right to terminate the license agreement for convenience in its entirety upon 90 days' notice. Each party may terminate the agreement if the other party is in material breach subject to a 90 day remedy period. We have the right to acquire ownership of the TRACERx patents upon either: (i) the occurrence of a royalty product for use in the therapeutic field; (ii) CRT shareholders cease to hold any ordinary shares in the Company; (iii) we undergo an initial public offering; or (iv) we are acquired by a third party for more than £25.0 million. Upon our IPO, we gave notice to CRT to exercise the option to acquire the TRACERx patents with no consideration in accordance with the terms of the CRT Agreement. The acquisition was finalized in accordance with an assignment and licence agreement, or Assignment Agreement, with effective date November 29, 2023. Under the terms of the Assignment Agreement the relevant TRACERx patents were assigned to us and we license back certain rights to CRT in relation to those assigned patents.

Components of our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for ATL001 or any of our future candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of ATL001 for our current programs, additional follow-on indications and enhancement of our existing technology platform. Research and development expenses consist of:

- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our clinical trials, research activities and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing clinical trial materials;
- expenses to acquire technologies to be used in research and development;
- employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- costs of outside consultants, including their fees, share-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing clinical trial materials;
- costs related to compliance with regulatory requirements;
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs; and
- upfront, milestone and management fees for maintaining licenses under our third-party licensing agreements.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. As a result, our research and development expenses may vary substantially from period to period based on the timing of our research and development activities. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as a prepaid expense or accrued research and development expenses.

UK R&D tax credits are recorded as an offset to R&D expense. See “Income Tax Expenses.”

Our direct research and development expenses are tracked on an indication-by-indication basis and consist primarily of external costs, such as fees paid to outside consultants, CROs and central laboratories in connection with our research activities, process development, manufacturing and clinical development activities. License fees and other costs incurred after a product candidate has been selected that are directly related to a product candidate are included in direct research and development expenses for that program. License fees and other costs incurred prior to designating a product candidate are included in other program expense. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee the research and development as well as to manage our research activities, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and related product manufacturing expenses. As a result, we expect that our research and development expenses will continue to increase over the next several years as we: (i) expedite the clinical development and obtain marketing approval for ATL001 for advanced NSCLC and

metastatic or recurrent melanoma; (ii) initiate additional clinical trials for ATL001 or any future product candidates, (iii) improve the efficiency and scalability of our manufacturing processes and supply chain including enhancing the capability of our PELEUS AI-powered platform for selecting clonal neoantigens; and (iv) build our in-house process development, analytical and manufacturing capabilities and continue to discover and develop additional product candidates, increase personnel costs and prepare for regulatory filings related to ATL001 and any future product candidates. We also expect to incur additional expenses related to milestone payments, royalty payments and maintenance fees payable to third parties with whom we have entered into license agreements.

The successful development and commercialization of ATL001 or any of our future product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with development and commercialization, including the following:

- completing research activities for the development of ATL001 and identifying new cNeT product candidates;
- establishing an appropriate safety profile with IND- and CTA-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities and reimbursement and market access from third-party payors;
- our ability to establish commercial manufacturing capabilities and maintain suitable arrangements with third-party manufacturers for ATL001 and any future product candidates;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- defending against third-party infringement, misappropriation or other violation of intellectual property rights claims;
- significant and changing government regulation;
- establishing and maintaining temperature controlled product logistics;
- launching commercial sales of ATL001 and any future product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

A change in the outcome of any of these variables with respect to the development of ATL001 and any future product candidates in development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA, EMA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to commit significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, share-based compensation expense, travel and other expenses incurred by personnel in executive, finance and administrative functions. These expenses include professional fees for legal, including patent costs, consulting, accounting and audit services. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of ATL001 and any future product candidates.

We also anticipate we will continue to incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

Other Income (Expense), Net

Interest Income

Interest income consists primarily of interest earned on our cash and cash equivalents.

Other Income/Expense

Foreign currency transactions in currencies different from the functional currency of our entity are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange differences resulting from the settlement of such transactions and from the translation at period-end exchange rates in foreign currencies are recorded in other income (expense), net in the statement of operations and comprehensive loss. As such, our other income (expense), net may be impacted by future changes in exchange rates. See Item 11 - Quantitative and Qualitative Disclosures About Market Risks, for further discussion.

Income Taxes

We are subject to corporate taxation in the United States and corporation tax in the UK. Due to the nature of our business, we have generated losses since inception and have therefore not paid UK corporation tax. As a company that carries out extensive R&D activities, we seek to benefit from one of two UK R&D tax credit cash rebate regimes: the SME, Program or the RDEC Program. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects for which we do not receive income.

Based on criteria established by HMRC, a portion of expenditures being carried in relation to our pipeline R&D, clinical trials management and manufacturing development activities were eligible for the SME Program for the years ended December 31, 2021, 2022 and 2023. We claimed R&D tax credits in 2020, 2021 and 2022 which were paid in 2021, 2022 and 2023, respectively. We have claimed R&D tax credits for 2023, which we expect will be paid to us in 2024 from HMRC. As a company that carries out extensive R&D activities, the Company benefits from the UK research and development tax credit regime under the scheme for small or medium-sized enterprises ("SME"). Under the current SME regime, the Company can surrender some of its trading losses that arise from qualifying R&D activities for a cash rebate of 33.35% of qualifying R&D expenditure incurred prior to April 1, 2023 (after taking into account the enhanced rate of deduction) and decreasing to 18.6% of qualifying R&D expenditure after April 1, 2023 (after taking into account the enhanced rate of deduction). Additionally, the UK Government has enacted further changes to the SME regime in February 2024, which include the introduction of a new rate for R&D intensive companies of 26.97% (which the Company is expected to qualify for) and comes into effect for qualifying R&D expenditures incurred after April 1, 2023.

Unsurrendered UK losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of UK taxable profits. After accounting for tax credits receivable, we had accumulated tax losses for carry forward in the UK of $121.7 million as of December 31, 2023. We have recorded an insignificant amount of income tax provisions for the year ended December 31, 2023, which relate to income tax obligations of our operating company in the U.S., which generates a profit for tax purposes.

Benefit from R&D, tax credits is received in the UK and recorded as an offset to R&D expenses. The UK R&D tax credit, as described above, is fully refundable to us and is not dependent on current or future taxable income. As a result, we have recorded the entire benefit from the UK R&D tax credit as a benefit which is included in our net loss before income tax and accordingly, not reflected as part of the income tax provision. If, in the future, any UK R&D tax credits generated are needed to offset a corporation tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded as an offset to R&D expenses.

In the event we generate revenues in the future, we may benefit from the UK "patent box" regime that allows profits attributable to revenues from patents or patented products to be taxed at an effective rate of 10%.

UK Value Added Tax, or VAT, is broadly charged on all taxable supplies of goods and services by VAT-registered businesses established or operating in the UK. Under current rates as determined for VAT purposes, the VAT on goods or services supplied is added to all relevant sales invoices and is payable to HMRC. Similarly, VAT paid on purchase invoices is generally reclaimable from HMRC (whether by repayment or credit).

Consolidated Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our consolidated results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 58,246	$ 57,263	$ 983
General and administrative	17,009	21,120	(4,111)
Total operating expenses	75,255	78,383	(3,128)
Loss from operations	(75,255)	(78,383)	3,128
Other income (expense), net:			—
Other income (expense)	6,081	7,318	(1,237)
Total other income (expense), net	6,081	7,318	(1,237)
Loss before provision for income taxes	(69,174)	(71,065)	1,891
Provision for income taxes	(491)	(111)	(380)
Net loss	$ (69,665)	$ (71,176)	$ 1,511

Research and Development Expenses

The table below summarizes our research and development expenses incurred by program for the year ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,		
	2023	2022	Change
Direct research and development expense by program:			
NSCLC	$ 14,394	$ 9,659	$ 4,735
Melanoma	11,475	8,298	3,177
Other pre-clinical and technology development cost	3,187	6,280	(3,093)
Unallocated research and development expense:			
Personnel expenses	17,766	17,273	493
Other expenses	11,424	15,753	(4,329)
Total research and development expenses	$ 58,246	$ 57,263	$ 983

Research and development expenses were net of research and development tax credit reimbursement of $9.4 million and $15.6 million for the year ended December 31, 2023 and 2022, respectively. The net increase in research and development expenses was $1.0 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 and was primarily due to an increase of $4.7 million in our NSCLC program specifically in relation to our ongoing Phase I/II CHIRON clinical trial and an increase of $3.2 million in our metastatic or recurrent melanoma program specifically in relation to our ongoing Phase I/II THETIS clinical trial. Our unallocated research and development expense decreased by $3.8 million for the year ended December 31, 2023, primarily as a result of an impairment loss of $6.7 million recorded in 2022 in assets under construction related to costs associated with the detailed design of a flexible GMP modular facility in West London. Following a review of manufacturing plans, the Company had mothballed the construction of the facility and project and subsequently terminated the lease in October 2023 (See Note 9, “Leases,” for further details). Other pre-clinical and technology development costs decreased by $3.1 million on lower IND enabling activities.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the year ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,		
	2023	2022	Change
Personnel expenses	$ 9,536	$ 11,275	$ (1,739)
Professional services fees	2,421	2,513	(92)
Facilities and other expense	5,052	7,332	(2,280)
	$ 17,009	$ 21,120	$ (4,111)

General and administrative expenses were $17.0 million for the year ended December 31, 2023, compared to $21.1 million for the year ended December 31, 2022. The decrease of $4.1 million consisted of a decrease in facilities and other expense of $2.3 million primarily from savings in connection with the termination of the West London lease in October 2023 and a higher utilization of our facilities for R&D purposes. Lower personnel expenses of $1.7 million were attributable to a decrease in headcount.

Total Other Income (Expense), Net

Other income (expense), net was income of $6.1 million for the year ended December 31, 2023, compared to income of $7.3 million for the year ended December 31, 2022. The decrease in other income of $1.2 million was primarily due to a decrease in foreign exchange gains of $4.9 million, partially offset by an increase in interest income of $3.7 million.

Provision for Income Taxes

The provision for income taxes was $0.5 million for the year ended December 31, 2023 and $0.1 million for the year ended December 31, 2022, which is related to income tax obligations of our operating company in the U.S., which generates a profit for tax purposes.

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our consolidated results of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 57,263	$ 42,224	$ 15,039
General and administrative	21,120	21,971	(851)
Total operating expenses	78,383	64,195	14,188
Loss from operations	(78,383)	(64,195)	(14,188)
Other income (expense), net:			—
Other income (expense)	7,318	3,133	4,185
Total other income (expense), net	7,318	3,133	4,185
Loss before provision for income taxes	(71,065)	(61,062)	(10,003)
Provision for income taxes	(111)	(37)	(74)
Net loss	$ (71,176)	$ (61,099)	$ (10,077)

Research and Development Expenses

The table below summarizes our research and development expenses incurred by program for the year ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	Change
Direct research and development expense by program:			
NSCLC	$ 9,659	$ 8,729	$ 930
Melanoma	8,298	7,858	440
Other pre-clinical and technology development cost	6,280	6,710	(430)
Unallocated research and development expense:			
Personnel expenses	17,273	13,717	3,556
Other expenses	15,753	5,210	10,543
Total research and development expenses	$ 57,263	$ 42,224	$ 15,039

Research and development expenses were net of research and development tax credit reimbursement of $15.6 million and $10.7 million for the year ended December 31, 2022 and 2021, respectively. The net increase in research and development expenses was $15.0 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. The net increase in direct research and development expense was attributable to $0.9 million in our NSCLC program specifically in relation to our ongoing Phase I/II CHIRON clinical trial. Our unallocated research and development expense increased by $14.1 million for the year ended December 31, 2022, primarily as a result of an impairment loss of $6.7 million in assets under construction primarily related to costs associated with the detailed design of a flexible GMP modular facility in west London. Due to challenging economic and market conditions, the Company has mothballed the construction of the facility and project. In addition, higher personnel costs of $3.6 million as a result of a higher average headcount in the current year and an impairment loss of $0.5 million related to discontinued software implementation costs drove the increase. This was partially offset by a decrease of $0.4 million primarily related to lower IND enabling activities primarily for new follow-on indication.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	Change
Personnel expenses	$ 11,275	$ 11,227	$ 48
Professional services fees	2,513	3,424	(911)
Facilities and other expense	7,332	7,320	12
	$ 21,120	$ 21,971	$ (851)

General and administrative expenses were $21.1 million for the year ended December 31, 2022, compared to $22.0 million for the year ended December 31, 2021. The decrease of $0.9 million consisted primarily of a decrease in legal and professional fees that were incurred in the prior year related to becoming a public company in 2021.

Total Other Income (Expense), Net

Other income (expense), net was income of $7.3 million for the year ended December 31, 2022, compared to income of $3.1 million for the year ended December 31, 2021. The increase in other income of $4.2 million was primarily due to an increase in interest income of $2.0 million and an increase in foreign exchange gains of $1.3 million.

Provision for Income Taxes

The provision for income taxes was $0.1 million for the year ended December 31, 2022 and less than $0.1 million for the year ended December 31, 2021, which is related to income tax obligations of our operating company in the U.S., which generates a profit for tax purposes.

B. Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales or any other sources and have incurred significant net losses in each period and on an aggregate basis. We have not yet commercialized any product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. We have funded our operations to date primarily with proceeds from the sale of preferred shares and ordinary shares. Through December 31, 2023, we had received net cash proceeds of $230.9 million from investors in our preferred shares financings and $160.6 million net proceeds from the sales of ADSs through our IPO after deducting underwriting discounts and commissions and other offering expenses. As of December 31, 2023, we had cash and cash equivalents of $131.5 million.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our manufacturing and lease obligations described below.

Cash Flows

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

	Year ended December 31,		
	2023	**2022**	**2021**
Net cash used in operating activities	$ (48,449)	$ (59,535)	$ (59,284)
Net cash used in investing activities	(1,100)	(7,512)	(7,634)
Net cash provided by financing activities	9	1	160,755
Effect of exchange rate changes on cash, cash equivalents and restricted cash	7,741	(25,935)	(5,334)
Net (decrease) increase in cash	$ (41,799)	$ (92,981)	$ 88,503

Net Cash Used in Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was $48.4 million, primarily resulting from our net loss of $69.7 million, adjusted for share-based compensation of $6.4 million and depreciation and amortization of $4.7 million and changes in right of use assets and liabilities of $0.2 million. The net loss was also partially offset by $9.2 million related to changes in components of working capital due to: (i) decreased prepaid expenses and other current assets in conjunction with the payment of the UK R&D tax credit in September 2023; (ii) increased accounts payable for payment of vendors' invoices; (iii) decreased accrued R&D expenses; and (iv) decreased income taxes payable.

During the year ended December 31, 2022, net cash used in operating activities was $59.5 million, primarily resulting from our net loss of $71.2 million, adjusted for non-cash loss on impairment charges of $7.4 million, non-cash share-based compensation of $7.0 million, depreciation and amortization of $3.7 million and changes in right of use assets and operating lease liabilities of $0.6 million. The net loss also was adjusted by $5.7 million related to changes in components of working capital due to: (i) increased prepaid expenses and other current assets in conjunction with accrued UK R&D tax credits; (ii) increased accounts payable for payment of vendors' invoices; and (iii) decreased accrued R&D expenses.

During the year ended December 31, 2021, net cash used in operating activities was $59.3 million, primarily resulting from our net loss of $61.1 million, adjusted for share-based compensation of $6.3 million, depreciation and amortization of $3.3 million The net loss also was adjusted by $7.4 million related to changes in components of working capital due to: (i) decreased accounts payable for payment of vendors' invoices; (ii) increased accrued R&D, increased accrued expenses incurred in relation to our IPO costs and increased accrued facility costs in conjunction with lease of new laboratory and office space; and (iii) increased prepaid expenses and other current assets in conjunction with accrued UK R&D tax credits. In addition, changes in other assets of $0.5 million primarily due to the capitalization of cloud-based implementation costs during the year ended December 31, 2021 increased cash used.

Net Cash Used in Investing Activities

During the years ended December 31, 2023, 2022 and 2021, net cash used in investing activities was $1.1 million, $7.5 million and $7.6 million, respectively, primarily driven by purchases of property and equipment related to lab equipment and leasehold improvements.

Net Cash Provided by Financing Activities

During the year ended December 31, 2023 and 2022, net cash provided by financing activities was less than $0.1 million related to the issuance of shares under the employee share purchase plan.

During the year ended December 31, 2021, net cash provided in financing activities was $160.8 million, primarily related to the net proceeds from sales of our ADSs through our IPO.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the research activities, manufacturing and clinical trials of product candidates. In addition, following our IPO, we incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

With increased focus on the ongoing Phase I/IIa CHIRON and THETIS clinical trials and de-prioritization of non-core activities, we believe that our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2025. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. As we progress with our development programs and the regulatory review process, we expect to incur significant expenses related to product manufacturing, pre-commercial activities and commercialization.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates and programs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the initiation, progress, timing, costs and results of our pipeline discovery programs and clinical activities for our existing programs for advanced NSCLC and metastatic or recurrent melanoma, and any additional product candidates or follow-on indications that we may develop or pursue;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- our ability to enroll clinical trials in a timely manner and to quickly resolve any delays or clinical holds that may be imposed on our development programs;
- timing delays with respect to development of our current and any future product candidates, including as a result of global health crises, such as the COVID-19 pandemic, and global political and economic events, such as the conflict between Russia and the Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the unrest in the Middle East resulting from the Israel-Hamas war, the effects of inflation and global market instability;
- the costs of expanding our facilities to accommodate our future growth in personnel;
- the costs, timing and outcome of potential future commercialization activities, including manufacturing, marketing, sales and distribution for our product candidates for which we receive marketing approval;
- the extent to which we acquire technologies;
- the sales price and availability of adequate third-party coverage and reimbursement for our product candidates, if and when approved;
- the availability and scope of the UK R&D tax credit for which we are eligible; and
- the costs of operating as a public company.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity, current ownership interests will be diluted. If we raise additional funds through government or third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or

terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

As of December 31, 2023, we are committed to make minimum payments of $4.8 million due for our office and laboratory space leases. See Note 9, "Leases," to our financial statements appearing at the end of this Annual Report for our annual expected payments under our operating lease obligations at December 31, 2023. In addition, we are committed to make payments of $3.5 million, with approximately $3.1 million to be made in 2024, for costs associated with our certain vendors, which we engaged to provide clinical trial materials and contractual commitments for capital expenditures. These purchase commitments included non-cancellable minimum quantities to be purchased as of December 31, 2023.

We enter into contracts in the normal course of business with CROs and other third-party vendors for clinical trials, clinical and commercial supply manufacturing, support for pre-commercial activities, research and development activities and other services and products for our operations. Our agreements generally provide for termination within 30 to 90 days of notice. Such agreements are cancellable contracts and have not been included above.

We may incur potential contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable, or we may be required to make royalty payments under the CRT Agreement. Due to the uncertainty of the achievement and timing of the events requiring payment under that agreement, the amounts to be paid by us are not fixed or determinable at this time and have not been included above.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies. However, we may choose to early adopt these standards.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

We may take advantage of these exemptions for up to the last day of the fiscal year ending after the fifth anniversary of our IPO or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) December 31, 2026, which is the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "Summary of significant accounting policies" to our financial statements appearing at the end of this Annual Report.

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in Item 4.B. "Information on the Company—Business Overview" and Item 5.A. "Operating and Financial Review and Prospects—Operating Results" within this Annual Report.

D. Trend Information.

See Item 4.B. "Information on the Company—Business Overview," Item 5.A. "Operating and Financial Review and Prospects—Operating Results" and Item 5.B. "Operating and Financial Review and Prospects—Liquidity and Capital Resources" within this Annual Report.

E. Critical Accounting Estimates

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

We believe that there are no critical accounting policies used in the preparation of our financial statements for the year ended December 31, 2023.

Other Accounting Policies, Judgments and Estimates

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. The estimate of accrued research and development expense is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party service providers. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities; and
- CROs and investigative sites in connection with preclinical studies and clinical trials.

We base our expenses related to research activities and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense.

Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Share-Based Compensation

We measure share-based awards granted to employees, non-employees and directors based on the fair value on the date of the grant. Forfeitures are accounted for as they occur. We issue share-based awards with service-based vesting conditions and/or performance-based vesting conditions. For equity awards that vest based on a service condition, the share-based compensation expense is recognized on a straight-line basis over the requisite service period. For equity awards that vest based on a combination of service and performance conditions, we recognize share-based compensation expense using a straight-line basis over the requisite service period when the achievement of a performance-based milestone is probable, based on the relative satisfaction of the performance condition as of the reporting date.

Determination of the Fair Value of the Share Options

Prior to our IPO, the estimated fair value of the ordinary shares underlying our ADSs had been determined by our board of directors as of the date of each award grant, with input from management, considering our most recently available third-party valuations of our common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Subsequent to our IPO, the fair value of our ordinary shares underlying our ADSs is based on quoted market prices. We measure share options granted to employees based on the fair value on the date of the grant and recognize the corresponding compensation expense of those share options over the requisite service period, which is generally the vesting period of the respective share options. We have only issued share options with service-based vesting conditions and record the expense for these awards using the straight-line method.

We estimate the fair value of each share options grant using the Black-Scholes option-pricing model, which uses as inputs the estimated fair value of our ordinary shares and assumptions we make for the volatility of our ordinary shares, the expected term of our share options, the risk-free interest rate for a period that approximates the expected term of our share options and our expected dividend yield.

We determined the assumptions for the Black-Scholes option-pricing model as discussed below. Each of these inputs is subjective and generally requires judgment, and in particular the expected term and the expected volatility inputs, to determine:

- Fair Value of our Ordinary Shares. Prior to the completion of our IPO, our ordinary shares were not publicly traded, and therefore we estimated the fair value of our ordinary shares on the basis referred to above. Subsequent to the IPO, the fair value of each share option grant is estimated on the date of grant using the market price of our ordinary shares in the Black-Scholes option pricing model applying assumptions used in connection with share option grants made during the periods described further below.

- Expected Term. The expected term represents the period that the share-based awards are expected to be outstanding. The expected term of share options granted has been determined using the simplified method as there is a limited trading history of our ordinary shares, which uses the midpoint between the vesting date and the contractual term.
- Risk-Free Interest Rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the share-based award's expected term.
- Expected Volatility. Because we have a limited trading history of our ordinary shares, the expected volatility was derived from the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the share-based awards.
- Dividend Rate. The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

If any of the assumptions used in the Black-Scholes model change significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

Leases

Our right of use assets and lease liabilities associated with leases for leasehold properties are recognized at lease commencement date based on the present value of minimum lease payments over the lease term. Since the rate implicit in the lease is not readily determinable, we use the incremental borrowing rates based on indicative borrowing rates that would be available based on the value, currency and borrowing term provided by financial institutions, adjusted for company and market specific factors. This incremental borrowing rate is the rate of interest that we would have to pay to borrow on a collateralized basis an amount equal to the lease payments over a similar term in a similar economic environment, based on the information available at commencement date in determining the discount rate used to calculate the present value of lease payments. Although we do not expect our estimates of the incremental borrowing rate, or IBR, to generate material differences within a range of sensitivities, judgment is involved in selecting an appropriate rate and the rate selected for each lease will have an impact on the value of the right-of-use asset and corresponding lease liability in the consolidated balance sheets.

Item 6. Directors, Senior Management and Employees.

A. Directors and Senior Management.

The following table sets forth the name, age and position of our senior management and directors as of the date of this Annual Report. Unless otherwise stated, the business address of our members of senior management and our directors is c/o Achilles Therapeutics plc, 245 Hammersmith Road, London, W6 8PW, United Kingdom. Less than a majority of the directors of our board of directors are citizens or residents of the United States.

Name	Age	Position
Senior Management:		
Iraj Ali, Ph.D.	48	Chief Executive Officer and Director
Robert Coutts	40	Chief Financial Officer
Karl Peggs. M.D.	57	Chief Medical Officer
Sergio Quezada, Ph.D.	49	Chief Scientific Officer
Non—Executive Directors:		
Edwin Moses. Ph.D.[(1)(2)(3)]	69	Chairman of the Board of Directors
Michael F. Giordano. M.D. [(2)(3)(4)]	66	Director
Carsten Boess [(1)(2)(3)]	57	Director
Bernhard Ehmer	69	Director
Julie O'Neill [(1)]	58	Director

(1) Member of Audit Committee
(2) Member of Remuneration Committee
(3) Member of Nominating Committee
(4) Member of Research & Development Committee

Senior Management

Iraj Ali, *Ph.D.* has served as our Chief Executive Officer since January 2018 and a member of our board of directors since March 2016. Previously, Dr. Ali served as a Managing Partner of Syncona Ltd., or Syncona, a leading healthcare investment company focused on founding, building and funding global leaders in life sciences and a major shareholder of our company, from December 2016 to December 2018. Dr. Ali was also an Investment Partner at Syncona from September 2012 to December 2018. Dr. Ali has a Ph.D. in Biochemistry from Cambridge University and a B.S. in Biochemistry from the University of Reading. We believe that Dr. Ali is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive global pharmaceutical experience.

Robert Coutts has served as our Chief Financial Officer since November 2020. Previously, Mr. Coutts served as our Finance Director, from November 2017 to November 2020 and as Subsidiary Financial Controller at Syncona from June 2015 to November 2017. Mr. Coutts has a M.Sc. in Management from the Cass Business School, City University and a B.A. in Politics, Philosophy and Economics from New College, Oxford University and is a qualified chartered accountant.

Karl Peggs, M.D. is one of our founders and has served as our Chief Medical Officer since January 2021. From May 2016 to December 2020, Dr. Peggs served on our board of directors. Dr. Peggs received a M.A. from Cambridge University, a M.B., B.Ch. from Oxford University Medical School and is a Member of the Royal College of Medicine and Fellow of the Royal College of Pathologists.

Sergio Quezada, Ph.D. is one of our founders and has served as our Chief Scientific Officer since April 2020. He has also been a Professor of Cancer Immunology and Immunotherapy at University College London Cancer Institute since January 2011, as well as a Cancer Research UK, or CRUK, senior cancer research fellow since January 2011. Previously, Dr. Quezada co-led the development of novel antibody for the depletion of regulatory T cells for TUSK Therapeutics Ltd., a company focused on developing novel immuno-oncology products. Dr. Quezada holds a Ph.D. from Dartmouth Medical School and a B.S. in Biochemistry and Molecular Biology from the Pontificia Universidad Católica de Chile. From 2004 to 2010, Dr. Quezada completed his post-doctoral training at Memorial Sloan-Kettering Cancer Center.

Non-Executive directors

Edwin Moses, Ph.D. has served as the Chairman and a member of our board of directors since December 2018. He was the Chief Executive Officer of Ablynx N.V., or Ablynx, a biopharmaceutical company, a position he held from March 2006 until Ablynx's acquisition by Sanofi in June 2018. Dr. Moses also served on the board of directors of Ablynx from 2004 until 2018. Dr. Moses received his B.S. and Ph.D. in Chemistry from the University of Sheffield. We believe that Dr. Moses is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive executive experience. Dr. Moses is also currently Chairman of Advantium NV and LabGenius LTD.

Michael F. Giordano, M.D. has served on our board of directors since September 2018. Dr. Giordano has served as a Clinical Advisor and Interim Chief Medical Officer to Epizyme, Inc., or Epizyme, a biopharmaceutical company, from December 2017 to August 2018. From 1999 to 2017, Dr. Giordano worked at Bristol-Myers Squibb Company, a pharmaceutical company, most recently serving as Senior Vice President and Head of Development, Oncology and Immuno-Oncology from February 2012 to February 2017. Dr. Giordano has also served on the board of directors of Epizyme from March 2018 until August 2022 when it was acquired by Ipsen, and on the board of directors of RAPT Therapeutics, Inc. since February 2018. He earned his M.D. and completed his residency and fellowship training at New York Presbyterian-Weill Cornell Medical Center, and received his B.A. in Natural Sciences from The Johns Hopkins University. We believe that Mr. Giordano is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive pharmaceutical experience.

Carsten Boess has served on our board of directors since April 2020. Previously, Mr. Boess was the Executive Vice President of Corporate Affairs at Kiniksa Pharmaceuticals, Ltd., a biotechnology company, from August 2015 until February 2020. Mr. Boess has also served as a director for Rocket Pharmaceuticals, Inc. since January 2016 and Avidity Biosciences, Inc. since April 2020. Mr. Boess received a B.S. and M.S. in Economics and Finance, specializing in Accounting and Finance, from the University of Odense, Denmark. We believe that Mr. Boess is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive executive experience.

Bernhard Ehmer has served on our board of directors since April 2022. He is a veteran biotechnology and pharmaceutical executive with more than three decades in senior leadership roles. He most recently served as CEO of Biotest AG in Germany and also served as chairman of the board of directors at Symphogen A/S, Denmark until its acquisition by Servier SA in June 2020. Prior to this, he worked for ImClone Systems, a wholly owned subsidiary of Eli Lilly, as President of ImClone Systems Inc. in the United States and as managing director in Germany. Before this he was CEO of Fresenius Biotech, where he was instrumental in the EU approval of Removab®, a treatment for malignant ascites. Since May 2022, he has been Chairman of the Supervisory Board of Biotest AG. We believe that Mr. Ehmer is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive executive experience.

Julie O'Neill has served as a member of our board of directors since May 2021. Ms. O'Neill has more than two decades of executive experience in senior leadership roles. From January 2015 to September 2018, Ms. O'Neill served as Executive Vice President, Global Operations at Alexion Pharmaceuticals, Inc., or Alexion, a pharmaceutical company, where she led the Global Operations business including product development, manufacturing, quality, supply chain and global real estate functions. Prior to joining Alexion, she served as Vice President of Operations and General

Manager of Ireland at Gilead Sciences, Inc., a pharmaceutical company, from 2011 to 2014. Ms. O'Neill serves as a member of the board of directors of ICON plc, DBV Technologies S.A., ILC Dover, Advancion (formerly known as Angus Chemical Company) and Hookipa Pharma Inc. She is also on the Board of Ireland's National Institute for Bioprocessing Research & Training. We believe that Ms. O'Neill is qualified to serve on our board of directors because of her experience, qualifications, attributes and skills, including her extensive biotechnology experience.

Board Diversity

The table below provides certain information regarding the diversity of our board of directors as of the date of this Annual Report.

Board Diversity Matrix				
Country of Principal Executive Offices	United Kingdom			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
Total Number of Directors	6			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	5	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	1			
LGBTQ+	1			
Did Not Disclose Demographic Background	0			

Family Relationships

There are no family relationships among any of our executive officers or directors.

B. Compensation.

The following section provides the amount of compensation paid, and benefits in-kind granted, by us and our subsidiaries to our directors, members of our senior management and non-employee directors for services in all capacities to us and our subsidiaries for the year ended December 31, 2023.

Director Compensation

For the year ended December 31, 2023, the table below sets forth the compensation paid to our directors (in thousands):

Name	Salary/Fees	Bonus	Pension Benefit	All Other Compensation	Total
Executive Director					
Iraj Ali	$ 463	$ 119	$ 14	$ 1,102	$ 1,698
Non-Executive Directors					
Carsten Boess	$ 92	-	-	$ 84	$ 176
Bernhard Ehmer	$ 75	-	-	$ 31	$ 106
Edwin Moses	$ 153	-	-	$ 226	$ 379
Julie O'Neill	$ 75	-	-	$ 27	$ 102
Michael Giordano	$ 92	-	-	$ 97	$ 189

Non-Executive Letters of Appointment

The compensation of our non-executive directors is determined by our board of directors as a whole, based, in part, on a review of current practices in other companies. We have entered into appointment letters with our non-executive directors and these agreements provide for an annual fee and a grant of share options under our share incentive plan arrangement. All Directors are subject to re-election annually at the Annual General Meeting.

Employment Agreements

We have entered into employment agreements with our chief executive officer, or CEO, who is our sole executive director, and the wider senior management. Each of these employment agreements provides for an initial annual salary, discretionary annual bonus opportunity and equity incentive opportunities, as well as participation in certain retirement and welfare benefit plans. The agreements provide payment in lieu of notice termination rights and we are required to give six months' prior written notice of a termination of employment. These agreements contain intellectual property and confidentiality provisions which survive termination and also contain 12-month non-competition and non-solicitation restrictive covenants.

Incentive Compensation Program

The board of directors maintains an annual incentive compensation program for all employees. The incentive compensation program is designed to offer incentive compensation to our employees by rewarding the achievement of company goals and specifically measured personal goals that are consistent with and support the achievement of the company goals. The key terms of the incentive compensation program are summarized below.

Administration and Eligibility. The board of directors is responsible for the oversight and administration of the incentive compensation program at a company level and manages this through delegation to the remuneration committee of the board. This remuneration committee is responsible for approving any incentive awards to our chief executive officer and other members of our senior management. The CEO is responsible for approving any incentive awards to other employees, in accordance with parameters set by the remuneration committee.

Form and Determination of Incentive Awards. Incentive award payments are paid in cash. After the end of the plan year under review, the actual achievement of the company and individual goals is determined resulting in the calculation of the individual's total incentive award. Payment of incentive awards is made in February.

Termination of Employment. If a participant in the incentive compensation program gives or receives notice of termination of her or his employment prior to the payment of an incentive award under the incentive compensation program, the employee is not eligible to receive an incentive award.

Amendment. Our board of directors or the remuneration committee of the board, may abolish or alter the incentive compensation program at any time before, during or after a plan year is completed.

Outstanding Equity Awards

The following table summarizes the options that we granted to members of our board of directors and senior management during the year ended December 31, 2023:

	Ordinary Shares Underlying Option Covered		Exercise Price	Expiration Date
Senior Management:				
Iraj Ali	225,024	$	1.21	2/1/2033
Robert Coutts	100,032	$	1.21	2/1/2033
Karl Peggs	100,032	$	1.21	2/1/2033
Sergio Quezada	100,032	$	1.21	2/1/2033
Non-Executive Directors:				
Carsten Boess	25,000	$	0.98	6/27/2033
Bernhard Ehmer	22,500	$	1.21	2/1/2033
Bernhard Ehmer	25,000	$	0.98	6/27/2033
Michael Giordano	25,000	$	0.98	6/27/2033
Edwin Moses	25,000	$	0.98	6/27/2033
Julie O'Neill	22,500	$	1.21	2/1/2033
Julie O'Neill	25,000	$	0.98	6/27/2033

No options were exercised by any members of our board of directors and senior management during the year ended December 31, 2023.

Employee Shares and Options issued prior to IPO

Under our shareholder and subscription agreements, which were effective until the date of IPO, we were authorized to grant equity awards to individuals including a director of and/or a person who is employed by or who directly or indirectly provides consultancy services to us, in the form of D, E, F, G, H, I, J, K, L, M and N ordinary shares, collectively referred to as Employee Shares and share options. All Employee Shares converted into ordinary shares in accordance with the reverse share split implemented on IPO (see Note 1 to our financial statements appearing at the end of this Annual Report). The share options granted prior to IPO were granted pursuant to the terms of the 2020 Share Omnibus Plan, or the 2020 Plan.

Upon and following closing of the IPO, no further equity awards were granted under the 2020 Plan. To the extent outstanding options granted under the 2020 Plan are cancelled, forfeited or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2020 Plan, the number of shares underlying such awards will be available for future grant under our 2021 Omnibus Plan (see below). In anticipation of IPO, we and the holders of Employee Shares entered into individual vesting agreements, or Vesting Agreements, which apply the same terms to vesting of Employee Shares as applied prior to IPO under our pre-IPO Articles of

Association, except that following the IPO Employee Shares that would pre-IPO have converted to deferred shares, will be transferred back to us and cancelled within twelve months of an employee leaving employment with us.

2021 Share Omnibus Plan

In March 2021, the Company's board of directors adopted, and the Company's shareholders approved, the 2021 Share Omnibus Plan, or the 2021 Plan, which became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The 2021 Plan allows the remuneration committee to make equity-based and cash-based incentive awards to our officers, employees, directors and other key persons (including consultants).

We initially reserved 2,572,558 of its ordinary shares for the issuance of awards under the 2021 Plan. The 2021 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by 4% of the outstanding number of ordinary shares on the immediately preceding December 31, or such lesser number of shares as determined by our remuneration committee. This number is subject to adjustment in the event of a sub-division, consolidation, share dividend or other change in our capitalization. The total number of ordinary shares that may be issued under the 2021 Plan was 5,834,006 shares as of December 31, 2023, of which 1,141,189 shares remained available for future grant after taking into account options granted and adding back forfeitures in the period.

2021 Employee Share Purchase Plan

Our 2021 Employee Share Purchase Plan, or ESPP, was adopted by the Board in March 2021 and approved by shareholders in March 2021 and became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The ESPP initially reserved and authorized the issuance of up to a total of 467,738 ordinary shares to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter, by the least of: (i) 1% of the outstanding number of ordinary shares on the immediately preceding December 31; (ii) 467,738 ordinary shares or (iii) such number of shares as determined by the remuneration committee. The number of shares reserved under the ESPP is subject to change in the event of a share split, share dividend or other change in our capitalization. The purpose of the ESPP is to: (i) provide U.S. employees the opportunity to purchase ordinary shares or ADSs at 85% of the fair market value of the ADSs on the offering date or the exercise date, whichever is lower, and (ii) provide UK-based employees with ordinary shares or ADSs under the SIP Plan as further discussed below.

The total number of ordinary shares that had been approved for issue under the ESPP was 877,065 shares as of December 31, 2023. The initial purchase period under the ESPP commenced in February 2022. The Company estimated the fair value of the option component of the ESPP at the date of grant using a Black-Scholes valuation model.

2021 Share Incentive Plan

The Achilles Therapeutics plc Share Incentive Plan, or SIP Plan is a sub plan of the ESPP. This SIP Plan is an HMRC approved Plan for UK tax-paying employees. Under the SIP Plan, eligible employees can receive "Free Shares" within HMRC guidelines, purchase ordinary shares from the market, or Partnership Shares, as well as receive "Matching Shares" which are issued without any consideration payment in connection with an acquisition of Partnership Shares (collectively referred to as "SIP Shares"). For any award of Matching Shares, the Board must specify the ratio of Matching Shares to Partnership Shares. The ratio determined by the Board must not exceed two Matching Shares for every Partnership Share.

There is no minimum service condition on the Partnership Shares, and the participants can sell/transfer the shares after their acquisition from the market. There is a minimum service condition for the Free and Matching Shares that requires the participants to provide continuing service for at least 36 months from the date of grant. If the participants are no longer with the Company or its subsidiaries before the completion of 36 months' service (with the relevant date

determined as the last day of employment), the Free and Matching Shares generally will be 100% forfeited and available for future issuance.

During the year ended December 31, 2023, 394,563 shares were issued under the ESPP. This reduced the number of shares reserved and available to grant under the ESPP to 231,972 shares available to grant as of December 31, 2023.

Employee Shares and SIP Shares

We typically grant incentive shares which vest over a four-year service period with 25% of the award vesting on the first anniversary of the vesting commencement date, and the balance vesting periodically over the remaining three years.

Unvested Employee Shares are forfeited upon the giving or receiving of notice of termination of employment or service relationship in accordance with our Articles (prior to IPO, and in accordance with the Vesting Agreements post-IPO) and 2020 Plan. Before IPO, the forfeited shares were converted into deferred shares, with a repurchase right for a nominal amount in favor of us. As of December 31, 2020, we repurchased 1,509,384 deferred shares with the consideration of £0.01 to each holder for all of the deferred shares held by that holder. As part of our reorganization, 109,058 outstanding deferred shares immediately before the IPO were cancelled upon the IPO, and a single deferred share with a nominal value of £92,451.851 in the capital of the Company was created. As of December 31, 2023, we had one deferred share which could be repurchased by us at any time for nil consideration.

In accordance with the relevant Vesting Agreements, in 2022 and 2023, we cancelled 6,036 shares and 174,595 shares, respectively, that were held by employees who left employment with us since the IPO.

We measure all share-based awards using the fair value on the date of grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We have granted Employee Shares to employees and non-employees with service-based conditions and record expense for these awards using the straight-line method.

IPO Grants

In connection with our IPO and in the ordinary course thereafter, our board of directors granted awards under the 2021 Plan to certain of our employees, representing an aggregate of 897,243 ordinary shares. These awards are one-time grants solely related to the IPO offering and the number of ordinary shares subject to the awards described above were priced at a premium to the market at the time of grant. The exercise price of these options was set at $15.28. Each award is subject to the terms and conditions of the 2021 Plan and an option award agreement entered into with the applicable grantee.

C. Board Practices.

Composition of our Board of Directors

Our board of directors presently has six members. As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors. However, our board of directors has determined that Dr. Moses, Mr. Boess, Dr. Giordano, Ms. O'Neill and Mr. Ehmer, representing five of our six directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of director and that each of these directors is "independent" as that term is defined under Nasdaq rules.

In accordance with our Articles of Association, our board of directors will consist of one class of directors constituting our entire board. At each annual general meeting, the successors to directors will be elected to serve from the time of election and qualification until the subsequent annual meeting following election. Each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal.

Committees of our Board of Directors

Our board of directors has three standing committees: an audit committee, a remuneration committee and a nominating committee. The board has adopted a written charter for each of the committees below that is available to shareholders on our website at https://www.achillestx.com.

Audit Committee

The audit committee is composed of Mr. Boess (Chairman), Dr. Moses and Ms. O'Neill, and assists the board of directors in overseeing our accounting and financial reporting processes. The audit committee consists exclusively of members of our board who are financially literate, and our board of directors has determined that Mr. Boess and Dr. Moses is each an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board of directors has determined that each member of the audit committee is an independent director under Nasdaq listing rules and under Rule 10A-3 under the Exchange Act. Our audit committee meets at least four times per year and oversees and reviews our internal controls, accounting policies and financial reporting, and provides a forum through which our independent registered public accounting firm reports. Our audit committee meets regularly with our independent registered public accounting firm without management present.

The primary functions of the audit committee include:

- recommending the appointment of the independent auditor to shareholders for approval at the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board of directors;
- reviewing and discussing with management and our independent registered public accounting firm our financial statements and our financial reporting process; and
- reviewing, approving or ratifying any related party transactions.

Remuneration Committee

The remuneration committee is composed of Dr. Moses (chairman), Mr. Boess and Dr. Giordano. Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard board member fees. Although foreign private issuers are not required to meet this heightened standard, all of our compensation committee members meet this heightened standard.

The primary functions of the compensation committee include:

- identifying, reviewing, overseeing and proposing policies relevant to the compensation and benefits of our directors and senior management;
- evaluating the performance of senior management in light of such policies and reporting to the board; and
- overseeing and administering our share option plan, equity incentive plan and other benefit plans in operation from time to time.

Nominating Committee

The nominating committee is composed of Dr. Moses (chairman), Mr. Boess and Mr. Giordano.

The primary functions of the nominating committee include:

- drawing up selection criteria and appointment procedures for directors; and
- recommending nominees for appointment to our board of directors and its corresponding committees.

D. Employees.

As of December 31, 2023, 2022 and 2021, we had 215, 242 and 252 employees, respectively.

	As of December 31,		
	2023	2022	2021
Function:			
Research and development	181	208	210
General and administrative	34	34	42
Total	215	242	252
Geography:			
United Kingdom	209	233	243
United States	6	9	9
Total	215	242	252

We have no collective bargaining agreements with our employees and we have not experienced any labor strikes.

E. Share Ownership.

For information regarding the share ownership of our directors and executive officers, please refer to Item 6.B. "Directors, Senior Management and Employees—Compensation," Item 7.A. "Major Shareholders and Related Party Transactions—Major Shareholders" and Item 7.B. "Major Shareholders and Related Party Transactions—Related Party Transactions."

F. Disclosure of a registrant's action to recover erroneously awarded compensation.

Not applicable.

Item 7. Major Shareholders and Related Party Transactions.

A. Major Shareholders.

The following table sets forth information, as of March 1, 2024, regarding the beneficial ownership of our ordinary shares for:

- each beneficial owner of 5% or more of our outstanding ordinary shares;
- each of our directors and members of senior management; and
- all of our directors and senior management as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include ordinary shares that can be acquired within 60 days of March 1, 2024. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable or are exercisable within 60 days of March 1, 2024 or issuable upon the conversion of Class A ordinary shares held by the person. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

The percentage of shares beneficially owned is computed on the basis of 39,879,126 ordinary shares outstanding (including ordinary shares in the form of ADS calculated as set out above) as of March 1, 2024.

To our knowledge, as of March 1, 2024, 39,879,126 ADSs were held by one record holder in the United States, representing approximately 97.06% of our total outstanding shares. The record holder is The Bank of New York Mellon, the depositary of our ADS program. The number of beneficial owners of our ADSs in the United States is likely to be much larger than the number of record holders of our ADSs in the United States.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares, which may be in the form of ADSs, and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

Except as otherwise indicated in the table below, the address of each of the directors, executive officers and named beneficial owners is c/o Achilles Therapeutics plc, 245 Hammersmith Road, London, W6 8PW, United Kingdom.

NAME OF BENEFICIAL OWNER	Number of Ordinary Shares Beneficially Owned (#)	Percentage of Ordinary Shares Beneficially Owned (#)
5% or Greater Shareholders[8]:		
Syncona Portfolio Limited[1]	11,086,909	27.80%
Forbion Capital Fund IV Cooperatief U.A.[2]	2,390,050	5.99%
Entities affiliated with Baker Bros. Advisors LP[3]	3,311,567	8.10%
Entities affiliated with Invus Public Equities, L.P.[4]	2,255,375	5.66%
Executive Officers and Directors:		
Iraj Ali	1,112,325	2.77%
Robert Coutts	269,600	*
Karl Peggs	560,137	1.40%
Sergio Quezada	461,835	1.15%
Edwin Moses[5]	261,250	*
Carsten Boess[6]	111,217	*
Bernhard Ehmer[7]	29,375	*
Michael Giordano[8]	191,085	*
Julie O'Neill[9]	44,375	*
All directors and senior management as a group (9 persons)	3,041,199	7.43%

* Represents beneficial ownership of less than one percent.

1. The information shown is based, in part, upon disclosures jointly filed on a Schedule 13G/A on February 13th, 2024 by Syncona Portfolio Limited, Syncona Holdings Limited, Syncona Investment Management Limited; Syncona Limited; Roel Bulthuis and Christopher Hollowood. Syncona Portfolio Limited is a controlled subsidiary of Syncona Holdings Limited, which in turn is a controlled subsidiary of Syncona Limited. Each of Syncona Holdings Limited and Syncona Limited may be deemed to have voting and dispositive power over the shares held by Syncona Portfolio Limited. Investment and voting decisions with respect to these shares are made by Syncona Portfolio Limited acting upon the recommendation of an investment committee of Syncona Investment Management Limited, also a subsidiary of Syncona Holdings Limited. The members of this investment committee consist of Roel Bulthuis and Chris Hollowood. For the purposes of Section 13 of the Securities Exchange Act 1934 and the associated SEC Schedule 13G form reporting requirement, each of these entities and individuals disclaims beneficial ownership of these shares except to the extent of any pecuniary interest therein. The address for Syncona Investment Management Limited is 2nd Floor, 8 Bloomsbury Street, London WC1B 3SR, United Kingdom. The address for Syncona Portfolio Limited is Frances House, PO Box 273, Sir William Place, St. Peter Port, Guernsey, GY1 3RD, Channel Islands.

2. The information shown is based, in part, upon disclosures filed on a Form 13G/A on February 14th, 2023 by Forbion Capital Fund IV Coöperatief U.A.. or FCF IV. Forbion IV Management B.V., or Forbion Management, the

director of FCF IV, may be deemed to have voting and dispositive power over the shares held by FCF IV. Investment decisions with respect to the common shares held by FCF IV can be made by its investment committee which may delegate such powers to the authorized representatives of Forbion Management. Mssrs. Slootweg, van Osch, Mulder, van Houten, van Deventer, Reithinger, Kersten and Rooswinkel and Boorsma are partners of Forbion Management, which acts as the investment advisor to the directors of FCF IV. Rogier Rooswinkel, who was formerly a member of our board of directors, is a partner of Forbion Management and a member of the investment committee of Forbion Management. Forbion Management disclaims beneficial ownership of the shares, except to the extent of their pecuniary interest therein. The address of FCFIV and Forbion Management are Gooimeer 2-35, 1411 DC Naarden, The Netherlands.

3. The information shown is based, in part, upon disclosures filed on a Form 13G/A on February 14th, 2024 by Baker Bros. Advisors LP, and in part upon disclosures filed on a Form 13G/A on February 14, 2022 by Baker Bros. Advisors LP. The number consists of 2,102,792 Ordinary Shares and 1,208,775 Class A non-voting shares. The Class A non-voting ordinary shares are only convertible to the extent that after giving effect to such conversion the holder thereof, their affiliates and any persons who are members of a Section 13(d) group with the holders or their affiliates would beneficially own in the aggregate, for purposes of Rule 13d-3 under the Exchange Act, no more than 9.99% of the outstanding Ordinary Shares, or the Beneficial Ownership Limitation. By written notice to the Company, each holder of Class A non-voting ordinary shares may from time to time increase the Beneficial Ownership Limitation, applicable to that holder to any other percentage not in excess of 19.9%. Any such increase will not be effective until the 61st day after such notice is delivered to the Company. As a result of this restriction, the number of Ordinary Shares that may be issued upon conversion of the Class A non-voting ordinary shares by the above holders may change depending upon changes in the outstanding Ordinary Shares. We refer to 667, L.P. and Baker Brothers Life Sciences, L.P. together as the Baker Entities. Baker Bros. Advisors LP is the investment advisor of the Baker Entities and has sole voting and dispositive power with respect to the ordinary shares held by the Baker Entities. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. The managing members of Baker Bros. Advisors (GP) LLC are Julian C. Baker and Felix J. Baker and, as such, they may be deemed to have voting and dispositive power with respect to the ordinary shares held by the Baker Entities. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of the ordinary shares held by the Baker Entities except to the extent of their pecuniary interest. The address for both Baker Brothers Life Sciences, L.P. and 667, L.P. is 860 Washington Street, 3rd Floor, New York, New York 10014.

4. Invus Public Equities, L.P. (“Invus PE”) directly holds 2,255,375 shares of Achilles Therapeutics plc consisting of 755,375 ordinary shares and 1,500,000 ordinary shares represented by American Depositary Shares (together the “Shares”). Invus Public Equities Advisors, LLC (“Invus PE Advisors”) controls Invus PE, as its general partner and accordingly, may be deemed to beneficially own the Shares held by Invus PE. The Geneva branch of Artal International S.C.A. (“Artal International”) controls Invus PE Advisors, as its managing member and accordingly, may be deemed to beneficially own the Shares held by Invus PE. Artal International Management S.A. (“Artal International Management”), as the managing partner of Artal International, controls Artal International and accordingly, may be deemed to beneficially own the Shares that Artal International may be deemed to beneficially own. Artal Group S.A. (“Artal Group”), as the sole stockholder of Artal International Management, controls Artal International Management and accordingly, may be deemed to beneficially own the Shares that Artal International Management may be deemed to beneficially own. Westend S.A. (“Westend”), as the parent company of Artal Group, controls Artal Group and accordingly, may be deemed to beneficially own the shares that Artal Group may be deemed to beneficially own. Stichting Administratiekantoor Westend (the “Stichting”), as majority shareholder of Westend, controls Westend and accordingly, may be deemed to beneficially own the Shares that Westend may be deemed to beneficially own. Mr. Amaury Wittouck, as the sole member of the board of the Stichting, controls the Stichting and accordingly, may be deemed to beneficially own the Shares that the Stichting may be deemed to beneficially own. The address for Invus PE and Invus PE Advisors is 750 Lexington Avenue, 30th Floor, New York, NY 10022. The address for Artal International, Artal International Management, Artal Group, Westend and Mr. Wittouck is Valley Park, 44, Rue de la Vallée, L-2661, Luxembourg. The address for the Stichting is Claude Debussylaan, 46, 1082 MD Amsterdam, The Netherlands. The information shown is based, in part, upon disclosures filed on a Schedule 13G on February 13, 2023 by Artal International S.C.A.

5. Consists of: (i) 226,250 of our ordinary shares; and (ii) 35,000 of our ordinary shares issuable upon exercise of options within 60 days of March 1, 2024.

6. Consists of 111,217 of our ordinary shares issuable upon exercise of options within 60 days of March 1, 2024.

7. Consists of 29,375 of our ordinary shares issuable upon exercise of options within 60 days of March 1, 2024.

8. Consists of: (i) 46,663 of our ordinary shares; and (ii) 144,422 of our ordinary shares issuable upon exercise of options within 60 days of March 1, 2024.

9. Consists of 44,375 of our ordinary shares issuable upon exercise of options within 60 days of March 1, 2024.

B. Related Party Transactions.

Within this section, we have calculated the dollar amounts using the historical exchange rate as of the date of each transaction. Other than compensation arrangements described elsewhere in this document, since January 1, 2023, we have engaged in the transactions set out below with our executive officers, directors or holders of more than 5% of our share capital, including their affiliates, which we refer to as our 'related parties'.

In connection with the subscriptions of our preferred shares, we entered into subscription and shareholder agreements containing information rights, among other things, with certain holders of our preferred shares. These shareholder agreements terminated upon the consummation of our IPO, except for the registration rights granted under our registration rights agreement, as more fully described in our prospectus dated March 30, 2021, filed with the SEC pursuant to Rule 424(b), under the heading "Description of share capital and articles of association—Registration rights."

Agreements with Shareholders

In connection with the subscriptions of our preferred shares, we entered into subscription and shareholder agreements containing information rights, among other things, with certain holders of our preferred shares. These shareholder agreements terminated upon the consummation of our IPO, except for the registration rights granted under our registration rights agreement, as more fully described in our prospectus dated March 30, 2021, filed with the SEC pursuant to Rule 424(b), under the heading "Description of share capital and articles of association—Registration rights." We filed a registration statement on Form F-3 on November 28, 2022, that was declared effective by the SEC on November 17, 2022, registering 5,543,454 of our ADSs for Syncona Portfolio Limited in connection with our obligations under the subscription and shareholder agreements.

Agreements with our Senior Management and Directors

We have entered into employment agreements with certain members of our management and service agreements with our non-executive directors and officers. These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers and non-executive directors. The enforceability of the non-competition provisions may be limited under applicable law.

Indemnification Agreements

To the extent permitted by the Companies Act 2006 and in accordance with our Articles, we are empowered to indemnify our directors against any liability they incur by reason of their role. Prior to the completion of our IPO, we obtained and maintain directors' and officers' insurance to insure such persons against certain liabilities. We entered into a deed of indemnity with each of our directors, members of our senior management and other officers. These agreements and our Articles require us to indemnify our directors, members of our senior management and other officers to the fullest extent permitted by law.

Related Party Transaction Policy

We have adopted a related party transaction policy. This policy became effective on March 30, 2021, the date on which our registration statement on Form F-1 in connection with our IPO was declared effective by the SEC. Pursuant to this policy, the audit and risk committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related parties in which the related party has a direct or indirect material interest. For purposes of this policy, a related party is defined as a director, executive director, nominee for director, or greater than 5% beneficial owner of any class of our voting securities, and their immediate family members.

C. Interests of Experts and Counsel.

Not applicable.

Item 8. Financial Information.

A. Consolidated Statements and Other Financial Information.

Consolidated Financial Statements

Our consolidated financial statements are included at the end of this Annual Report in "Item 18. Financial Statements."

Legal Proceedings

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Within the past twelve months, we have not been party to any litigation, arbitration proceedings or administrative proceedings that may have a material effect on our financial condition or profitability, and we are not aware of any such proceedings pending or being threatened.

Dividend Distribution Policy

We have not paid any dividends on our ordinary shares since our inception, and we currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate that we will declare or pay any cash dividends in the foreseeable future. Under English law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

B. Significant Changes.

Not applicable.

Item 9. The Offer and Listing.

A. Offer and Listing Details.

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol "ACHL" since March 31, 2021. Prior to that date, there was no public trading market for our ADSs.

B. Plan of Distribution.

Not applicable.

C. Markets.

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol "ACHL" since March 31, 2021.

D. Selling Shareholders.

Not applicable.

E. Dilution.

Not applicable.

F. Expenses of the Issue.

Not applicable.

Item 10. Additional Information.

A. Share Capital.

Not applicable.

B. Memorandum and Articles of Association.

The information set forth in our prospectus dated March 30, 2021, filed with the SEC pursuant to Rule 424(b), under the headings "Description of share capital and articles of association—Issued share capital," "Description of share capital and articles of association—Ordinary shares," "Description of share capital and articles of association—Class A ordinary shares," "Description of share capital and articles of association—Deferred shares," "Description of share capital and articles of association—Registration rights," "Description of share capital and articles of association—Key provisions of our post-IPO articles of association," "Description of share capital and articles of association—Other relevant UK laws and regulations," "Description of share capital and articles of association—Differences in corporate law," and "Service of process and enforcement of liabilities" is incorporated herein by reference.

C. Material Contracts.

For additional information on our material contracts, please see the sections of this Annual Report titled "Item 4—Information on the Company," "Item 7.A.—Major Shareholders," and "Item 7.B.—Related Party Transactions."

D. Exchange Controls.

There are no governmental laws, decrees, regulations or other legislation in the UK that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ADSs, other than

withholding tax requirements. There is no limitation imposed by the laws of England and Wales or our Articles of Association on the right of non-residents to hold or vote shares.

E. Taxation.

The following summary contains a description of material UK and U.S. federal income tax consequences of the acquisition, ownership and disposition of our ordinary shares or ADSs.

UK Taxation

The following is intended as a general guide to current UK tax law and HM Revenue & Customs, or HMRC, published practice (which is not binding) applying as at the date of this Annual Report (both of which are subject to change at any time, possibly with retrospective effect) relating to the holding of ADSs. It does not constitute legal or tax advice and does not purport to be a complete analysis of all UK tax considerations relating to the holding of ADSs, or all of the circumstances in which holders of ADSs may benefit from an exemption or relief from UK taxation. It is written on the basis that we do not (and will not) directly or indirectly at any time derive 75% or more of our qualifying asset value from UK land, and that we are and will remain solely resident in the UK for tax purposes and will therefore be subject to the UK tax regime and not the U.S. tax regime save as set out above under "Material U.S. Federal Income Tax Considerations for U.S. Holders."

Except to the extent that the position of non-UK resident persons is expressly referred to, this guide relates only to persons who are resident (and, in the case of individuals, domiciled or deemed domiciled) for tax purposes solely in the UK and do not have a permanent establishment, branch or agency (or equivalent) in any other jurisdiction with which the holding of the ADSs is connected, or UK Holders, who are absolute beneficial owners of the ADSs (and do not hold the ADSs through an Individual Savings Account or a Self-Invested Personal Pension) and any dividends paid in respect of the ADSs or underlying ordinary shares (where the dividends are regarded for UK tax purposes as that person's own income) and who hold their ADSs as investments.

This guide may not relate to certain classes of UK Holders, such as (but not limited to):

- persons who are connected with us;
- financial institutions;
- insurance companies;
- charities or tax-exempt organizations;
- collective investment schemes;
- pension schemes;
- market makers, intermediaries, brokers or dealers in securities;
- persons who have (or are deemed to have) acquired their ADSs by virtue of an office or employment or who are or have been our officers or employees or any of our affiliates; and
- individuals who are subject to UK taxation on a remittance basis or to whom split-year treatment applies.

The decision of the First-tier Tribunal (Tax Chamber) in HSBC Holdings PLC and The Bank of New York Mellon Corporation v HMRC (2012) cast some doubt on whether a holder of a depositary receipt is the beneficial owner of the underlying shares. However, based on published HMRC guidance we would expect that HMRC will regard a holder of ADSs as holding the beneficial interest in the underlying shares and therefore these paragraphs assume that a holder of ADSs is the beneficial owner of the underlying ordinary shares and any dividends paid in respect of the underlying ordinary shares (where the dividends are regarded for UK purposes as that person's own income) for UK direct tax purposes.

THESE PARAGRAPHS ARE A SUMMARY OF CERTAIN UK TAX CONSIDERATIONS AND ARE INTENDED AS A GENERAL GUIDE ONLY. IT IS RECOMMENDED THAT ALL HOLDERS OF ADSs OBTAIN ADVICE AS TO THE CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF THE ADSs IN THEIR OWN PARTICULAR CIRCUMSTANCES FROM THEIR OWN TAX ADVISORS. IN PARTICULAR, NON-UK RESIDENT OR DOMICILED PERSONS OR PERSONS SUBJECT TO TAXATION IN ANY JURISDICTION OTHER THAN THE UK ARE ADVISED TO CONSIDER THE POTENTIAL IMPACT OF ANY RELEVANT DOUBLE TAXATION AGREEMENTS.

Dividends

Dividend Distribution Policy

We have not paid any dividends on our ordinary shares since our inception, and we currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate that we will declare or pay any cash dividends in the foreseeable future. Under English law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

Withholding Tax

Dividends that we pay will not be subject to any withholding or deduction for or on account of UK tax.

Income Tax

An individual UK Holder may, depending on his or her particular circumstances, be subject to UK tax on dividends received from us. An individual holder of ADSs who is not resident for tax purposes in the UK should not be chargeable to UK income tax on dividends received from us unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the UK through a branch or agency to which the ADSs are attributable. There are certain exceptions for trading in the UK through independent agents, such as some brokers and investment managers.

Dividend income is treated as the top slice of the total income chargeable to UK income tax for an individual UK Holder. An individual UK Holder who receives a dividend in the 2023/2024 tax year will be entitled to a dividend tax-free allowance of £1,000. However, the UK government has announced that the dividend tax-free allowance of £1,000 will be reduced to £500 with effect from April 2024. Income within the dividend tax-free allowance counts towards an individual's basic, higher or additional rate limits and may, therefore, affect the level of income tax personal allowance to which they are entitled. Dividend income received in excess of the dividend tax-free allowance will (subject to the availability of any income tax personal allowance) be charged at 8.75% to the extent the excess amount falls within the basic rate band, 33.75% to the extent the excess amount falls within the higher rate band, and 39.35% to the extent the excess amount falls within the additional rate band.

Corporation Tax

A corporate holder of ADSs who is not resident for tax purposes in the UK should not be chargeable to UK corporation tax on dividends received from us unless it carries on (whether solely or in partnership) a trade in the UK through a permanent establishment to which the ADSs are attributable.

Corporate UK Holders should not be subject to UK corporation tax on any dividend received from us so long as the dividends qualify for exemption, which should be the case, although certain conditions must be met. It should be noted that the exemptions, whilst of wide application, are not comprehensive and are subject to anti-avoidance rules. If the conditions for the exemption are not satisfied, such anti-avoidance provisions apply, or such UK Holder elects for an

otherwise exempt dividend to be taxable, UK corporation tax will be chargeable on the amount of any dividends at the current rate of 25% for companies with profits of more than £250,000, or 19% for companies with profits not exceeding £50,000 with a marginal relief applying to profits between £50,000 and £250,000, in each case for the 2023/2024 tax year.

Chargeable Gains

A disposal or deemed disposal of ADSs by a UK Holder may, depending on the UK Holder's circumstances and subject to any available exemptions or reliefs (such as the annual exemption), give rise to a chargeable gain or an allowable loss for the purposes of UK capital gains tax (for individual UK Holders) and corporation tax on chargeable gains (for corporate UK Holders).

If an individual UK Holder who is subject to UK income tax at either the higher or the additional rate is liable to UK capital gains tax on the disposal of ADSs, the current applicable rate will be 20% (for the tax year 2023/2024). For an individual UK Holder who is subject to UK income tax at the basic rate and liable to UK capital gains tax on such disposal, the current applicable rate would be 10% (for the tax year 2023/2024), save to the extent that any capital gains when aggregated with the UK Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the capital gains tax rate currently applicable to the excess would be 20% (for the tax year 2023/2024).

If a corporate UK Holder is or becomes liable to UK corporation tax on the disposal (or deemed disposal) of ADSs, the main rate of UK corporation tax would apply (currently at 25% for companies with profits of more than £250,000 or 19% for companies with profits not exceeding £50,000 with a marginal relief applying to profits between £50,000 and £250,000, in each case, for the 2023/2024 tax year).

Any chargeable gain (or allowable loss) will generally be calculated by reference to the consideration received for the disposal of the ADSs less the allowable cost to the UK Holder of acquiring such ADSs.

A holder of ADSs that is not resident for tax purposes in the UK and, in the case of an individual holder, not temporarily non-resident, should not normally be liable to UK capital gains tax or corporation tax on chargeable gains on a disposal (or deemed disposal) of ADSs, unless the person is carrying on (whether solely or in partnership) a trade, profession or vocation in the UK through a branch or agency (or, in the case of a corporate holder of ADSs, through a permanent establishment) to which the ADSs are attributable. However, an individual holder of ADSs who has ceased to be resident for tax purposes in the UK or is treated as resident outside the UK for the purposes of a double taxation treaty for a period of five years or less and who disposes of ADSs during that period of temporary non-residence may be liable on his or her return to the UK (or upon ceasing to be regarded as resident outside the UK for the purposes of any relevant double taxation treaty) to UK tax on any capital gain realized (subject to any available exemption or relief).

Stamp Duty and Stamp Duty Reserve Tax

The discussion below relates to the holders of our ordinary shares or ADSs wherever resident, however it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries.

Issue of Ordinary Shares

As a general rule (and except in relation to depositary receipt systems and clearance services (as to which see below)), no UK stamp duty or stamp duty reserve tax, or SDRT, is payable on the issue of the ordinary shares underlying the ADSs.

Transfer of Ordinary Shares

An unconditional agreement to transfer ordinary shares will normally give rise to a charge to SDRT at the rate of 0.5% of the amount or value of the consideration payable for the transfer unless the transfer is to a connected company and in which case market value may apply. The purchaser of the shares is liable for the SDRT. Transfers of ordinary shares by way of written instrument of transfer are generally also subject to stamp duty at the rate of 0.5% of the amount or value of the consideration given for the transfer (rounded up to the nearest £5.00), similarly where the transfer is to a connected company where market value may apply. Stamp duty is normally paid by the purchaser. The charge to SDRT will be cancelled or, if already paid, repaid (generally with interest), where a transfer instrument has been duly stamped within six years of the charge arising, (either by paying the stamp duty or by claiming an appropriate relief) or if the instrument is otherwise exempt from stamp duty.

Clearance Services and Depositary Receipts

Under current UK tax law (including certain provisions of the Finance Bill 2023-24 which have been given temporary statutory effect from January 1, 2024 until the Finance Bill 2023 - 2024 has received royal assent), no UK SDRT (or, where effected by a written instrument, UK stamp duty) should generally be payable in respect of an issue or transfer of ordinary shares or an unconditional agreement to transfer ordinary shares to a clearance service or a depositary receipt system (including to a nominee or agent for, a person whose business is or includes the issue of depositary receipts or the provision of clearance services) where the transfer is carried out for the purpose of raising new capital unless the clearance service has made and maintained an election under section 97A of the UK Finance Act 1986, or a section 97A election. It is understood that HMRC regards the facilities of DTC as a clearance service for these purposes and we are not aware of any section 97A election having been made by the DTC.

Any stamp duty or SDRT payable on a transfer of ordinary shares to a depositary receipt system or clearance service or in respect of a transfer within a depositary receipt system or clearance service, will strictly be accountable by the clearance service or depositary receipt system operator or their nominee, as the case may be, but will in practice generally be paid by the transferors or participants in the clearance service or depositary receipt system. Specific professional advice should be sought before incurring or reimbursing the costs of a UK stamp duty or UK SDRT charge in any circumstances.

Issue or Transfers of ADSs

No UK stamp duty or SDRT should be payable on the issue of ADSs in the Company.

No UK stamp duty or SDRT should be required to be paid in respect of a paperless transfer of ADSs through the facilities of DTC, provided that no section 97A election has been made and maintained by DTC, and such ADSs are held through DTC at the time of any agreement for their transfer. We are not aware of any section 97A election having been made by the DTC.

U.S. Taxation

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of acquiring, owning and disposing of our ordinary shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that is an initial purchaser of the ordinary shares or ADSs pursuant to the offering and that holds our ordinary shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate or gift tax consequences, alternative minimum tax consequences, the potential application of the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;

- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- persons holding ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- tax-exempt entities or government organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the Code (as defined below), respectively;
- S corporations, partnerships (including entities or arrangements classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or persons that will hold our ordinary shares or ADSs through such an entity;
- regulated investment companies, grantor trusts or real estate investment trusts;
- persons that own or are deemed to own 10% or more of the voting power or value of all classes of our ordinary shares or ADSs;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons subject to Section 451(b) of the Code; and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of acquiring, holding and disposing of ordinary shares or ADSs.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between the UK and the United States, all as of the date hereof, changes to any of which may affect the tax consequences described herein-possibly with retroactive effect. There can be no assurances that the Internal Revenue Service, or the IRS, will not take a contrary or different position concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares or ADSs or that such a position would not be sustained by a court. We have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax considerations relating to the purchase, ownership or disposition of our ordinary shares or ADSs. Holders should consult their own tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of our ordinary shares or ADSs in their particular circumstances.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our ordinary shares or ADSs and is:

(i) An individual who is a citizen or resident of the United States;

(ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

(iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

(iv) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Accordingly, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS and no gain or loss will generally be recognized upon an exchange of the ADSs for ordinary shares.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a "passive foreign investment company," or PFIC.

PERSONS CONSIDERING AN INVESTMENT IN ORDINARY SHARES OR ADSs SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEM RELATING TO THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ORDINARY SHARES OR ADSs, INCLUDING THE APPLICABILITY OF U.S. FEDERAL, STATE, LOCAL AND NON-U.S. TAX LAWS.

Passive Foreign Investment Company Rules

If we are classified as a passive foreign investment company in any taxable year, in which a U.S. Holder holds the ordinary shares or ADSs, the U.S. Holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (such as interest income), or the income test; or
- at least 50% of the value of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income, or the asset test.

We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other entity treated as a corporation for U.S. federal income tax purposes, the equity of which we own, directly or indirectly, 25% or more (by value).

We believe that we were classified as a PFIC for our taxable year ended December 31, 2023. Based on the current and expected composition of our income and assets and the value of our assets, we expect to be a PFIC for the current taxable year ending December 31, 2024. However, no assurances regarding our PFIC status can be provided for any past, current or future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. As a result, our PFIC status may change from year to year. Subject to certain exceptions, for purposes of the asset test, if we are treated as a non-publicly traded CFC for the year being tested for purposes of the PFIC rules (which is determined, under certain proposed Treasury Regulations that are not yet effective, based on whether such shares and ADSs are publicly traded for the majority of days during the year), the value of our assets for purposes of the asset test will be measured by the adjusted tax basis of our assets, which could increase the likelihood that we are treated as a PFIC. If we are a publicly traded CFC or not a CFC for such year, the value of our assets generally will be determined by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. The income test depends on the nature and composition of our income. The composition of our income and assets is also affected by how fast we spend the cash we raise in any offering.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless: (i) we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules; or (ii) the U.S. Holder makes a Qualified Electing Fund Election, or QEF Election, as discussed below, with respect to all taxable years during such U.S. Holder's holding period in which we are a PFIC. If the "deemed sale" election is made, a U.S. Holder will be deemed to have sold the ordinary shares or ADSs the U.S. Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder's ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. Holder receives from us or any gain from an actual sale or other disposition of the ordinary shares or ADSs. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be a PFIC and such election becomes available.

For each taxable year we are treated as a PFIC with respect to a U.S. Holder, the U.S. Holder will be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including, under certain circumstances, a pledge) of ordinary shares or ADSs, unless: (i) such U.S. Holder makes a QEF Election as discussed below; or (ii) our ordinary shares or ADSs constitute "marketable" securities, and such U.S. Holder makes a mark-to-market election as discussed below. Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions the U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder's holding period for the ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder's holding period for the ordinary shares or ADSs;
- the amount allocated to the taxable year of the excess distribution or disposition, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year for individuals or corporations, as appropriate, and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ordinary shares or ADSs cannot be treated as capital gains, even if a U.S. Holder holds the ordinary shares or ADSs as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ordinary shares or ADSs. A U.S. Holder may avoid the general tax treatment for PFICs described above by electing to treat us as a "qualified electing fund" under Section 1295 of the Code, or QEF, for each of the taxable years during the U.S. Holder's holding period that we are a PFIC. If a QEF election is not in effect for the first taxable year in the U.S. Holder's holding period in which we are a PFIC, a QEF election generally can only be made if the U.S. Holder elects to make an applicable deemed sale or deemed dividend election on the first day of its taxable year in which the PFIC becomes a QEF pursuant to the QEF election. The deemed sale or deemed dividend recognized with respect to such an election would be subject to the general tax treatment of PFICs discussed above. We intend to determine our PFIC status at the end of each taxable year and to satisfy any applicable record keeping and reporting requirements that apply to a QEF, and will endeavor to provide to U.S. Holders, for each taxable year

that we determine we are a PFIC, a PFIC Annual Information Statement containing information necessary for a U.S. Holder to make a QEF Election with respect to us. We may elect to provide such information on our website. However, U.S. Holders should be aware that we can provide no assurances that we will provide any such information relating to any of our subsidiaries that are PFICs.

If a U.S. Holder makes a QEF election with respect to a PFIC, it will be taxed currently on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is a PFIC, even if no distributions were received. Any distributions we make out of our earnings and profits that were previously included in such a U.S. Holder's income under the QEF election would not be taxable to such U.S. Holder. Such U.S. Holder's tax basis in its ordinary shares or ADSs would be increased by an amount equal to any income included under the QEF election and decreased by any amount distributed on the ordinary shares or ADSs that is not included in its income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of its ordinary shares or ADSs in an amount equal to the difference between the amount realized and its adjusted tax basis in the ordinary shares or ADSs, each as determined in U.S. dollars. Once made, a QEF election remains in effect unless invalidated or terminated by the IRS or revoked by the shareholder. A QEF election can be revoked only with the consent of the IRS. A U.S. Holder will not be currently taxed on the ordinary earnings and net capital gain of a PFIC with respect to which a QEF election was made for any taxable year of the non-U.S. corporation that such corporation is not classified as a PFIC. Each U.S. Holder should consult its tax advisor regarding the availability of, and procedure for making, any deemed sale, deemed dividend or QEF election.

Alternatively, U.S. Holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares or ADSs by making a mark-to-market election with respect to the ordinary shares or ADSs, provided that the ordinary shares or ADSs are "marketable." The ordinary shares or ADSs will be marketable if they are "regularly traded" on certain U.S. stock exchanges or on a foreign stock exchange that meets certain conditions. For these purposes, the ordinary shares or ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs are listed on Nasdaq, which is a qualified exchange for these purposes. Consequently, if the ADSs remain listed on Nasdaq and are regularly traded, and you are a U.S. Holder of the ADSs, we expect the mark-to-market election would be available to you if we are a PFIC. Each U.S. Holder should consult its tax advisor as to whether a mark-to-market election is available or advisable with respect to the ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares or ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in the ordinary shares or ADSs at that time. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the ordinary shares or ADSs over the fair market value of the ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other taxable disposition of the ordinary shares or ADSs will be treated as ordinary income, and any losses incurred on a sale or other taxable disposition of the shares or ADSs will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS, unless the ordinary shares or ADSs cease to be marketable.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable." As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of the lower-tier PFICs. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an Annual Report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the Annual Report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the Annual Report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.

Taxation of Distributions

Subject to the discussion above under "Passive Foreign Investment Company Rules," distributions paid on our ordinary shares or ADSs, other than certain pro rata distributions of ordinary shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of earnings and profits will be non-taxable to the U.S. Holder to the extent of, and will be applied against and reduce, the U.S. Holder's adjusted tax basis in the ordinary shares or the ADSs. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. Holder as either long-term or short-term capital gain depending upon whether the U.S. Holder has held the ordinary shares or the ADSs for more than one year as of the time such distribution is received. However, because we may not calculate our earnings and profits under U.S. federal income tax principles (if we are not or cease to be a PFIC), we expect that distributions generally will be reported to U.S. Holders as dividends, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income" if we are a "qualified foreign corporation" and certain other requirements are met. However, the qualified dividend income treatment will not apply if we are treated as a PFIC with respect to the U.S. Holder for either the taxable year in which the dividend was paid or the preceding taxable year. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain pro rata distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution.

For foreign tax credit limitation purposes, our dividends will generally be treated as passive category income. Because no UK income taxes will be withheld from dividends on ordinary shares or ADSs, there will be no creditable foreign taxes associated with any dividends that a U.S. Holder will receive. The rules governing foreign tax credits are complex and U.S. Holders should therefore consult their tax advisors regarding the effect of the receipt of dividends for foreign tax credit limitation purposes.

Sale or Other Taxable Disposition of Ordinary Shares and ADSs

Subject to the discussion above under "Passive Foreign Investment Company Rules," gain or loss realized on the sale or other taxable disposition of our ordinary shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares or ADSs for more than one year at the time of sale or other taxable disposition. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares or ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. Subject to the PFIC rules described above, long-term capital gains recognized by certain non-corporate U.S. Holders (including individuals) will generally be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ordinary shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis U.S. Holder or an accrual basis U.S. Holder that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis U.S. Holder that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date , and such gain or loss will generally constitute ordinary income or loss.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless: (i) the U.S. Holder is a corporation or other exempt recipient; or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding on a duly executed IRS Form W-9 or otherwise establishes an exemption.

The amount of any backup withholding from a payment to a U.S. Holder may be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

Information Reporting and Information with Respect to Foreign Financial Assets

Certain U.S. Holders may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) to report a transfer of property (including cash) to us. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement and the period of limitations on assessment and collection of U.S. federal income taxes will be extended in the event of a failure to comply. In addition, certain U.S. Holders who are individuals (and, under regulations, certain entities) may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs and with respect to their possible obligation to file IRS Form 926.

F. Dividends and Paying Agents.

Not applicable.

G. Statement by Experts.

Not applicable.

H. Documents on Display.

We are subject to certain reporting requirements of the Exchange Act. As a "foreign private issuer," we are exempt from the rules under the Exchange Act prescribing certain disclosure and procedural requirements for proxy solicitations, and our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act, with respect to their purchases and sales of shares. In addition, we are not required to file reports and Financial Statements with the SEC as frequently or as promptly as companies that are not foreign private issuers whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within 4 months after the end of each fiscal year, an Annual Report on Form 20-F containing Financial Statements audited by an independent accounting firm and interactive data comprising Financial Statements in extensible business reporting language. We publish unaudited interim financial information after the end of each quarter. We furnish this quarterly financial information to the SEC under cover of a Form 6-K.

The SEC maintains a website at http://www.sec.gov that contains reports and other information regarding registrants that are required to file electronically with the SEC.

I. Subsidiary Information.

Not applicable.

Item 11. Quantitative and Qualitative Disclosures about Market Risk.

Market risk represents the risk that changes in market prices, such as foreign exchange rates, interest rates or equity prices, will affect Achilles's results of operations or the value of the financial instruments held. Achilles is exposed to both foreign currency exchange risk and interest rate risks.

Foreign Currency Exchange Risk

We maintain our financial statements in our functional currency, which is pound sterling. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net income (loss) for the respective periods. We recorded foreign currency losses of $1.0 million for the year ended December 31, 2023 and foreign currency gains of $3.8 million and $2.5 million, for the years ended December 31, 2022, and 2021, respectively. With our functional currency being British Pounds Sterling, our results are exposed to fluctuations to this and the U.S. dollar. These exchange gains arising from foreign currency transactions are included in other income (expense), net in the statements of operations and comprehensive loss.

For financial reporting purposes our financial statements have been presented in U.S. dollars, the reporting currency. The financial statements of entities are translated from their functional currency into the reporting currency as follows: assets and liabilities are translated at the exchange rates at the balance sheet dates, revenue and expenses are translated at the average exchange rates and shareholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net loss but are included as a foreign exchange adjustment to other comprehensive loss, a component of shareholders' equity.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

Interest Rate Risk

As of December 31, 2023, we had cash and cash equivalents of $131.5 million. Our exposure to interest rate sensitivity is impacted by changes in the underlying UK and U.S. bank interest rates. Our surplus cash has been invested in interest-bearing savings accounts and money market funds from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

As of December 31, 2023 and 2022, we had no debt outstanding and are therefore not subject to interest rate risk related to debt.

Item 12. Description of Securities Other than Equity Securities.

A. Debt Securities.

Not Applicable.

B. Warrants and Rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares.

The Bank of New York Mellon, as depositary, registers and delivers ADSs. Each ADS represents one deposited share with The Bank of New York Mellon, as custodian for the depositary in the UK. Each ADS also represents any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered is located at 240 Greenwich Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at 240 Greenwich Street, New York, New York 10286.

A deposit agreement among us, the depositary and the ADS holders sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	*For:*
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancelation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$0.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

None.

Item 15. Controls and Procedures.

A. Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2023.

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2023, our disclosure controls and procedures were effective.

B. Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the framework in *Internal Control—Integrated Framework 2013* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. For so long as we qualify as an "emerging growth company" as defined under the JOBS Act, our registered public accounting firm is not required to issue an attestation report on our internal control over financial reporting.

D. Changes in Internal Control over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to further strengthen controls and increase efficiency, while ensuring that we maintain an effective internal control environment.

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal year 2023, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved.]

Item 16A. Audit Committee Financial Expert.

Our board of directors has determined that Carsten Boess and Edwin Moses are audit committee financial experts as defined by SEC rules and have the requisite financial sophistication under the applicable Nasdaq rules and regulations and that Carsten Boess and Edwin Moses are independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of The Nasdaq Stock Market.

Item 16B. Code of Ethics.

We have adopted a written code of business conduct and ethics, or code of conduct, which outlines the principles of legal and ethical business conduct under which we do business. The code of conduct applies to all of our and our subsidiaries' employees, independent contractors, senior management and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The full text of the code of conduct is available on our website at *www.achillestx.com*. If we make any amendment to our code of conduct or grant any waivers, including any implicit waiver, from a provision of that code, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC.

Item 16C. Principal Accountant Fees and Services.

KPMG LLP, or KPMG, has served as our independent registered public accounting firm for the years ending December 31, 2023 and 2022. The following table sets out the aggregate fees for professional audit services and other services rendered by KPMG and their member firms and/or affiliates in 2023 and 2022 (in thousands):

	Year Ended December 31,	
Description	**2023**	**2022**
Audit fees	$ 862	$ 869
Fees for tax and other assurance services	-	-
Total	$ 862	$ 869

Audit fees relate to the audit of the financial statements as set out in this Annual Report, and other professional services provided in connection with the statutory and regulatory filings or engagements, including fees for the review of our interim financial information.

The Audit Committee has approved the audit fees for the years 2023 and 2022. The Audit Committee monitors compliance with the UK and U.S. rules on non-audit services provided by an independent registered public accounting firm. On a yearly basis, the Audit Committee pre-approves non-audit services performed by the independent registered public accounting firm up to a limit in line with UK regulation.

Item 16D. Exemptions from the Listing Standards for Audit Committees.

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant.

Not applicable.

Item 16G. Corporate Governance.

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with Nasdaq listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events;
- exemption from Section 16 rules requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades in a short period of time, which will provide less data in this regard than shareholders of U.S. companies that are subject to the Exchange Act;
- exemption from the Nasdaq requirement requiring disclosure of any waivers of the Code of Business Conduct and Ethics, or Code of Ethics, for directors and officers;
- exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans;
- exemption from the requirement that our audit committee have review and oversight over all "related party transactions," as defined in Item 7.B of Form 20-F;
- exemption from the requirement that our board have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- exemption from the requirement to have independent director oversight of director nominations.

We intend to follow UK corporate governance practices in lieu of Nasdaq corporate governance requirements as follows:

- We do not intend to follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under English law. In accordance with generally accepted business practice, our Articles of Association will provide alternative quorum requirements that are generally applicable to meetings of shareholders; and
- We do not intend to follow Nasdaq Rule 5605(b)(2), which requires that independent directors regularly meet in executive sessions where only independent directors are present. Our independent directors may choose to meet in executive sessions at their discretion.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq's Notification of Noncompliance requirement (Nasdaq Rule 5625) and the Voting Rights requirement (Nasdaq Rule 5640). Further, we must have an audit committee that satisfies Nasdaq Rule 5605(c)(3), which addresses audit committee responsibilities and authority and requires that the audit committee consist of members who meet the independence requirements of Nasdaq Rule 5605(c)(2)(A)(ii).

Because we are a foreign private issuer, our directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and Nasdaq listing rules.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

Item 16H. Mine Safety Disclosure.

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Item 16J. Insider Trading Policies.

Not applicable.

Item 16K. Cybersecurity.

The Company uses, stores, and processes data for and about its patients, employees, partners, and suppliers. We also own valuable intellectual property that we use to operate our business and differentiates us from competitors. Protecting our know-how and the information with which we are entrusted from cybersecurity threats is important to the position of trust we maintain with our patients, investors, and other stakeholders, as well as our overall business strategy, results of operations, and financial condition.

The Company, under the oversight of the audit committee of the board of directors, has implemented and maintains an enterprise risk management program that includes a cybersecurity risk management program designed to identify, assess, and mitigate critical risks from cybersecurity threats. Our cybersecurity risk management program incorporates a number of components, including, but not limited to, periodic information security risk assessments and other vulnerability analyses, and ongoing monitoring of critical risks from cybersecurity threats using automated tools. Additionally, we have implemented an employee education and training program, offered during onboarding and on an annual basis thereafter, that is designed to raise awareness of cybersecurity threats across functions. To support our cybersecurity risk management program, we leverage a managed service provider, or MSP, and also engage with other third-party providers and consultants as appropriate, including engagement of third parties to perform periodic penetration testing and to provide incident response services as required. We have a process to monitor and address identified cyber risks.

As part of our cybersecurity risk management program, we maintain processes related to third-party vendor risk management, including a framework for managing third-party information security risks. This framework, which applies to certain third-party vendors and service providers who have access to our systems and/or process our sensitive information, includes a process for assessing and reviewing the cybersecurity practices of such third parties prior to onboarding, including, as appropriate, through review of System and Organization Controls (SOC) reports and security questionnaires, and the inclusion of cybersecurity requirements in contracts.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, as is the case for other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents relating to our and our third-party vendors' information systems. For more information, please see Item 3, part D - Risk Factors.

Governance Related to Cybersecurity Risks

Our Director of Information Technology, or IT, in coordination with the IT team and under the supervision of our Chief Financial Officer, is responsible for the establishment and maintenance of our cybersecurity risk management program, including the day-to-day oversight of the assessment and management of cybersecurity risks. Our Director of IT reports directly to our Chief Financial Officer. The individual who currently holds the title of Director of IT holds a bachelor of science in Computer Science and Networking and has over 13 years of experience in IT roles at mature enterprises across industry sectors including pharmaceutical, telecoms and insurance. Our Chief Financial Officer reviews the potential financial impact of identified cybersecurity risks and provides oversight of risk mitigation processes to address the assessed risks on an ongoing basis. Our Chief Legal Officer/General Counsel reviews our cybersecurity risk management program to ensure it is designed to account for the Company's obligations under

applicable privacy regulations and laws, including those related to notification requirements that could be triggered by a cybersecurity incident.

The Director of IT meets with the Chief Financial Officer or other members of the management team, including the Chief Legal Officer/General Counsel, periodically to discuss and review our cybersecurity risk management processes and to address matters related to potential cybersecurity and information technology risks, with input from the Company's third-party MSP as appropriate.

Our board of directors, directly and through its committees, has responsibility for our enterprise risk management program, including as pertains to cybersecurity risks. The board of directors has, pursuant to the audit committee charter, delegated oversight of the Company's cybersecurity risk management program to the audit committee. On a periodic basis, the Director of IT provides reports to the audit committee on cybersecurity matters and associated risks. The audit committee's review process includes consideration of information about the sources and nature of cybersecurity risks the Company faces, how management assesses the materiality of such risks – including in terms of likelihood and severity of impact – progress on vulnerability remediation, and current developments in the cybersecurity threat landscape. The chair of the audit committee periodically reports on risk management to the full board of directors.

PART III

Item 17. Financial Statements.

We have elected to provide financial statements pursuant to Item 18.

Item 18. Financial Statements.

The financial statements required under this Item 18 are filed as part of this Annual Report beginning on page 174 The audit report of KPMG LLP, independent registered public accounting firm, is included herein preceding the financial statements.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Achilles Therapeutics Plc

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Achilles Therapeutics Plc and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, statement of shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

Reading, United Kingdom
April 4, 2024

ACHILLES THERAPEUTICS PLC

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 131,539	$ 173,338
Prepaid expenses and other current assets	14,094	23,242
Total current assets	145,633	196,580
Non-current assets:		
Property and equipment, net	9,171	12,399
Operating lease right of use assets	4,372	8,081
Deferred tax assets	41	251
Restricted cash	33	33
Other assets	2,206	3,014
Total non-current assets	15,823	23,778
TOTAL ASSETS	$ 161,456	$ 220,358
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,629	$ 5,187
Income taxes payable	—	326
Accrued expenses and other liabilities	7,828	8,292
Operating lease liabilities—current	3,539	4,188
Total current liabilities	16,996	17,993
Non-current liabilities:		
Operating lease liabilities-non-current	1,076	4,388
Other long-term liability	1,015	933
Total non-current liabilities	2,091	5,321
Total liabilities	19,087	23,314
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Ordinary shares, £0.001 par value; 41,082,948 and 40,932,727 shares authorized, issued and outstanding at December 31,2023 and 2022, respectively	54	54
Deferred shares, £92,451.851 par value, one share authorized, issued and outstanding at December 31, 2023 and 2022	128	128
Additional paid in capital	415,210	408,844
Accumulated other comprehensive income	(13,071)	(21,695)
Accumulated deficit	(259,952)	(190,287)
Total shareholders' equity	142,369	197,044
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 161,456	$ 220,358

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

ACHILLES THERAPEUTICS PLC

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Years ended December 31,		
	2023	**2022**	**2021**
OPERATING EXPENSES:			
Research and development	$ 58,246	$ 57,263	$ 42,224
General and administrative	17,009	21,120	21,971
Total operating expenses	75,255	78,383	64,195
Loss from operations	(75,255)	(78,383)	(64,195)
OTHER INCOME (EXPENSE), NET:			
Other income (expense)	6,081	7,318	3,133
Total other income (expense), net	6,081	7,318	3,133
Loss before provision for income taxes	(69,174)	(71,065)	(61,062)
Provision for income taxes	(491)	(111)	(37)
Net loss	(69,665)	(71,176)	(61,099)
Other comprehensive income:			
Foreign exchange translation adjustment	8,624	(28,331)	(5,686)
Comprehensive loss	$ (61,041)	$ (99,507)	$ (66,785)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (1.74)	$ (1.82)	$ (2.13)
Weighted average ordinary shares outstanding—basic and diluted	39,973,059	39,139,693	28,654,760

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

ACHILLES THERAPEUTICS PLC

Consolidated Statements of Shareholders' Equity

(in thousands, except share amounts)

	Convertible preferred shares													
	Series A $0.001 par value		Series B $0.001 par value		Series C $0.001 par value		Ordinary $0.001 par value		Deferred shares $0.001 par value		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2020	28,250,000	$36	52,192,070	$66	24,412,603	$32	4,389,920	$6	30,521	$—	$234,922	$12,322	$(58,012)	$189,372
Conversion of ordinary shares into deferred shares	—	—	—	—	—	—	(18,262)	—	78,537	—	—	—	—	—
Effect of corporate reorganization including conversion of preferred share to ordinary share	(28,250,000)	(36)	(52,192,070)	(66)	(24,412,603)	(32)	26,481,831	34	(109,057)	128	(28)	—	—	—
Issuance of ordinary shares (Note 7)	—	—	—	—	—	—	9,750,000	14	—	—	160,610	—	—	160,624
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	6,317	—	—	6,317
Unrealized loss on foreign currency translation	—	—	—	—	—	—	—	—	—	—	—	(5,686)	—	(5,686)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(61,099)	(61,099)
Balance at December 31, 2021	—	—	—	—	—	—	40,603,489	54	1	128	401,821	6,636	(119,111)	289,528
Conversion of ordinary shares into deferred shares							334,781							—
Issuance of ordinary shares under employee share purchase plan	—	—	—	—	—	—	493				1			1
Issuance of ordinary shares (Note 7)	—	—	—	—	—	—	—	—	—	—	— —	— —	—	—
Forfeiture of ordinary shares	—	—	—	—	—		(6,036)							
Share-based compensation expense	—	—	—	—	—	—	—	—	—	—	7,022 —	— —	—	7,022
Unrealized loss on foreign currency translation	—	—	—	—	—			—	—	—	—	(28,331)		(28,331)
Net loss	—	—	—	—	—	—	—	— —	— —	— —	— —	—	(71,176)	(71,176)
Balance at December 31, 2022	—	—	—	—	—	—	40,932,727	54	1	128	408,844	(21,695)	(190,287)	197,044
Issuance of ordinary shares under employee share purchase plan	—	—	—	—	—	—	12,210				9			9
Issuance of ordinary shares (Note 7)	—	—	—	—	—	—	312,606	—	—	—	—	— —	—	—
Forfeiture of ordinary shares	—	—	—	—	—		(174,595)	—	—	—	—	—	—	—
Share-based compensation expense	—	—	—	—	—	—		—	—	—	6,357 —	— —	—	6,357
Unrealized gain on foreign currency translation	—	—	—	—	—			—	—	—		8,624		8,624
Net loss	—	—	—	—	—	—		— —	— —	— —	— —	—	(69,665)	(69,665)
Balance at December 31, 2023	—	$—	—	$—	—	$—	41,082,948	$54	1	$128	$415,210	$(13,071)	$(259,952)	$142,369

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

ACHILLES THERAPEUTICS PLC
Consolidated statements of cash flows
(in thousands)

	2023	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (69,665)	$ (71,176)	$ (61,099)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	4,713	3,690	3,288
Loss on disposal of property and equipment	2	(10)	156
Gain on termination of operating lease	(45)	—	—
Loss on impairment	16	7,446	—
Changes in right of use assets and operating lease liabilities, net	(231)	(601)	(18)
Non-cash loss on foreign currency remeasurement	(5)	50	3
Non-cash share-based compensation	6,357	7,022	6,317
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	10,109	(6,845)	(9,771)
Accounts payable	257	1,907	(2,572)
Income taxes payable	(326)	326	(7)
Accrued expenses and other liabilities	(801)	(1,114)	4,937
Other long-term liability	33	321	47
Deferred tax assets	210	(225)	(22)
Other assets	927	(326)	(543)
Net cash used in operating activities	(48,449)	(59,535)	(59,284)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property and equipment	(1,100)	(7,512)	(7,634)
Net cash used in investing activities	(1,100)	(7,512)	(7,634)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of shares	9	1	-
Issuance of ADRs in initial public offering, net of issuance costs under the employee share purchase plan	—	—	160,755
Proceeds of issuance of convertible preferred shares, net of issuance costs	—	—	—
Payments of initial public offering costs	—	—	—
Net cash provided by financing activities	9	1	160,755
Effect of exchange rate changes on cash equivalents and restricted cash	7,741	(25,935)	(5,334)
Net (decrease) increase in cash	(41,799)	(92,981)	88,503
Cash, cash equivalents and restricted cash, beginning of year	173,371	266,352	177,849
Cash, cash equivalents and restricted cash, end of year	$ 131,572	$ 173,371	$ 266,352
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Right of use assets obtained in exchange for new operating lease liabilities	$ 2,108	$ 2,111	$ 314
Right of use assets terminated in exchange for operating lease liabilities, net	(1,916)	—	—
Property and equipment purchases in accrued expenses	540	649	726
Cash paid for income taxes	$ 626	$ 76	$ 8

The following table provides a reconciliation of the cash, cash equivalents and restricted cash balances as of each of the periods, shown above:

	2023	2022	2021
Cash and cash equivalents	$ 131,539	$ 173,338	$ 266,319
Restricted cash	33	$ 33	$ 33
Total cash, cash equivalents and restricted cash	$ 131,572	$ 173,371	$ 266,352

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

1. Nature of the business

Achilles Therapeutics plc (formerly Achilles TX Limited) and subsidiaries, or the Company, is a biopharmaceutical company developing AI-powered precision T cell therapies targeting clonal neoantigens to treat solid tumors. The Company is focused on advancing immuno-oncology therapeutics by exploiting its pioneering work in the field of tumor evolution and clonal neoantigens.

The Company is a public limited company originally incorporated pursuant to the laws of England and Wales in November 2020 as a private limited company named Achilles TX Limited, with nominal assets and liabilities, for the purposes of becoming the ultimate holding company for Achilles Therapeutics UK Limited (formerly Achilles Therapeutics Limited). Achilles Therapeutics UK Limited was incorporated in May 2016 under the laws of England and Wales and its registered office and principal place of business is currently 245 Hammersmith Road, London W6 8PW. Achilles TX Limited and Achilles Therapeutics Holdings Limited (a wholly owned direct subsidiary of Achilles TX Limited formed in November 2020 for the purpose of becoming the direct holding company of Achilles Therapeutics UK Limited and Achilles Therapeutics US, Inc.) have not conducted any operations prior to the corporate reorganization other than activities incidental to their formation.

The Company has devoted its efforts principally to research and development since formation. The Company has not yet completed product development, filed for or obtained regulatory approvals for any products, nor verified the market acceptance and demand for such products. As a result, the Company is subject to risks that are common to emerging companies in the biotech industry, including the uncertainties of the product discovery and development process, dependence on key individuals, development of the same or similar technological innovations by the Company's competitors, protection of proprietary technology, compliance with government regulations and approval requirements, the Company's ability to access capital and uncertainty of market acceptance of products.

Going concern

In accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern.

The Company has historically been loss making and anticipates that it will continue to incur losses for the foreseeable future and had an accumulated deficit of $260.0 million as of December 31, 2023. The Company has funded these losses principally through the issuance of ordinary and preferred shares. The Company expects to continue to incur operating losses and negative cash outflows until such time as it generates a level of revenue that is sufficient to support its cost structure.

The Company continues to assess the impact of the disruption of global financial markets, including as a result of global health concerns or pandemics, global economic uncertainty and geo-political events, including the war between Russia and Ukraine and the unrest in the Middle East resulting from the Israel-Hamas war and other global macroeconomic factors such as inflation, increases in commodity prices, energy and fuel prices, credit and capital markets instability and supply chain interruptions could reduce our ability to access capital, which could, in the future, negatively affect our business and the value of our common shares.

Geopolitical events, including the ongoing conflict between Russia and Ukraine and the unrest in the Middle East resulting from the Israel-Hamas war, have created global economic uncertainty. This has led to significant increases in commodity prices, energy and fuel prices, credit and capital market instability and supply chain interruptions which have led to increasing inflation. This may in turn adversely impact the Company's ability to deliver its goals.

As of December 31, 2023, the Company had cash and cash equivalents of $131.5 million. The Directors have reviewed the financial projections of the Company for the 12 months subsequent to the date of issuance of these financial statements including consideration of severe but plausible scenarios that may affect the Company in that period. These show that the Company will be able to pay (or otherwise discharge) its debts as they fall due immediately following the date of signing of this Balance Sheet and for the period considered by the forecast.

Accordingly, the financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and settlement of liabilities and commitments as they fall due in the ordinary course of business for at least 12 months from the date of issuance of the financial statements.

2. Summary of significant accounting policies

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America or U.S. GAAP and are presented in U.S. dollars. All significant inter–company accounts and transactions between the Company and its subsidiaries have been eliminated upon consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting periods. Estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual for research and development expenses, the fair value of share options granted and incremental borrowing rate for leases. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company operates in a single segment, focusing on researching, developing and commercializing potentially novel cancer immunotherapies targeting clonal neoantigens. Consistent with its operational structure, its chief operating decision maker, the Company's chief executive officer, views and manages the Company's operations and manages its business as a single operating segment. The majority of long-lived assets of the Company reside in the UK.

Foreign currency translation

The functional currency of the Company is pound sterling which is its local currency. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in other income/expense, net in the Consolidated statement of operations and comprehensive loss. The Company recorded foreign exchange losses of $1.0 million and foreign exchange gains of $3.8 million and $2.5 million for the years ended December 31, 2022 and 2021, respectively.

For financial reporting purposes, the financial statements of the Company have been presented in the U.S. dollar, the reporting currency. The financial statements of entities are translated from their functional currency into the reporting currency as follows: assets and liabilities are translated at the exchange rates at the balance sheet dates, revenue and

expenses are translated at the average exchange rates and shareholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net loss but are included as a foreign exchange adjustment to accumulated other comprehensive (loss)/income, a component of shareholders' equity.

Cash and cash equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. In connection with a lease, the Company maintains a required minimum balance, currently less than $0.1 million in connection with a letter of credit issued for the benefit of the landlord for its commercial facility used as a security deposit for the lease. The total amount is classified as Restricted Cash and has been classified as a non-current asset in the Consolidated Balance Sheets.

Fair value of financial instruments

The carrying values of the Company's cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and certain accruals approximate their fair value due to their short-term nature. The Company has a money-market fund that is measured under the fair value hierarchy as Level 1 as there are quoted prices in active markets for identical assets. See Note 3, Fair Value of Financial Instruments.

Concentrations of credit risk and off-balance sheet risk

Financial instruments that subject the Company to credit risk consist solely of cash and cash equivalents. The Company maintains cash balances in excess of amounts insured by the UK Government Financial Services Compensation Scheme in the UK. The Company has no significant off-balance-sheet risk or concentration of credit risk, such as foreign exchange contracts, options contracts, or other foreign hedging arrangements.

Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

	Estimated useful life
Lab equipment	5 years
Fixture and fittings	5 years
Office equipment and computers	3 years
Leasehold improvements	Shorter of useful life or remaining lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the statement of operations and other comprehensive loss. Expenditures for repairs and maintenance are charged to expense as incurred. Assets under construction are not depreciated until the asset is available and ready for use.

Impairment loss

The Company evaluates assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value. For the year ended December 31, 2022, the Company recognized an impairment loss of $6.7 million in assets under construction primarily related to costs associated with the detailed design of a flexible GMP modular facility in West London. Following a review of manufacturing plans, the Company had mothballed the

construction of the facility and project in 2022 and terminated the West London lease in October 2023. See Note 9, "Leases," for further details. In addition, the Company recognized an impairment loss of $0.5 million related to discontinued software implementation costs in the year ended December 31, 2022. The Company recognized an impairment loss of less than $0.1 million in the years ended December 31, 2023 and 2021. These impairment losses were recorded within research and development in the Company's Consolidated Statements of Operations and Comprehensive Loss.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, non-cash share-based compensation and benefits, depreciation expense, travel, third-party license fees, and external costs of outside vendors engaged to conduct clinical development activities, clinical trials, cost to manufacture clinical trial materials and net of tax credits associated with research and development activities. Acquired in-process research and development (IPR&D) assets that are used for research and development and have no future alternative use are expensed as incurred in-process research and development.

Research contract costs and accruals

The Company has entered into various research and development-related contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. Accruals for research and development expenses typically include fees paid to vendors in conjunction with preclinical development activities, CROs and investigative sites in connection with preclinical and clinical activities and costs to manufacture clinical trial materials in connection with the manufacturing of drug formulations for use in preclinical and clinical activities. When estimating accruals for research and development expenses as of each balance sheet date, the Company analyzes progress of the preclinical activities or clinical trials, including the phase or completion of services performed relative to invoices received and contracted costs. Actual results could differ from the Company’s estimates. The Company’s historical accrual estimates of research and development expenses have not been materially different from the actual costs.

Asset Retirement and Environmental Obligations

Pursuant to ASC 410, Asset Retirement and Environmental Obligations, an asset retirement obligation (“ARO” or “AROs”) is recorded when there is a legal obligation associated with the retirement of a tangible long-lived asset and the fair value of the liability can reasonably be estimated. Upon initial recognition, AROs are recorded as a liability at their estimated present value, with an offsetting increase to the carrying amount of the long-lived asset. Over time, the liabilities are accreted for the change in their present value through charges to operations costs. If the fair value of the estimated ARO changes, an adjustment is recorded to both the ARO and the asset retirement cost. Revisions in estimated liabilities can result from revisions of estimated inflation rates, escalating retirement costs, and changes in the estimated timing of settling ARO liabilities.

Total ARO consists of amounts for decommissioning and restoration of rented facilities to be performed in the future. The Company computes the liability for AROs based on assumptions from third-party estimates of the total restoration costs, adjusted for inflation. These values are discounted to present value using our credit adjusted incremental borrowing rate of the related rental facility and recorded ARO in other long-term liabilities. Periodic accretion of the discount on the ARO is recorded as part of accretion expense.

Share-based compensation

The Company recognizes compensation expense for equity awards based on the grant date fair value of the award, which may include share options and restricted ordinary shares. For equity awards that vest based on a service condition, the share-based compensation expense is recognized on a straight-line basis over the requisite service period. The Company accounts for forfeitures as they occur. For equity awards with performance conditions, the

Company recognizes share-based compensation expense using a straight-line basis over the requisite service commitments period when the achievement of a performance-based milestone is probable, based on the relative satisfaction of the performance condition as of the reporting date. The Company uses the fair value of its ordinary shares to determine the fair value of Employee Shares, C ordinary shares and K ordinary shares awarded to employees and directors.

Stock-based awards granted to nonemployees are accounted for in the same manner as awards granted to employees and directors as described above. The adoption of this new guidance did not have a material impact on the Company's financial statements.

There have been no performance conditions attached to the share options granted by the Company to date. The fair value of each share option grant is estimated on the date of grant using the Black-Scholes option pricing model. See Note 8, "Share-based compensation," for the Company's assumptions used in connection with option grants made during the periods covered by these consolidated financial statements. Assumptions used in the option pricing model include the following:

Expected volatility. As Achilles became a listed, public company in April 2021, the Company has limited company-specific historical and implied volatility information for its ordinary shares. Therefore, it estimates its expected share volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price.

Expected term. The expected term of the Company's share options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options as there is a limited trading history of our ordinary shares.

Risk-free interest rate. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods that are approximately equal to the expected term of the award.

Expected dividend. Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

Given the absence of an active market for the Company's ordinary shares prior to the IPO, the Company estimated the fair value of its ordinary shares with input from an independent third-party valuation specialist firm in accordance with the guidelines in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the "Practice Aid"). The Company's valuations of ordinary shares were prepared using either a market approach based on precedent transactions in the ordinary and preferred shares or a market adjusted equity value method to estimate the Company's total equity value, and using an option-pricing backsolve method ("OPM") to allocate the equity value to each class of the Company's securities. In some cases, the Company determined that there were no significant events occurring between a prior valuation date and a subsequent grant. As such, in these cases the Company used the most recent share price valuation as an input to the determination of share-based compensation. After IPO, the fair value of ordinary shares is determined by reference to the closing price of ADSs on the Nasdaq Global Select Market on the date of grant.

The OPM backsolve method derives an equity value such that the value indicated for ordinary shares is consistent with the investment price, and it provides an allocation of this equity value to each of the Company's securities. The OPM treats the various classes of ordinary shares and preferred shares as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, each class of ordinary shares has value only if the funds available for distribution to shareholders exceeded the value of the preferred share liquidation preferences at the time of the liquidity event. Key inputs into the OPM backsolve calculation included the valuation of equity, probability weighted expected time to liquidity and volatility. A reasonable discount for lack of marketability was applied to the total per share value to arrive at an estimate of the total fair value of an ordinary share on a non-marketable basis.

Leases

Effective January 1, 2019, the Company adopted ASU No. 2016-02, Leases (Topic 842), as amended, using the modified retrospective method and utilizing the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under ASC 840, Leases ("ASC 840"). At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable. Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and to allocate all the contract consideration to the lease component only. All the Company's leases are classified as operating leases.

Lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts has not been readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. As the Company does not have a rating agency-based credit rating, quotes were obtained from lenders to establish an estimated secured rate to borrow based on Company and market-based factors as of the respective lease measurement dates. The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes the non-cancelable lease term in its assessment of a lease arrangement unless there is an option to extend the lease that is reasonably certain of exercise. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

Operating lease costs are recognized on a straight-line basis over the lease term, and they are categorized within research and development and general and administrative expenses in the statement of operations. The operating lease cash flows are categorized under net cash used in operating activities in the statement of cash flows.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in its tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that deferred tax assets will be recovered in the future and to the extent management believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company uses a two-step approach for recognizing and measuring uncertain tax positions. The first step is to evaluate tax positions taken or expected to be taken in a tax return by assessing whether they are more likely than not sustainable, based solely on their technical merits, upon examination, and including resolution of any related appeals or litigation process. The second step is to measure the associated tax benefit for each position as the largest amount that the Company believes is more likely than not realizable. Differences between the amount of tax benefits taken or expected to be taken in the Company's income tax returns and the amount of tax benefits recognized in the financial statements represent the Company's unrecognized income tax benefits, which is either recorded as a liability or reduction of deferred tax assets.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying statement of operations. As of December 31, 2023, 2022 and 2021, no accrued interest or penalties have been incurred.

Research and development tax credit

The Company is subject to corporation tax in the United Kingdom, or UK. Due to the nature of the business, the Company has generated losses since inception. The benefit from research and development ("R&D") tax credits is recognized in the statements of operations and comprehensive loss as a reduction of research and development costs and represents the sum of the R&D tax credits recoverable in the UK.

The UK R&D tax credit is fully refundable to the Company and is not dependent on current or future taxable income. As a result, the Company has recorded the entire benefit from the UK R&D tax credit as a benefit which is included in net loss before income tax and accordingly, not reflected as part of the income tax provision. If, in the future, any UK R&D tax credits generated are needed to offset a corporation tax liability in the UK, that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded as a reduction of research and development costs.

As a company that carries out extensive R&D activities, the Company benefits from the UK research and development tax credit regime under the scheme for small or medium-sized enterprises ("SME"). Under the current SME regime, the Company can surrender some of its trading losses that arise from qualifying R&D activities for a cash rebate of 33.35% of qualifying R&D expenditure incurred prior to April 1, 2023 (after taking into account the enhanced rate of deduction) and decreasing to 18.6% of qualifying R&D expenditure after April 1, 2023 (after taking into account the enhanced rate of deduction). Additionally, the UK Government has enacted further changes to the SME regime in February 2024, which include the introduction of a new rate for R&D intensive companies of 26.97% (which the Company is expected to qualify for) and comes into effect for qualifying R&D expenditures incurred after April 1, 2023.

The Company may not be able to continue to claim R&D tax credits under the SME regime in the future because it may no longer qualify as a small or medium-sized company. Additional changes to the R&D tax relief legislation, which took effect from April 2023, introduced restrictions on relief that may be claimed for expenditure on sub-contracted R&D activity, broadly requiring either that workers carrying on such activity are subject to UK PAYE or, where work is undertaken outside the UK, that this must be due to geographical, environmental or social conditions not replicable in the UK. These restrictions may impact the quantum of R&D relief that we are able to claim in the future.

It should also be noted that there is a cap on SME R&D tax credit claims to a multiple of payroll taxes (broadly, to a maximum payable credit equal to £20,000 plus three times the total UK PAYE and NICs liability of the company) subject to an exception which prevents the cap from applying. That exception requires the Company to be creating, taking steps to create or managing intellectual property, as well as having qualifying R&D expenditure in respect of externally provided workers by connected parties or on subcontracting R&D to connected parties which does not exceed 15% of the total claimed. If such exception does not apply, this could restrict the amount of payable R&D tax credit that we are able to claim.

SME R&D reliefs (whether by way of additional deductions or payable tax credits) are also limited on a project basis to a to a maximum total aid of EUR 7.5 million per R&D project.

Unsurrendered UK losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to an allowance of £5.0 million plus an incremental 50% of UK trading profits after deduction of the allowance.
The Company recognizes R&D tax credit reimbursements under 'Research and Development' in the Consolidated Statements of Operations and Comprehensive Loss.

R&D tax credits of $9.4 million, $15.6 million and $10.7 million were recorded for the years ended December 31, 2023, 2022 and 2021, respectively. The income from R&D tax credits was recorded within research and development in the Company's Consolidated Statements of Operations and Comprehensive Loss.

Comprehensive income (loss)

Comprehensive income (loss) includes net loss as well as other changes in shareholders' equity that result from transactions and economic events other than those with shareholders.

Net loss per share

The Company has reported losses since inception and has computed basic net loss per share attributable to ordinary shareholders by dividing net loss attributable to ordinary shareholders by the weighted-average number of ordinary shares outstanding for the period, without consideration for potentially dilutive securities. For purpose of this calculation, unvested Employee Shares and convertible preferred shares are considered potential dilutive ordinary shares. The Company computes diluted net loss per ordinary share after giving consideration to all potentially dilutive ordinary shares, including unvested Employee Shares and convertible preferred shares, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential ordinary shares have been anti-dilutive and basic and diluted loss per share were the same for all periods presented.

Government grants

The Company receives certain government grants that support specific research and development activities. Income in respect of grants also includes contributions towards the costs of research and development. Income is recognized when costs under each grant are incurred in accordance with the terms and conditions of the grant and the collectability of the receivable is reasonably assured. Government grants relating to costs are deferred and recognized in the income statement over the period necessary to match them with the costs they are intended to compensate. The Group recognizes income from government grants under 'Other income—net' in the Company's consolidated statement of comprehensive loss.

The Company recorded income from government grants of $1.0 million, $0.4 million and $0.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. The income from government grants was recorded within other income/(expense) in the Company's Consolidated Statements of Operations and Comprehensive Loss.

Recent accounting pronouncements

Recently adopted accounting standards

In November 2023, the FASB issued ASU 2023-07, "*Segment Reporting - Topic 280 – Improvements to Reportable Segment Disclosures,"* which requires disclosure of incremental segment information on an annual and interim basis. This includes the disclosure of: segment expenses that are reviewed by the chief operating decision maker (CODM) and included within each reported measure of segment profit or loss; an amount for other segment items by reportable segment and a description of its composition; all annual disclosures about a reportable segment's profit or loss currently required by Topic 280 in interim periods; clarify that if the CODM uses more than one measure of a segment's profit or loss, provide disclosure of one or more of those additional measures; the title and position of the CODM and an explanation of how the CODM uses the reported measure (s) of segment profit or loss; and requiring an entity that has a single reportable segment to provide all disclosures required by the amendments in the ASU and all existing segment disclosures in 280. ASU 2023-09 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. However, early adoption is permitted. The new guidance is not expected to have a material impact on the Company's financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, "*Income Taxes - Topic 740 – Improvements to Income Tax Disclosures,"* which enhances the transparency and decision usefulness of income tax disclosures. The amendments in this update address investor requests for transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024; however, early adoption is permitted. The new guidance is not expected to have a material impact on the Company's financial statements and related disclosures.

In November 2021, the FASB issued ASU 2021-10, "*Government Assistance – Topic 832 – Disclosures by Business Entities about Government Assistance*," which increases the transparency of government assistance including the disclosure of (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. The amendments in this Update require the following annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy: 1. Information about the nature of the transactions and the related accounting policy used to account for the transactions. 2. The line items on the balance sheet and income statement that are affected by the transactions, and the amounts applicable to each financial statement line item. 3. Significant terms and conditions of the transactions, including commitments and contingencies. ASU 2021-10 is effective for annual periods beginning after December 15, 2021; however, early adoption is permitted. The new guidance was adopted on January 1, 2022 and did not have a material impact on the Company's financial statements and related disclosures.

3. Fair Value of Financial Instruments

The following tables show assets measured at fair value on a recurring basis as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023		
	Level 1	**Level 2**	**Level 3**
Cash equivalents:			
Money market funds	$ 76,257	$ —	$ —
Total	$ 76,257	$ —	$ —

	December 31, 2022		
	Level 1	**Level 2**	**Level 3**
Cash equivalents:			
Money market funds	$ 51,901	$ —	$ —
Total	$ 51,901	$ —	$ —

There were no liabilities measured at fair value on a recurring basis as of December 31, 2023 and 2022.

4. Prepaid expenses and other current assets

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

	December 31,	
	2023	**2022**
U.K. R&D tax credit	$ 9,558	$ 15,232
Prepaid research and development	1,074	3,473
Prepaid insurance	690	1,151
VAT recoverable	793	771
Other current assets	1,979	2,615
	$ 14,094	$ 23,242

5. Property and Equipment, net

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

	December 31,	
	2023	2022
Lab equipment	$ 9,914	$ 8,707
Leasehold improvements	9,451	8,929
Office equipment and computers	1,636	1,577
Fixtures and fittings	1,085	1,040
	22,086	20,253
Less: Accumulated depreciation	(12,915)	(7,854)
	$ 9,171	$ 12,399

Depreciation expense was $4.7 million, $3.7 million and $3.3 million for the years ended December 31, 2023, 2022 and 2021, respectively. For the year ended December 31, 2022, the Company recognized an impairment loss of $6.7 million in assets under construction primarily related to costs associated with the detailed design of a flexible GMP modular facility in West London. Following a review of manufacturing plans, the Company had mothballed the construction of the facility and project in 2022 and terminated the West London lease in October 2023. See Note 9, "Leases", for details of the West London lease.

6. Accrued expenses and other liabilities

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

	December 31,	
	2023	2022
Compensation and benefits	$ 2,949	$ 2,972
External research and development expenses	3,227	2,188
Professional services	373	795
Property and equipment	115	217
Facility costs	314	910
Other liabilities	850	1,210
	$ 7,828	$ 8,292

7. Shareholders' equity

Ordinary shares

As of December 31, 2023 and 2022, the Company had the following number of ordinary shares with a par value £0.001 (equivalent to $0.001) issued and outstanding:

	December 31,	
	2023	2022
Ordinary shares	39,466,581	39,316,360
Class A non-voting ordinary shares	1,616,367	1,616,367
Deferred Shares	1	1
Total ordinary and deferred shares	41,082,949	40,932,728

On April 6, 2021, all the Employee Shares, Convertible Preferred Shares (see below) and B ordinary shares were converted into ordinary shares or Class A non-voting ordinary shares. Please refer to the details in Note 1. Class A non-voting ordinary shares have same rights and privileges as ordinary shares, except for the voting rights.

As of December 31, 2023, the Company has not declared any dividends.

***Deferred* shares**

On April 6, 2021, all the deferred shares were cancelled. In addition, a single deferred share with a nominal value of £92,451.851 in the capital of the Company was created as part of the Company's reorganization. As of December 31, 2023, the Company had one deferred share which could be repurchased at any time by the Company for nil consideration.

Convertible preferred shares

The Company issued series A convertible preferred shares ("Series A"), series A-1 convertible preferred shares ("Series A-1"), series B preferred shares ("Series B") and series C preferred shares ("Series C") (collectively, "Convertible Preferred Shares").

On April 6, 2021, all the Convertible Preferred Shares were converted into ordinary shares or Class A non-voting ordinary shares. There are no Convertible Preferred Shares outstanding as of December 31, 2023.

8. Share-based compensation

2020 Share Omnibus Plan

Under the Company's shareholder and subscription agreements, which were effective until the date of IPO, the Company was authorized to grant equity awards to individuals including a director of and/or a person who is employed by or who directly or indirectly provides consultancy services to the Company, in the form of D, E, F, G, H, I, J, K, L, M and N ordinary shares, collectively referred to as Employee Shares and share options. All Employee Shares converted into ordinary shares in accordance with the reverse share split implemented on IPO (see Note 1, "Nature of business," to our financial statements appearing at the end of this Annual Report). The share options were granted pursuant to the terms of the 2020 Share Omnibus Plan, or the 2020 Plan.

Upon and following closing of the IPO, no further equity awards were granted under the 2020 Plan. To the extent outstanding options granted under the 2020 Plan are cancelled, forfeited or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2020 Plan, the number of shares underlying such awards will be available for future grant under the Company's 2021 Omnibus Plan (see below). In anticipation of IPO, the holders of Employee Shares and the Company entered into individual vesting agreements, or Vesting Agreements, which apply the same terms to vesting of Employee Shares as applied prior to IPO under the Company's pre-IPO Articles of Association, except that following the IPO Employee Shares that would pre-IPO have converted to deferred shares, will be transferred back to the Company and cancelled within twelve months of an employee leaving the Company.

2021 Share Omnibus Plan

In March 2021, the Company's board of directors adopted, and the Company's shareholders approved, the 2021 Share Omnibus Plan, or the 2021 Plan, which became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The 2021 Plan allows the remuneration committee to make equity-based and cash-based incentive awards to our officers, employees, directors and other key persons (including consultants).

The Company committee initially reserved 2,572,558 of its ordinary shares for the issuance of awards under the 2021 Plan. The 2021 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by 4% of the outstanding number of ordinary shares on the immediately preceding December 31, or such lesser number of shares as determined by our remuneration committee. This number is subject to adjustment in the event of a sub-division, consolidation, share dividend or other change in our capitalization. The total number of ordinary shares that may be issued under the 2021 Plan was 5,834,006 shares as of December 31, 2023, of which 1,141,189 shares remained available for future grant after taking into account options granted and adding back forfeitures in the period.

2021 Employee Share Purchase Plan

The Company's 2021 Employee Share Purchase Plan, or ESPP, was adopted by the Board in March 2021 and approved by shareholders in March 2021 and became effective upon the effectiveness of the Company's Registration Statement on Form F-1 in connection with the IPO. The ESPP initially reserved and authorized the issuance of up to a total of 467,738 ordinary shares to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter through January 1, 2022, by the least of: (i) 1% of the outstanding number of ordinary shares on the immediately preceding December 31; (ii) 467,738 ordinary shares or (iii) such number of shares as determined by the remuneration committee. The number of shares reserved under the ESPP is subject to change in the event of a share split, share dividend or other change in our capitalization. The purpose of the ESPP is to: (i) provide U.S. employees the opportunity to purchase ordinary shares or ADSs at 85% of the fair market value of the ADSs on the offering date or the exercise date, whichever is lower, and (ii) provide UK-based employees with ordinary shares or ADSs under the SIP Plan as further discussed below.

The total number of ordinary shares that had been approved for issue under the ESPP was 877,065 shares as of December 31, 2023. The initial purchase period under the ESPP commenced in February 2022. The Company estimated the fair value of the option component of the ESPP at the date of grant using a Black-Scholes valuation model. During the year ended December 31, 2023, the compensation expense from ESPP shares, including SIP shares was $0.3 million.

2021 Share Incentive Plan

The Achilles Therapeutics plc Share Incentive Plan, or SIP Plan is a sub plan of the ESPP. This SIP Plan is an HMRC approved Plan for UK tax-paying employees. Under the SIP Plan, eligible employees can receive "Free Shares" within HMRC guidelines, purchase ordinary shares from the market, or Partnership Shares, as well as receive "Matching Shares" which are issued without any consideration payment in connection with an acquisition of Partnership Shares (collectively referred to as "SIP Shares"). For any award of Matching Shares, the renumeration committee must specify the ratio of Matching Shares to Partnership Shares. Under HMRC rules, the ratio determined by the renumeration committee must not exceed two Matching Shares for every Partnership Share.

There is no minimum service condition on the Partnership Shares, and the participants can sell/transfer the shares after their acquisition from the market. There is a minimum service condition for the Free and Matching Shares that requires the participants to provide continuing service for at least 36 months from the date of grant. If the participants are no longer with the Company or its subsidiaries before the completion of 36 months' service (with the relevant date determined as the last day of employment), the Free and Matching Shares generally will be 100% forfeited and available for future issuance.

During the year ended December 31, 2023, 394,563 shares were issued under the ESPP, including SIP shares. This reduced the number of shares reserved and available to grant under the ESPP to 231,972 shares available to grant as of December 31, 2023.

Employee Shares and SIP Shares

Prior to the IPO, the Company typically granted shares which vested over a four-year service period with 25% of the award vesting on the first anniversary of the vesting commencement date, and the balance vesting periodically over the remaining three years.

Post IPO, the Company typically grants SIP Shares under the SIP Plan. SIP Shares effectively vest in full on the third anniversary of the service commencement date.

Unvested Employee Shares are forfeited upon the termination of employment or service relationship in accordance with the process set out in the Articles of the Company prior to IPO, and in accordance with the process set out in the Vesting Agreements post-IPO and 2020 Plan, or in the case of the SIP Plan, SIP shares in accordance with the rules of the SIP Plan. Before IPO, the forfeited shares were converted into deferred shares, with a repurchase right for a nominal amount in favor of the Company. As of December 31, 2020, the Company repurchased 1,509,384 deferred shares for consideration of £0.01 to each holder for all of the deferred shares held by that holder. As part of the Company's reorganization, 109,058 outstanding deferred shares in existence immediately before the IPO were cancelled upon the IPO, and a single deferred share with a nominal value of £92,451.851 in the capital of the Company was created. As of December 31, 2022, the Company had one deferred share which could be repurchased by the Company at any time for nil consideration. SIP shares forfeited under the rules of the SIP Plan are made available under the ESPP for future issuances. In accordance with the relevant Vesting Agreements, in 2022 and 2023, we cancelled 6,036 shares and 174,595 shares, respectively, that were held by employees who left employment with the Company since the IPO.

The Company measures all share-based awards using the fair value on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company has granted Employee Shares to employees and non-employees with service-based conditions and SIP Shares to employees with service-based conditions, and in both cases records expense for these awards using the straight-line method. A summary of the changes in the Company's unvested ordinary shares from December 31, 2021 through December 31, 2023 are as follows:

	Number of unvested ordinary shares		Weighted average grant date fair value
Unvested ordinary shares as of December 31, 2021	1,903,058	$	6.43
Granted	356,566		2.86
Vested	(915,817)		5.29
Forfeited	(49,004)		3.53
Unvested ordinary shares as of December 31, 2022	1,294,803	$	4.89
Granted	383,126		0.95
Vested	(595,202)		6.25
Forfeited	(243,882)		4.79
Unvested ordinary shares as of December 31, 2023	838,845	$	3.92

As of December 31, 2023 and 2022, there was $2.6 million and $6.1 million of unrecognized compensation costs related to unvested Employee Shares outstanding, which is expected to be recognized over a weighted-average period of 1.2 years and 1.8 years, respectively.

Share Options

The following table summarizes the Company's share options activity for the year ended December 31, 2023:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	2,993,641	$ 6.18	8.51	$ 150
Granted	2,453,312	$ 1.15		
Exercised				
Forfeited	(389,854)	$ 4.13		
Outstanding as of December 31, 2023	5,057,099	$ 4.09	8.27	$ 232
Exercisable as of December 31, 2023	1,388,148	$ 7.36	7.19	$ 37
Unvested as of December 31, 2023	3,668,951	$ 2.86	8.68	$ 195

The weighted average grant-date fair value of share options granted during the year ended December 31, 2023 and 2022 was $0.81 and $2.02 per share, respectively.

As of December 31, 2023, there was $4.8 million of unrecognized compensation cost related to share options outstanding, which is expected to be recognized over a weighted-average period of 2.2 years.

Share Option Valuation

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the share options granted to employees during the year ended December 31, 2023 and 2022 were as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Expected term (in years)	6.02	6.04
Expected volatility	72.81%	69.74%
Expected dividend yield	0.00%	0.00%
Risk free interest rate	3.53%	2.00%
Fair value of underlying ordinary shares	$ 1.19	$ 3.06

Share-based Compensation Expense

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

	Years Ended December 31,		
	2023	2022	2021
Research and development	$ 3,500	$ 3,750	$ 3,362
General and administrative	2,857	3,272	2,955
	$ 6,357	$ 7,022	$ 6,317

9. Leases

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to use, or control the use of, identified property, plant, or equipment for a period of time in exchange for consideration. Leases may be classified as finance leases or operating leases. All the Company's leases are classified as operating leases. Operating lease right-of-use assets and operating lease liabilities are recognized in the Consolidated Balance Sheets. The operating leases of the Company are for real property for office and laboratory use, for which the Company recorded right-of-use assets and lease liabilities as of the ASU 2016-02 effective date or lease commencement date, if later. In addition, three of the Company's leases met the short-term exception, having lease terms of 12 months or less, and are therefore not recorded on the Company's balance sheet. The Company's leases do not include purchase options. Where the Company's leases contain options to extend the lease term, the extended lease term is only included in the measurement of the lease when it is reasonably certain to remain in the lease beyond the non-cancelable term. The Company's leases contain variable lease costs, which pertain to common area maintenance and other operating charges, that are expensed as incurred.

Operating leases

On July 8, 2016, the Company entered into a Master Service Agreement ("MSA") with Royal Free London NHS Foundation Trust, which included access rights to the laboratory space at the Royal Free Hospital, Pond Street, London, with a 5-year term. The Master Service Agreement was due to expire on August 31, 2020. On June 1, 2020, the Master Service Agreement was renewed and was due to expire on August 31, 2023. These leases were renewed and expire on May 31, 2025. In addition, in October 2023, the Company entered into a lease under this MSA for additional office space at this location expiring in June 2024, with a three-month rolling break clause.

On February 1, 2019, the Company entered into six agreements with Stevenage Bioscience Catalyst to lease office and laboratory suites at Gunnels Wood Road, Stevenage, Hertfordshire, which were due to expire on January 31, 2021. In February 2021, the Company renewed the agreements which expired on July 31, 2022. On July 29, 2022, the Company renewed five of the agreements which commenced on August 1, 2022 with three of the leases expiring in April 2024 and two of the leases expiring on December 31, 2023. with a two-month rolling break clause. The two leases that expired on December 31, 2023 were not renewed.

In December 2020, the Company entered into a new lease of a warehouse in west London, United Kingdom for a period of 10 years, with a break clause at 5 years. In October 2023, the Company terminated this lease subject to the payment of a lease termination premium of $0.3 million and derecognized the related right-of-use asset of $1.9 million and operating lease liabilities of $2.0 million, resulting in a gain of less than $0.1 million.

On February 21, 2020, the Company entered into a non-cancellable operating lease in relation to office premises at Hammersmith Road, London for a period of 10 years, with a break clause at 5 years.

On February 28, 2020, the Company entered into a 4-year manufacturing services collaboration agreement for laboratory space access at Gunnels Wood Road, Stevenage, Hertfordshire, with cancellation penalties of up to £0.1 million or $0.2 million as of December 31, 2023 should the Company terminate without due cause. On February 22, 2024, the Company entered into an amendment to the manufacturing services collaboration agreement which extended the term through March 31, 2025.

In June 2021, the Company entered into a new lease of office premises in London, United Kingdom for a period of 3 years, with a break clause at 2 years. The Company elected not to exercise the break in December 2022. As a result, the lease expires in June 10, 2024.

On October 1, 2021, the Company entered into a non-cancellable operating lease in relation to office and laboratory premises in Philadelphia, Pennsylvania in the United States for a period of 38 months. The right-of-use asset and lease liability was recorded on the lease commencement date, which was in January 2022. In connection with this lease, the Company maintains a required minimum balance, currently less than $0.1 million, in connection with a letter of credit issued for the benefit of the landlord for its commercial facility used as a security deposit for the lease. The total

amount is classified as Restricted Cash and has been classified as a non-current asset on the Consolidated Balance Sheets. The letter of credit expires on September 30, 2024. However, it automatically extends for additional one-year periods, without written amendment agreement, in each succeeding calendar year, through the lease expiration date.

In June 2021, the Company entered into an obligation to take on a new lease of lab and office premises in Stevenage, Hertfordshire, United Kingdom for a period of 10 years, with a break clause at 3 and 6 years. This lease commenced in September 2022.

On March 11, 2022, the Company entered into an agreement to reserve manufacturing capacity with a Contract Manufacturing Organization, or CMO, in King of Prussia, PA. The Company concluded that this agreement contains embedded leases as up to two Good Manufacturing Practices, or GMP, suites and office space at the facility are designated for the Company's exclusive use during the term of the agreement. The leased space has not yet been placed into service or made available for its intended use and has therefore not commenced as of December 31, 2023.

Summary of lease costs recognized under ASU 2016-02

The following table contains a summary of the lease costs recognized under ASU 2016-02 and other information pertaining to the Company's operating leases for the years ended December 31, 2023, 2022, and 2021 (dollars in thousands):

	Years ended December 31,		
	2023	2022	2021
Lease cost			
Operating lease cost	$ 4,655	$ 4,512	$ 4,718
Variable lease cost	5,291	3,921	5,022
Short-term lease cost	379	363	65
	$ 10,325	$ 8,796	$ 9,805
Other information:			
Cash paid for amounts included in the measurement of lease liabilities: Operating cash flows used in operating leases	$ 4,537	$ 4,859	$ 4,736
Right of use assets obtained in exchange for new operating lease liabilities	$ 2,108	$ 2,111	$ 314
Right of use assets terminated in exchange for operating lease liabilities, net	$ (1,916)	$ —	$ —
Weighted average remaining lease term (in years)	1.3	2.3	3.1
Weighted average discount rate	6.61%	5.13%	4.86%

Variable lease cost is determined based on usage in accordance with the contractual agreements.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect as of December 31, 2023, the following table summarizes the Company's maturities of operating lease liabilities as of December 31, 2023 (in thousands):

	December 31, 2023
Operating lease liabilities payment	
2024	$ 3,717
2025	1,099
2026	
2027	-
Total lease payments	$ 4,816
Less: imputed interest	(201)
Present value of lease liability	$ 4,615

10. License agreements

CRT license

In May 2016, the Company entered into a License Agreement, or the License Agreement, with Cancer Research Technology Limited, or CRT, pursuant to which the Company obtained access rights to intellectual property and know-how from the TRACERx Study. Under the License Agreement, the Company is granted an exclusive, sublicensable license to the TRACERx patents and bioinformatic data for use in: (i) the therapeutic field of neoantigen cell therapies and adoptive cell transfer; and (ii) the neoantigen diagnostic field, for use in research and the potential development of products for commercialization. The Company is further granted, during the vaccine option period, an exclusive license to the TRACERx patents and the bioinformatic data in the private neoantigen therapeutic vaccine field for research and development but not in the development of products for commercial sale, and a non-exclusive license to the same in the public neoantigen therapeutic vaccine field. The Company also obtained a non-exclusive license to the TRACERx bioinformatic pipeline, patient sequencing and medical data, know-how, and materials.

CRT additionally granted the Company certain rights to new patent applications filed by the Founding Institutions in respect of inventions resulting from the TRACERx study through February 2023, including automatic exclusive licenses to patent rights relating to non-severable improvements of technology covered by the original TRACERx patents and non-exclusive rights to severable improvements.

In July 2017, the Company obtained a non-exclusive license to the LOHHLA patent under the License Agreement. In October 2018, the Company obtained an exclusive license to the LOHHLA patent under an addendum to the License Agreement. Under the License Agreement, the Company holds an option to exploit products in the therapeutic vaccine field (the "Vaccine Option"). In March 2021, the Company extended the Vaccine Option from May 2021 to May 2023 with a payment of less than £0.1 million or $0.1 million. The Company exercised the Vaccine Option on May 4, 2023.

Upon execution of the License Agreement the Company granted CRT 396,125 B ordinary shares and 67,793 C ordinary shares. The C ordinary shares granted to CRT were forfeited and transferred to the deferred shares during the year ended December 31, 2019, as the applicable performance conditions were not met. The B ordinary shares granted to CRT were converted into ordinary shares upon the IPO. The Company recorded $0.3 million of IP research and development expense in 2016. The Company is obligated to pay CRT milestone success payments up to an aggregate of £6.5 million for therapeutic products, and milestone success payments up to an aggregate £0.8 million for non-therapeutic products, as well as sub-single digit to low-single digit percentage royalty on net sales of products that utilize the licensed intellectual property, subject to certain customary reductions. The royalty obligations continue on a product-by-product and country-by-country basis until the later of: (i) the date there ceases to be a valid patent claim covering such product in the country in which it is sold; or (ii) with respect to contribution royalty products, ten years from the first commercial sale of the product, and with respect to a patent royalty product, five years from the first commercial sale of the product. On a product-by-product basis, the Company may also elect to provide other cash consideration at fair market value and forgo the milestone or royalty payment.

Unless terminated earlier, the term of the agreement continues until the later of the expiration of the royalty term in each country and such time as no further milestone payments are due, and upon such termination, the licenses granted shall become fully-paid, royalty-free, irrevocable, and perpetual. The Company has the right to terminate the license agreement for convenience in its entirety upon 90 days' notice. Each party may terminate the agreement if the other party is in material breach subject to a 90 day remedy period. The Company has the right to acquire ownership of the TRACERx patents upon either: (i) the occurrence of a royalty product for use in the therapeutic field; (ii) CRT shareholders cease to hold any ordinary shares in the Company; (iii) the Company undergoes an initial public offering; or (iv) the Company is acquired by a third party for more than £25.0 million. Upon its IPO, the Company gave notice to CRT to exercise the option to acquire the TRACERx patents with no consideration in accordance with the terms of the License Agreement. The acquisition was finalized in accordance with an assignment and license agreement, or Assignment Agreement, with effective date November 29, 2023. Under the terms of the Assignment Agreement the relevant TRACERx patents were assigned to the Company and the Company will license back certain rights to CRT in relation to those assigned patents.

Expenses of $0.1 million were recorded for the year ended December 31, 2023 and less than $0.1 million of expenses were recorded for the years ended December 31, 2022 and 2021 related to the CRT License Agreement.

11. Income taxes

The Company is domiciled in the United Kingdom and is primarily subject to taxation in that country. During the years ended December 31, 2023, 2022 and 2021, the Company recorded no income tax benefits for the net operating losses incurred in the UK in each period due to its uncertainty of realizing a benefit from those items. During the year ended December 31, 2023, 2022 and 2021, the Company recorded a tax provision related to income tax obligations of its operating company in the U.S., which generates a profit for tax purposes.

Loss before provision for income taxes consisted of the following (in thousands):

	December 31,		
	2023	**2022**	**2021**
United Kingdom	$ (69,329)	$ (71,405)	$ (61,182)
Foreign	155	340	120
	$ (69,174)	$ (71,065)	$ (61,062)

The income tax provision for the years ended December 31, 2023, 2022 and 2021 is comprised of the following (in thousands):

	December 31,		
	2023	**2022**	**2021**
Current expense:			
United Kingdom	$ —	$ —	$ —
Foreign	281	337	59
Total current expense:	281	337	59
Deferred expense (benefit):			
United Kingdom	—	—	—
Foreign	210	(226)	(22)
Total deferred expense (benefit):	210	(226)	(22)
Total income tax expense:	$ 491	$ 111	$ 37

The provision for income taxes for the years ended December 31, 2023, 2022 and 2021 was computed at the United Kingdom statutory income tax rate.

A reconciliation of income tax expense computed at the statutory UK income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

	Year Ended December 31,		
	2023	2022	2021
Income taxes at UK statutory rate	23.50 %	19.00 %	19.00 %
Return to provision	(9.95)%	6.87 %	—
R&D expenditure	(11.00)%	(8.30)%	(6.67)%
Change in valuation allowance	(3.39)%	(23.58)%	(20.12)%
Change in UK tax rate	0.13 %	5.66 %	7.64 %
Other	—	0.19 %	(0.13)%
	(0.71)%	(0.16)%	(0.28)%

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2023, 2022 and 2021 consist of the following (in thousands):

	December 31,		
	2023	2022	2021
Deferred tax assets			
Net operating loss carryforwards	$ 30,435	$ 35,121	$ 17,742
Non-cash share-based compensation	6,488	4,456	2,328
Depreciation	606	(7,989)	(1,311)
Other	112	2,143	329
Total deferred tax assets	$ 37,641	$ 33,731	$ 19,088
Valuation allowance	(37,600)	(33,480)	$ (19,062)
Net deferred tax assets	$ 41	$ 251	$ 26

As of December 31, 2023, 2022 and 2021, the Company had UK net operating loss carryforwards of $121.7 million, $140.5 million and $71.0 million, respectively, that can be carried forward indefinitely.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2023, 2022 and 2021 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards were as follows (in thousands):

	December 31,		
	2023	2022	2021
Valuation allowance at beginning of year	$ 33,480	$ 19,062	$ 7,088
Increases recorded to income tax provision	2,252	12,731	7,624
Exchange difference	1,774	(2,332)	(313)
Change in tax rate	94	4,019	4,663
Valuation allowance at end of year	$ 37,600	$ 33,480	$ 19,062

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2023, 2022 and 2021, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future

taxable income for the UK entity and determined that it is more likely than not the net deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance for the UK entity as of December 31, 2023, 2022 and 2021.

The Company applies the authoritative guidance on accounting for and disclosure of uncertainty in tax positions, which requires the Company to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals of litigation processes, based on the technical merits of the position. For tax positions meeting the more likely than not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than fifty percent likelihood of being realized upon the ultimate settlement with the relevant taxing authority. There were no material uncertain tax positions as of December 31, 2023, 2022 and 2021.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense when in a taxable income position. As of December 31, 2023 and 2022, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations.

The Company files income tax returns in the UK Generally, the tax years through 2022 in the UK remain open to examination. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the UK tax authorities, if such tax attributes are utilized in a future period. The Company also files income tax returns in the US. Generally, the tax years through 2021 in the U.S. remain open to examination.

On May 24, 2021, the Finance Act 2021 (the Act) was enacted in the UK. The Act increases the corporate income tax from 19% to 25% effective April 1, 2023 and enhances the first-year capital allowance on qualifying new plant and machinery assets effective April 1, 2021. The effects on the Company's existing deferred tax balances have been recorded and is offset by the valuation allowance maintained against the Company's UK net deferred tax assets.

As of December 31, 2023 and 2022, income taxes on undistributed earnings of the Company's U.S. subsidiary have not been provided for as the Company plans to indefinitely reinvest these amounts in the U.S. The cumulative undistributed foreign earnings were not material as of December 31, 2023 and 2022.

12. Net loss per share

Basic and diluted net loss per share attributable to ordinary shareholders was calculated as follows (in thousands, except share and per share amounts):

	Year ended December 31,		
	2023	**2022**	**2021**
Numerator			
Net loss	$ (69,665)	$ (71,176)	$ (61,099)
Net loss attributable to ordinary shareholders—basic and diluted	$ (69,665)	$ (71,176)	$ (61,099)
Denominator			
Weighted-average number of ordinary shares used in net loss per share—basic and diluted	39,973,059	39,139,693	28,654,760
Net loss per share—basic and diluted	$ (1.74)	$ (1.82)	$ (2.13)

The Company's potentially dilutive securities, which include warrants to purchase ordinary shares, unvested Employee Shares and Convertible Preferred Shares, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of ordinary

shares outstanding used to calculate both basic and diluted net loss per share attributable to ordinary shareholders is the same. The Company excluded the following potential ordinary shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to ordinary shareholders for the year ended December 31, 2023, 2022 and 2021 because including them would have had an anti-dilutive effect:

	Year ended December 31,		
	2023	2022	2021
Unvested ordinary shares	838,845	1,294,803	1,903,058
Share options	5,057,099	2,993,641	1,357,847
Total	5,895,944	4,288,444	3,260,905

13. Commitments and contingencies

Commitment with suppliers

The Company entered into several agreements with vendors that contain non-cancellable software arrangements and minimum purchase commitments of laboratory materials and consumables for the purpose of research and development activities as well as clinical development. The unused purchase commitment as of December 31, 2023 and 2022 was $3.5 million and $3.8 million, respectively.

Asset Retirement Obligations

The following is a reconciliation of our beginning and ending asset retirement obligation balances for 2023 and 2022 (in thousands):

	2023	2022
Balance, beginning of the year	$ 933	$ 690
Additional obligations recognized in the current year	-	168
Accretion expense	82	75
Balance, end of year	$ 1,015	$ 933

The Company's asset retirement obligations relate to post-closure reclamation costs for leases of office and laboratory space.

Legal proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. The Company was not a party to any litigation and did not have contingency reserves established for any liabilities as of December 31, 2023 and 2022.

Indemnification agreements

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

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

14. Related party transactions

The Company analyzed its transactions with related parties for the years ended December 31, 2023, 2022 and 2021, and determined that it had the no material transactions that have not been described elsewhere in the financial statements.

15. Employee benefit plans

In the UK, the Company makes contributions to private defined contribution pension schemes on behalf of its employees. The contributions to this scheme are expensed to the statement of operations as they fall due. The Company paid $2.3 million, $2.3 million and $1.8 million in contributions in the years ended December 31, 2023, 2022 and 2021, respectively.

In the United States, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company paid less than $0.1 million in contributions in the years ended December 31, 2023, 2022 and 2021, respectively.

16. Subsequent Events

The Company has completed an evaluation of all subsequent events through April 4, 2024, the date on which the financial statements were issued, to ensure that these financial statements include appropriate disclosure of events both recognized in these financial statements as of December 31, 2023, and events which occurred subsequently but were not recognized in these financial statements.

Item 19. Exhibits.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporation by Reference			
		Schedule/Form	File Number	Exhibit	File Date
1.1	Articles of Association of Achilles Therapeutics plc.	Form 20-F	001-40299	1.1	3/1/2022
2.1	Deposit Agreement, dated as of March 30, 2021, by and among the registrant, The Bank of New York Mellon, as the depositary bank, and the holders and beneficial holders from time to time of American Depositary Shares issued thereunder.	Form 20-F	001-40299	2.1	3/1/2022
2.2	Form of American Depositary Receipt (included in Exhibit 2.1).	Form 20-F	001-40299	2.2	3/1/2022
2.3	Description of Securities	Form 20-F	001-40299	2.3	3/1/2022
4.1#	2020 Omnibus Plan, as amended, and forms of award agreements thereunder.	Form F-1	333-253735	10.1	3/1/2021
4.2#	2021 Equity Stock Purchase Plan	Form F-1	333-253735	10.2	3/1/2021
4.3#	2021 Omnibus Plan	Form F-1	333-253735	10.3	3/1/2021
4.4	Form of Amended and Restated Registration Rights Agreement, by and between the registrant, Cancer Research Technology Limited and the shareholders listed therein.	Form F-1	333-253735	10.4	3/1/2021
4.5	Lease Agreement, by and between Achilles Therapeutics Limited, 245 Hammersmith Road Nominee 1 Limited, 245 Hammersmith Road Nominee 2 Limited and 245 Hammersmith Road Limited Partnership, dated as of February 21, 2020.	Form F-1	333-253735	10.5	3/1/2021
4.6	Collaboration Agreement, by and between Achilles Therapeutics Limited and Cell Therapy Catapult, dated as of February 28, 2020, as amended.	Form F-1	333-253735	10.6	3/1/2021
4.7*	Amendment Two, by and between Achilles Therapeutics UK Limited and Cell Therapy Catapult Limited, dated as of February 22, 2024.				
4.8†	License Agreement, by and between Achilles Therapeutics Limited and Cancer Research Technology Limited, dated as of May 24, 2016, as amended.	Form F-1/A	333-253735	10.7	3/10/2021
4.9†*	Patent Assignment and Licence Agreement, by and between Achilles Therapeutics Limited and Cancer Research Technology Limited, dated as of November 29, 2023.				

4.10	Lease Agreement, by and between Achilles Therapeutics Limited and RLUKREF Nominees (UK) One Limited and RLUKREF Nominees (UK) Two Limited, dated as of December 16, 2020.	Form F-1	333-253735	10.8	3/1/2021
4.11#	Form of Employment Agreement with Iraj Ali.	Form F-1	333-253735	10.9	3/1/2021
4.12#	Form of Deed of Indemnity between Achilles Therapeutics plc and each of its Directors and Officers.	Form F-1	333-253735	10.10	3/1/2021
8.1*	List of Subsidiaries.				
12.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.				
12.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.				
13.1+	Certification of Chief Executive Officer Pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934.				
13.2+	Certification of CFO Chief Financial Officer to Rule 13a-14(b) of the Securities Exchange Act of 1934.				
15.1*	Consent of Independent Registered Public Accounting Firm.				
97*	Compensation Recovery Policy				
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.
+ Furnished herewith.
† Certain portions of this exhibit have been omitted by means of redacting a portion of the text and replacing it with "[*]", because they are both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.
# Indicates a management contract or any compensatory plan, contract or arrangement.*

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

ACHILLES THERAPEUTICS PLC

Date: April 4, 2024

By: /s/ Iraj Ali

Name: Iraj Ali, Ph.D.

Title: Chief Executive Officer

Exhibit 4.7

This **Amendment Two** is effective from 22 February 2024

BETWEEN:

(1) **CELL THERAPY CATAPULT LIMITED,** trading as Cell and Gene Therapy Catapult, incorporated and registered in England and Wales with company number 07964711 whose registered office is at 12th Floor Tower Wing, Guys Hospital, Great Maze Pond, London, SE1 9RT ("**Catapult**"); and

(2) **ACHILLES THERAPEUTICS UK LIMITED,** a company incorporated in England and Wales with company number 10167668 whose registered office is at 245 Hammersmith Road, London, United Kingdom, W6 8PW ("**Achilles**"),

each a "**Party**" and together the "**Parties**".

BACKGROUND

(A) The Parties entered into a collaboration agreement dated 28th February 2020 in respect of Achilles' occupation of a module at Catapult's Manufacturing Centre located at Gunnels Wood Road, Stevenage SG1 2FX Stevenage, which was amended by agreement on 12 December 2022 (the "**Agreement**").

(B) The Parties are entering into this amendment to effect an extension to the term of the Agreement from 28 February 2024 to 31 March 2025.

(C) The Parties hereby agree to amend the Agreement as set out in this Amendment Two.

IT IS AGREED AS FOLLOWS:

1. Capitalised words that are not defined in this Amendment Two will have the meanings given to them in the Agreement.

2. This Amendment Two shall include the terms and conditions set out herein and the appendices attached hereto.

3. The Parties hereby agree to vary the Agreement as follows:

3.1 Clause 17.1 shall be deleted in its entirety and replaced with the following:

*"This Agreement, and the licences granted hereunder, will come into effect on the Effective Date and, unless terminated earlier in accordance with this **Clause 17** or unless specified in the continuing obligations provisions of this Agreement as having continued effect, will continue in force until 31 March 2025 (the "**Term**"), and on such date this Agreement will terminate automatically by expiry."*

4. Except as set forth in this Amendment Two, the Agreement and the Schedules thereto are unaffected and shall continue in full force and effect in accordance with its terms. Notwithstanding the relevant provisions of the Agreement, in the event of any conflict between

the terms of this Amendment Two and the terms of the Agreement, the terms of this Amendment Two shall prevail.

5. This Amendment Two (and all disputes arising out of or in connection with it) shall be governed by and construed in accordance with the laws of England and Wales and the parties hereby submit to the exclusive jurisdiction of the English Courts.

IN WITNESS WHEREOF this Amendment Two is executed as follows:

For and on behalf of **CELL THERAPY CATAPULT LIMITED:**		For and on behalf of **ACHILLES THERAPEUTICS UK LIMITED**	
Signed:	/s/ Matthew Durdy	Signed:	/s/ Iraj Ali
Print Name:	Matthew Durdy	Print Name:	Iraj Ali
Job Title:	Chief Executive Officer	Job Title:	CEO
Date:	22-Feb-2024 | 09:29 GMT	Date:	22-Feb-2024 | 09:39 GMT

Exhibit 4.9

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

DATED November 29, 2023

(1) CANCER RESEARCH TECHNOLOGY LIMITED

TRADING AS CANCER RESEARCH HORIZONS

- and -

(2) ACHILLES THERAPEUTICS UK LIMITED

PATENT ASSIGNMENT AND LICENCE

CONTENTS

THIS DEED is dated with effect from the date of the last signature below

BETWEEN:

(1) **ACHILLES THERAPEUTICS UK LIMITED (formerly named ACHILLESTX LIMITED** and **ACHILLES THERAPEUTICS LIMITED),** a company duly organised and validly existing under the laws of England (company number 10167668) with its registered office at 245 Hammersmith Road, London W6 8PW (**"AchillesTx"**); and

(2) **CANCER RESEARCH TECHNOLOGY LIMITED**, trading as **CANCER RESEARCH HORIZONS**, a company duly organised and validly existing under the laws of England (company number 01626049) with its registered office at [***] (**"CRT"**).

Each of the above parties is individually referred to as a "**Party**" and collectively as "**Parties**".

BACKGROUND:

(A) The Parties entered into a Licence Agreement dated 24 May 2016, which was subsequently amended on 18 May 2018, 11 October 2018 (the "**LOHHLA Addendum**"), 15 July 2020, 15 October 2020 and 22 January 2021 (together the "**Licence Agreement**") pursuant to which CRT granted various licences to AchillesTx including an exclusive licence, a non-exclusive licence, an exclusive vaccine licence and a non-exclusive vaccine licence in respect of the TRACERx Patents (as defined in the Licence Agreement). The Parties entered into the LOHHLA Addendum pursuant to which the LOHHLA Patents (as defined in the LOHHLA Addendum) were included in the TRACERx Patents and CRT granted various licences to the LOHHLA Patents to AchillesTx including an exclusive licence, a non-exclusive licence, an exclusive vaccine licence and a non-exclusive vaccine licence pursuant to the Licence Agreement. AchillesTx served a notice on CRT to exercise the Vaccine Option (as defined in the Licence Agreement) dated 4th May 2023.

(B) In accordance with clause 8.1 of the Licence Agreement, AchillesTx may seek assignment of certain TRACERx Patents on the occurrence of certain triggering events listed in the same clause (the "**Assignment Option**"). On 6 April 2021, AchillesTx completed an initial public offering of shares in Achilles Therapeutics plc (which wholly owns AchillesTx), which constitutes a triggering event under clause 8.1.3 of the Licence Agreement. On 4 May 2021, Achilles issued a notice to CRT of its intention to exercise its Assignment Option with respect to certain TRACERx Patents.

(C) For clarity, subject to the Assignment Option, the TRACERx Patents as at the Assignment Date are listed in Schedule 1 of this Deed (the "**Existing Assigned Patents**"). CRT agrees to assign the Existing Assigned Patents and all Patent Rights granted or issued from, associated with or derived from those patents (together the "**Assigned Patents**") to AchillesTx and pursuant to the Licence Agreement. AchillesTx agrees to licence the Assigned Patents to CRT, in accordance with this Deed.

(D) In accordance with the principles set out in the Licence Agreement, the Parties acknowledge that this Assignment Agreement (apart from ownership of the Assigned Patents) is not intended to affect the positions set out in the Licence Agreement.

(E) In accordance with clause 4.5 of the LOHHLA Addendum, the Assignment Option does not apply in respect of the LOHHLA Patents and therefore, AchillesTx's obligations in respect of the LOHHLA Patents shall continue in accordance with the Licence Agreement.

IT IS AGREED:

1. DEFINITIONS AND INTERPRETATION

1.1. In this Deed:

1.1.1. The words and expressions defined in the Licence Agreement (including in the LOHHLA Addendum) shall have the same meaning and effect in this Deed except where expressly stated otherwise or where the context requires otherwise.

1.1.2. In this Deed:

"**Assignment Date**"	means the date of this Deed;
"**Assignment Option**"	has the meaning given in the Background section of this Deed;
"**Assigned Patents**"	has the meaning given in the Background section of this Deed;
"Commercial"	any activity (including but not limited to Commercial Research), or party which is conducting any such activity, which is an activity: (i) that is, in whole or part, funded by a person or entity that is not a Funder; or (ii) that is undertaken at the request of or for the benefit of any entity that is not an Academic Organisation involved in such activity; or (iii) that is undertaken (as opposed to funded) in collaboration with any entity which is not an Academic Organisation; or (iv) under which a Third Party, which is not an Academic Organisation (or technology transfer organisation associated with such Academic Organisation) participating in such activity, will acquire any rights to, or access to, or ownership or control of, or exploitation of, (including by way of assignment or licence,) the results of such activity;
"**Licence Agreement**"	has the meaning given in the Background section of this Deed;
"**Licence Back Table 1**"	means the table attached as Schedule 2;
"**Licence Back Table 2**"	means the table attached as Schedule 3;
"**LOHHLA Addendum**"	has the meaning given in the Background section of this Deed;

1.2. In this Deed:

1.2.1. a reference to this Deed includes its schedules, appendices and annexes (if any), which shall be deemed to form a part of this Deed as if they had been expressly set out verbatim in the main body of this Deed;

1.2.2. a reference to a 'person' includes a natural person, corporate or unincorporated body (in each case whether or not having separate legal personality) and that person's personal representatives, successors and permitted assigns;

1.2.3. a reference to a gender encompasses said gender as well as all genders;

1.2.4. words in the singular include the plural and vice versa;

1.2.5. any words that follow 'include', 'includes', 'including', ‘in particular’ or any similar words and expressions shall be construed as illustrative only and shall not limit the sense of any word, phrase, term, definition or description preceding those words;

1.2.6. the table of contents and any clause, schedule or other headings in this Deed are included for convenience only and shall have no effect on the interpretation of this Deed; and

1.2.7. a reference to legislation is a reference to that legislation as amended, extended, re-enacted or consolidated from time to time.

2. ASSIGNMENT

2.1. In consideration of the sum of [***] (the receipt and sufficiency of which is hereby acknowledged by CRT), subject to the terms of this Deed including the licences granted to CRT under Clause 3, CRT hereby assigns to AchillesTx all of CRT’s right, title and interest in and to the Assigned Patents, including without limitation the right to claim priority therefrom, the right to apply for patent or similar protection in relation to any application in the Assigned Patents in any part of the world together with the right to bring, make, oppose, defend and appeal proceedings, claims or actions and obtain relief and recover damages in respect of all infringements and threatened infringements of such Assigned Patents, whether occurring before, on or after the Assignment Date. CRT warrants and represents as of the Assignment Date, that since the Effective Date of the Licence Agreement CRT has not granted, or agreed to grant, any licence to any Commercial Third Party in respect of the Assigned Patents to develop a Royalty Product with application in the Therapeutic Field or the Vaccine Therapeutic Field.

2.2. From the Assignment Date, the Parties’ rights and obligations in the Licence Agreement in respect of the Assigned Patents (but not in respect of any other Intellectual Property or assets) are hereby terminated except for the following rights and obligations under the Licence Agreement which shall continue in full force and effect in accordance with their terms, as the same may have been expressly modified by this Deed:

2.2.1. AchillesTx shall continue to observe and comply with the diligence obligations in accordance with clause 9 of the Licence Agreement;

2.2.2. AchillesTx (and its Affiliates) shall not assign or license or permit or suffer to be assigned or licensed the Assigned Patents to a Tobacco Party or to an Affiliate of a Tobacco Party;

2.2.3. Each Party shall continue to observe and comply with its obligations stated in:

(a) clause 12 of the Licence Agreement (Milestone Payments);

(b) clause 13 of the Licence Agreement (Royalties);

(c) clause 14 of the Licence Agreement (Reporting and Payment);

(d) clause 16.12 of the Licence Agreement (Indemnity Conditions);

(e) clause 17 of the Licence Agreement (Intellectual Property Enforcement) and AchillesTx shall keep CRT informed of any Enforcement Actions which are controlled by AchillesTx, including with respect to its obligations under clause 17.2.4 of the Licence Agreement and shall give due consideration to any reasonable comments and suggestions of CRT with respect to such Enforcement Action; and

(f) clause 18 of the Licence Agreement (Confidentiality); and

(g) any other provision of the Licence Agreement which (including in respect of any accrued rights and liabilities) is reasonably required to survive the termination or expiry of the Licence Agreement in order to put into effect any of the provisions of this Deed.

2.3. AchillesTx shall be responsible, in its sole discretion, to determine in which countries to maintain or Surrender the Assigned Patents. Achilles shall report to CRT once every calendar year details of the status of prosecution and maintenance of the Assigned Patents and respond to any questions that CRT may reasonably raise in respect of the information provided. Notwithstanding the foregoing discretion, if AchillesTx wishes to Surrender any of the Assigned Patents in any of the Core Countries (such Assigned Patents in such Core Countries being "**Surrendered Patents**") then the following shall apply:

2.3.1. prior to taking any steps to Surrender any of the Surrendered Patents, AchillesTx shall first provide CRT with at least [***] days' notice of its intention identifying the Surrendered Patents;

2.3.2. CRT shall have a right of step-in (to be exercised within [***] days of receiving notice from AchillesTx under Clause 2.3.1) to take over the Surrendered Patents (on its own behalf or on behalf of either or both of UCLB and the CRICK) and if it exercises such right: (i) AchillesTx will, at CRT's request, cost and expense, assign all its rights, title and interest in and to the Surrendered Patents to CRT and will sign, execute and deliver all such deeds and documents, as may be required for the purpose of giving full effect to this Clause 2.3.2 of this Deed including any relevant deeds and documents that may be held by AchillesTx's patent attorneys (provided that such patent attorneys shall be permitted to retain copies of such documents for recordkeeping purposes); (ii) CRT shall be responsible for all costs and expenses associated thereafter with the Surrendered Patents; and (iii) CRT and its licensees shall only have the right to undertake acts that would otherwise infringe the Surrendered Patents in the applicable Core Countries and CRT shall ensure that they do not actively solicit sales of any products manufactured in the applicable Core Countries under the Surrendered Patents outside of the applicable Core Countries (for the avoidance of doubt, CRT and its licensees shall not be prohibited from making sales to fulfil unsolicited orders received from customers outside of the Core Countries); and

2.3.3. if CRT does not exercise its step-in right in accordance with Clause 2.3.2, then AchillesTx may without breach of this Deed or the Licence Agreement, Surrender such Surrendered Patents.

2.4. Notwithstanding the assignment of the Assigned Patents to AchillesTx pursuant to this Deed, each Party's obligations in the Licence Agreement to the other Party in respect of the LOHHLA Patents shall remain in full force and effect.

2.5. If the Licence Agreement is terminated:

2.5.1. by AchillesTx pursuant to clause 22.2 of the Licence Agreement; or

2.5.2. by CRT pursuant to clause 22.3 of the Licence Agreement; then

upon written request from CRT, AchillesTx shall immediately cease all use and Exploitation of the Assigned Patents, and AchillesTx will and will procure that its Affiliates (as applicable) assign all of AchillesTx's (and its Affiliates) rights, title and interest in and to the Assigned Patents to CRT and at CRT's request, cost and expense it will sign, execute and deliver all such deeds and documents, as may be required for the purpose of giving full effect to this Clause 2.5. For clarity assignment by AchillesTx of the Assigned Patents, shall not include any enhancement, development or improvement in or to the Assigned Patents that are not Assigned Patents.

3. GRANT OF LICENCE

3.1. AchillesTx hereby grants to CRT under the Assigned Patents the licences set out in column 1 of Licence Back Table 1, each of which shall be deemed to be fully paid-up and royalty free. For clarity the back licences granted to CRT are as follows:

3.1.1. CRT Back Licence 1;

3.1.2. CRT Back Licence 2;

3.1.3. CRT Back Licence 3;

3.1.4. CRT Back Licence 4;

3.1.5. CRT Back Licence 5;

3.1.6. CRT Back Licence 6;

3.1.7. CRT Back Licence 7; and

3.1.8. CRT Back Licence 8.

3.2. Each of the above licences in this Deed, and in the event granted to CRT pursuant to Clause 3.7 each of the licences in Clause 3.7, is referred to individually as a "**CRT Back Licence**" and collectively as the "**CRT Back Licences**".

3.3. The CRT Back Licences set forth in Clause 3.1 are granted in accordance with the provisions of Clause 3.5 and Schedule 2 below.

3.4. Each CRT Back Licence is a separate licence that is discrete from all other CRT Back Licences and any variation, termination or disposition of any one CRT Licence shall not thereby affect any other CRT Back Licence.

3.5. With reference to Licence Back Table 1 each CRT Back Licence set forth in Clause 3.1 is granted respectively:

3.5.1. in the relevant Field stated in column 2; and

3.5.2. on the terms set out in column 3.

3.6. Save for the CRT Back Licences, CRT shall retain no other rights to the Assigned Patents that deviate from or otherwise encumber, limit or affect the Assigned Patents.

3.7. In the event that:

3.7.1. the CRT Licence under the Licence Agreement is terminated by CRT with respect to the Therapeutic Field pursuant to: (a) clause 9.14.2 of the Licence Agreement upon CRT request, and/or (b) unremedied material breach of clause 2.2.1 of this Assignment Agreement in relation to the Therapeutic Field by AchillesTx, AchillesTx shall immediately cease all use and Exploitation of the Assigned Patents in the Therapeutic Field, and AchillesTx hereby grants to CRT under the Assigned Patents the CRT Back Licence 9 set out in column 1 of Licence Back Table 2, which shall be deemed to be fully paid-up and royalty free; and CRT Back Licence 1 shall be deemed to be terminated.

3.7.2. the Vaccine Licence under the Licence Agreement is terminated by CRT with respect to the Therapeutic Vaccine Field pursuant to: (a) clause 9.14.1 of the Licence Agreement; and/or (b) unremedied material breach of clause 2.2.1 of this Assignment Agreement in relation to the Therapeutic Vaccine Field by AchillesTx, upon CRT request, AchillesTx shall immediately cease all use and Exploitation of the Assigned Patents in the Therapeutics Vaccine Field, and AchillesTx hereby grants to CRT under the Assigned Patents the CRT Back Licence 10 set out in column 1 of Licence Back Table 2, which shall be deemed to be fully paid-up and royalty free; and CRT Back Licence 2 shall be deemed to be terminated.

3.7.3. the CRT Licence under the Licence Agreement is terminated by CRT with respect to the Neo-Antigen Diagnostic Field pursuant to: (a) clause 9.14.3 of the Licence Agreement; and/or (b) unremedied material breach of clause 2.2.1 of this Assignment Agreement in relation to the Neo-Antigen Diagnostic Field by AchillesTx, upon CRT request, AchillesTx shall immediately cease all use and Exploitation of the Assigned Patents in the Neo-Antigen Diagnostic Field, and AchillesTx hereby grants to CRT under the Assigned Patents the CRT Back Licence 11 set out in column 1 of Licence Back Table 2, which shall be deemed to be fully paid-up and royalty free; and CRT Back Licence 3 shall be deemed to be terminated.

3.8. The CRT Back Licences set forth in Clause 3.7 are granted in accordance with the provisions of Clause 3.7 and Schedule 3 below.

3.9. With reference to Licence Back Table 2 each CRT Back Licence set forth in Clause 3.7 is granted respectively:

3.9.1. in the relevant Field stated in column 2;

3.9.2. on the terms set out in column 3.

3.10. The Parties agree that, notwithstanding the provisions of this Assignment Agreement, the following provisions of the Licence Agreement shall continue to apply in full force and effect, *mutatis mutandis*, in accordance with the agreed principle that this Assignment Agreement (apart from ownership of the Assigned Patents) is not intended to affect the positions set out in the Licence Agreement, and in the event of any conflict or inconsistency between them clauses 5 and 10 in the Licence Agreement shall take precedence over this Agreement:

3.10.1. clause 5; and

3.10.2. clause 10.

Licences Termination

3.11. The CRT Back Licences granted by AchillesTx pursuant to Clause 3 shall automatically terminate on a CRT Back Licence-by-CRT Back Licence basis and country-by-country basis on the earlier of:

3.11.1. the first date on which there are no longer any Valid Claims, whether as a result of expiry of Surrender; or

3.11.2. if AchillesTx assigns the Assigned Patents to CRT in accordance with Clause 2.3 or 2.5.

3.12. The termination of any or all of the CRT Back Licences granted pursuant to Clause 3 shall not affect any accrued rights and liabilities of either Party at any time up to the date of termination.

4. SUBLICENSING

4.1. CRT may grant written sublicences of each relevant CRT Back Licence stated to be sublicensable in Licence Back Table 1 or Licence Back Table 2 (as applicable) provided that each such CRT sublicence does not grant rights in the Assigned Patents beyond those granted to CRT in Clause 3.1.

4.2. If CRT wishes to enter into a written Commercial sublicence agreement with a Commercial third party after the Assignment Date under which CRT grants such Commercial third party a right to Exploit any Assigned Patents under CRT Back Licence 4, CRT Back Licence 5, CRT Back Licence 6, CRT Back Licence 7 and/or CRT Back Licence 8, CRT shall notify AchillesTX of the identity of the Commercial third party and the identity of the applicable CRT Back Licence(s) before negotiating the same and will provide: (i) the terms of the proposed Commercial sublicence prior to the proposed Commercial sublicence being entered into; and (ii) such further information, regarding the transaction as AchillesTx may reasonably request at the time. 3.1

5. FURTHER ASSURANCE

5.1. AchillesTx shall be solely responsible for recording the change of ownership of the Assigned Patents with all relevant registries and shall do so as soon as reasonably practicable following the execution of this Deed.

5.2. CRT agrees (at AchillesTx's request) to, at AchillesTx’s sole cost, use all reasonable endeavours to promptly execute such documents and perform such acts as may reasonably be required or desired by AchillesTx to give effect to this Deed, including any short form assignments required by the relevant registries.

6. WARRANTIES

6.1. Each Party warrants and represents that it has the right, power and authority to enter into this Deed and to perform its respective obligations in accordance with the terms of this Deed.

6.2. CRT acknowledges that any conditions, warranties or other terms implied by statute or common law with respect to the Assigned Patents are excluded from this Deed to the full extent permitted by law.

6.3. Neither Party gives to the other Party any warranty, representation or undertaking:

6.3.1. that any of the Assigned Patents are or will be valid or subsisting or (in the case of applications) will proceed to grant; or

6.3.2. that any Exploitation of any of the Assigned Patents or the exercise of any other rights licensed under this Deed, will not infringe the Intellectual Property or other rights of any third party.

7. INDEMNITY

7.1. If CRT enters into a Commercial sublicence agreement with a Commercial third party after the Assignment Date under which CRT grants such Commercial third party a right to Exploit any Assigned Patents under CRT Licence 4, CRT Licence 5, CRT Licence 6, CRT Licence 7 and/or CRT Licence 8 and under such sublicence agreement CRT obtains an indemnity from such Commercial third party in favour of CRT in respect of loss or damage caused by the use or Exploitation of the Assigned Patents that have been sublicensed, then CRT shall use all reasonable endeavours to extend that indemnity from such third party to AchillesTx and its wholly owned Affiliates and their officers and employees (each an **"AchillesTx Indemnified Party"** and together the **"AchillesTx Indemnified Parties"**) pursuant to such sublicence agreement, save to the extent such liability arises from: (i) a breach by AchillesTx of any term of this Deed and/or the Licence Agreement; or (ii) the negligence of any of the AchillesTx Indemnified Parties. The Parties acknowledge that CRT shall be able to enter into a binding written sublicence agreement with any Commercial third party under CRT Back Licence 4, CRT Back Licence 5, CRT Back Licence 6, CRT Back Licence 7, CRT Back Licence 8, CRT Back Licence 9, CRT Back Licence 10 and/or CRT Back Licence 11 (but not any other CRT Back Licence), without obtaining the indemnity in favour of the AchillesTx Indemnified Parties if, notwithstanding use of CRT's all reasonable endeavours, CRT has been unable to obtain the extension of the indemnity referred to above.

8. LIABILITY

Special, Indirect and Other Losses

8.1. Subject to clause 8.3, in no event shall any Party or any of their respective Affiliates be liable for breach of contract, statutory duty, negligence or in any other way for special, indirect, incidental, punitive or consequential damages or for any indirect economic loss or indirect loss of profits suffered by any other Party or their respective Affiliates.

Limitation

8.2. Any and all liability of CRT arising under or in connection with this Deed for any reason whatsoever including breach and negligence shall be covered by and form part of the cap on liability in favour of CRT set out in clause 20.2 of the Licence Agreement.

No Exclusion

8.3. Nothing in this Deed shall limit or be construed to limit in any way any liability under this Deed:

8.3.1. of either Party (or its respective Affiliates) in respect of (i) death or personal injury caused by that Party's (or its respective Affiliates') negligence; (ii) any fraud or fraudulent misrepresentation; or (iii) any other liability which, by rule of law, may not be excluded or limited by contract between Parties;

8.3.2. of AchillesTx under clauses 2.2.3 (a), (b) and (e).

9. CONFIDENTIAL INFORMATION

9.1. For clarity, any and all Confidential Information generated by either or both Parties under this Deed shall be deemed to be Confidential Information under the Licence Agreement and subject to clause 18 (Confidentiality) of the Licence Agreement.

10. ENTIRE AGREEMENT

This Deed and the Licence Agreement contain the entire understanding of each of the Parties hereto with respect to the transactions and matters contemplated hereby and supersedes all prior agreements and understandings relating to the subject matter hereof.

11. NOTICES

11.1. All notices required to be served by the Parties to this Deed under the terms hereof shall be sufficiently served if dispatched by first class post or commercial courier to the addresses of each of the Parties set out below. All such notices shall be deemed received within three (3) business days after such dispatch.

11.2. If to:

11.2.1. AchillesTx: 245 Hammersmith Road, London, United Kingdom, W6 8PW;

11.2.2. CRT: [***], marked for the attention of the Chief Executive Officer

and any modification or amendment to such address must itself be notified in writing to the other Parties in accordance with the terms of this Clause.

12. ANNOUNCEMENTS

No announcement or other public disclosure concerning this Deed or any of the matters contained in it shall be made by, or on behalf of, a Party without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except as required by law, any court, any governmental, regulatory or supervisory authority (including any recognised investment exchange) or any other authority of competent jurisdiction.

13. VARIATION

No variation of this Deed shall be valid or effective unless it is in writing, refers to this Deed and is duly signed or executed by, or on behalf of, each Party.

14. TRANSFER OF RIGHTS

CRT may not assign, or subcontract (not being a sublicence), any right or obligation under this Deed, in whole or in part, without AchillesTx's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed.

15. SEVERANCE

If any provision of this Deed (or part of any provision) is or becomes illegal, invalid or unenforceable, the legality, validity and enforceability of any other provision of this Deed shall not be affected.

16. WAIVER

No failure, delay or omission by either Party in exercising any right, power or remedy provided by law or under this Deed shall operate as a waiver of that right, power or remedy, nor shall it preclude or restrict any future exercise of that or any other right or remedy. No single or partial exercise of any right, power or remedy provided by law or under this Deed shall prevent any future exercise of it or the exercise of any other right, power or remedy.

17. COUNTERPARTS

17.1. This Deed may be executed in any number of separate counterparts, each of which when executed and delivered shall be an original, and such counterparts taken together shall constitute one and the same Deed.

17.2. Each Party may evidence their execution of this Deed by transmitting by email a signed signature page of this Deed in PDF format together with the final version of this Deed in PDF or Word format, which shall constitute an original signed counterpart of this Deed.

18. THIRD PARTY RIGHTS

Save where the provisions of sub-clause 29.7.8 of the Licence Agreement may continue to apply to matters referred to under Clause 2.2 of this Deed, no one other than a Party to this Deed their successors and permitted assignees shall have any right to enforce any of its provisions.

19. DISPUTE RESOLUTION, GOVERNING LAW AND JURISDICTION

All controversies or claims of whatever nature arising out of or relating in any manner whatsoever to this Deed or any of the documents referred to in this Deed, including but not limited to a controversy or claim involving the validity, enforceability, interpretation or construction of this Deed or any of the documents referred to in this Deed, shall be resolved in all respects in accordance with clause 31 of the Licence Agreement (with all references to the Agreement being deemed to be references to this Deed).

SCHEDULE 1

EXISTING ASSIGNED PATENTS

[***]

SCHEDULE 2

LICENCE BACK TABLE 1:
LICENCES GRANTED BY ACHILLES TO CRT

(1)	(2)	(3)
Name of Licence	**Field**	**Licence Back Terms**
"CRT Back Licence 1"	Therapeutic Field	Non-exclusive, worldwide, perpetual and irrevocable sub-licence (with a right to sub-licence across multiple tiers) to grant Academic Rights, in each case in accordance with, on the same terms, and subject to the same restrictions, as are set out in Clause 5 of the Licence Agreement.
"CRT Back Licence 2"	Therapeutic Vaccine Field concerning or targeting Private Neo-Antigens	Non-exclusive, worldwide, perpetual and irrevocable sub-licence (across multiple tiers): to grant Academic Rights, in each case in accordance with, on the same terms, and subject to the same restrictions, as are set out in Clause 5 of the Licence Agreement.
"CRT Back Licence 3"	Neo-Antigen Diagnostic Field	Non-exclusive, worldwide, perpetual and irrevocable sub-licence (across multiple tiers): to grant Academic Rights, in each case in accordance with, on the same terms, and subject to the same restrictions, as are set out in Clause 5 of the Licence Agreement

"CRT Back Licence 4"	Therapeutic Vaccine Field concerning or targeting Public Neo-Antigens	Non-exclusive, worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation
"CRT Back Licence 5"	All fields concerning or targeting Public Neo-Antigens outside: (i) the Therapeutic Vaccine Field; and (ii) the Therapeutic Field concerning or targeting Public Neo-Antigens	Exclusive (to the exclusion of AchillesTX), worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation
"CRT Back Licence 6"	Therapeutic Antibody Field	Non-exclusive, worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation
"CRT Back Licence 7"	Non Neo-Antigen Diagnostics Field	Non-exclusive, worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation
"CRT Back Licence 8"	All fields outside of Therapeutic Field, Therapeutic Vaccine Field, Therapeutic Antibody Field, Neo- Antigen Diagnostic Field and Non Neo-Antigen Diagnostic Field	Exclusive (to the exclusion of AchillesTX), worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation

All such licences are subject to the other provisions of this Assignment Agreement, including but not limited to Clause 3.10, as applicable.

SCHEDULE 3

LICENCE BACK TABLE 2:
ADDITIONAL LICENCES GRANTED BY ACHILLES TO CRT

(1)	(2)	(3)
Name of Licence	**Field**	**Licence Back Terms**
"CRT Back Licence 9"	Therapeutic Field	Exclusive (to the exclusion of AchillesTX), worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation
"CRT Back Licence 10"	Therapeutic Vaccine Field	Exclusive (to the exclusion of AchillesTX), worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation
"CRT Back Licence 11"	Neo-Antigen Diagnostic Field	Exclusive (to the exclusion of AchillesTX), worldwide, perpetual and irrevocable, with a right to sub-license across multiple tiers for all uses including Exploitation

All such licences are subject to the other provisions of this Assignment Agreement, including but not limited to Clause 3.10, as applicable.

EXECUTED as a deed by the parties and delivered on the date set out at the head of this Deed.

Executed as a deed by **CANCER RESEARCH TECHNOLOGY LIMITED** trading as **CANCER RESEARCH HORIZONS**

[***]
Director Name

[***]
Director Signature

November 29, 2023
Date

In the presence of:

[***]
Witness Name

[***]
Witness Signature

[***]
Witness Address

November 29, 2023
Date

Executed as a deed by **ACHILLES THERAPEUTICS UK LIMITED** acting by

[***]
Director Name

[***]
Director Signature

November 28, 2023
Date

In the presence of:

[***]
Witness Name

[***]
Witness Address

[***]
Witness Signature

November 28, 2023
Date

List of Subsidiaries **Exhibit 8.1**

Company	Country of incorporation	Percentage ownership and voting interest
Achilles Therapeutics Holdings Limited	England and Wales	100.00%
Achilles Therapeutics UK Limited	England and Wales	100.00%
Achilles Therapeutics US, Inc.	United States	100.00%

Exhibit 12.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Iraj Ali, certify that:

1. I have reviewed this Annual Report on Form 20-F of Achilles Therapeutics plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   A. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   B. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   C. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   D. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   A. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

B. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 4, 2024

/s/ Iraj Ali

Iraj Ali

Chief Executive Officer (Principal Executive Officer)

Exhibit 12.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Robert Coutts, certify that:

1. I have reviewed this Annual Report on Form 20-F of Achilles Therapeutics plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    A. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    B. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    C. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    D. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    A. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

B. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 4, 2024

/s/ Robert Coutts

Robert Coutts
Chief Financial Officer
(Principal Financial Officer)

Exhibit 13.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 20-F of Achilles Therapeutics plc (the "Company") for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 4, 2024

By: /s/ Iraj Ali
Name: Iraj Ali

Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 13.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 20-F of Achilles Therapeutics plc (the "Company") for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 4, 2024

by /s/ Robert Coutts

Name: Robert Coutts

Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-270344; 333-263220; and 333-255063) on Form S-8, and registration statement (No. 333-268239) on Form F-3 of our report dated April 4, 2024, with respect to the consolidated financial statements of Achilles Therapeutics plc.

/s/ KPMG LLP

Reading, United Kingdom
April 4, 2024

ACHILLES THERAPEUTICS PLC.
DODD-FRANK COMPENSATION RECOUPMENT POLICY

1. Purpose; Overview. The purpose of this Dodd-Frank Compensation Recoupment Policy (this "Policy") is to set forth the circumstances under which a Covered Executive will be required to repay or return Erroneously Awarded Compensation to Achilles Therapeutics plc (together with its Affiliates, the "Company"). The Committee has adopted this Policy in accordance with the terms herein and this Policy is intended to comply with Nasdaq Listing Rule 5608, as such rule may be amended from time to time (the "Listing Rule"). Capitalized terms not otherwise defined herein shall have the meanings assigned to such terms under Section 10 of this Policy.

2. Recovery of Erroneously Awarded Compensation. Upon the occurrence of a Restatement, if the Committee determines that a Covered Executive Received any Erroneously Awarded Compensation, the Company shall reasonably promptly take steps to recover such Erroneously Awarded Compensation, and each Covered Executive shall be required to take all actions necessary to enable such recovery, provided, however, that there shall be no duplication of recovery under this Policy and any of Section 304 of the Sarbanes-Oxley Act of 2002, Section 10D of the Exchange Act, or provisions or terms of other Company policies or compensation plans or awards. In no event shall the Company be required to award a Covered Executive an additional payment if the restated or accurate financial results would have resulted in a higher Incentive Compensation payment.

(a) *Means of Recovery*. The Committee shall determine, in its sole discretion and in a manner that effectuates the purpose of the Listing Rule, one or more methods for recovering any Erroneously Awarded Compensation hereunder, which may include, without limitation: (i) requiring cash reimbursement of cash Incentive Compensation previously paid; (ii) seeking recovery or forfeiture of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards granted as Incentive Compensation; (iii) offsetting the amount to be recovered from any compensation otherwise owed by the Company to the Covered Executive, or forfeiture of deferred compensation, to the extent consistent with Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations thereunder; (iv) cancelling outstanding, or forfeiting of, vested or unvested cash or equity awards (including those subject to service-based and/or performance-based vesting conditions, or for which such conditions have been satisfied); (v) cancelling, offsetting or reducing future compensation; and/or (vi) taking any other remedial and recovery action permitted by law, as determined by the Committee. Notwithstanding the foregoing, the Company makes no guarantee as to the treatment of such amounts under Section 409A, and shall have no liability with respect thereto.

(b) *Exceptions to the Recovery Requirement.* Notwithstanding anything in this Policy to the contrary, Erroneously Awarded Compensation need not be recovered pursuant to this Policy if the Committee determines that recovery would be impracticable as a result of any of the following:

i. the direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered; provided that, before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on the expense of enforcement, the Company must make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange;

ii. recovery would violate home country law where that law was adopted prior to November 28, 2022; provided that, before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company must obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or

iii. recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

(c) *Failure to Repay*. To the extent that a Covered Executive fails to repay all Erroneously Awarded Compensation to the Company when due, the Company shall take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Covered Executive. The applicable Covered Executive shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

3. Indemnification Prohibition. The Company shall not indemnify any Covered Executive against the loss of any Erroneously Awarded Compensation for which the Committee has determined to seek recovery pursuant to this Policy, and shall not reimburse any Covered Executive for their own costs of indemnification.

4. Administration; Interpretation. The Committee shall administer this Policy. The Committee shall have full authority to interpret and enforce the Policy in a manner consistent with its intent to meet the requirements of the Listing Rule and any other applicable law and shall otherwise be interpreted (including in the determination of amounts recoverable) in the business judgment of the Committee. Notwithstanding the foregoing, any determination that recovery would be impracticable (as described in Section 2(b)(i) of this Policy) must be made by a fully independent compensation committee as determined by the Board under the listing rules of the Exchange, or in the absence of such a fully independent compensation committee, the determination must be made by a majority of the independent directors serving on the Board. Any determinations made by the Committee shall be final, conclusive and binding on all affected individuals.

As further set forth in Section 8 below, this Policy is intended to supplement any other compensation recoupment policies and procedures that the Company may have in place from time to time pursuant to other applicable law, plans, policies or agreements.

5. Amendment. The Committee may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by any federal securities laws or the Listing Rule.

6. Required Disclosure. The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws.

7. Other Recovery Rights. The Committee intends that this Policy will be applied to the fullest extent of the law. The Committee may require that any employment or service agreement, cash-based bonus plan or program, equity award agreement, or similar agreement entered into on or after the adoption of this Policy shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights of recovery that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, cash-based bonus plan or program, or similar agreement and any other legal remedies available to the Company. For the avoidance of doubt, any right of recovery under this Policy will prevail over any other remedies or rights of recovery that may be available to the Company pursuant to the terms of any similar policy to the extent that a larger recovery amount would be recoverable under this Policy.

8. Successors. The Policy shall be binding and enforceable against each Covered Executive and, to the extent required by applicable law, his/her beneficiaries, heirs, executors, administrators or other legal representatives.

9. Defined Terms.

(a) "***Affiliate***" shall mean each entity that directly or indirectly controls, is controlled by, or is under common control with the Company.

(b) "***Board***" shall mean the Board of the Directors of the Company.

(c) "***Clawback Eligible Incentive Compensation***" shall mean Incentive Compensation Received by a Covered Executive (i) on or after October 2, 2023, (ii) after beginning service as a Covered Executive, (iii) at any time such individual served as a Covered Executive during the performance period for such Incentive Compensation (irrespective of whether such individual continued to serve as a Covered Executive upon or following the Restatement), (iv) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (v) during the applicable Clawback Period.

(d) "***Clawback Period***" shall mean, with respect to any Restatement, the three completed Fiscal Years of the Company immediately preceding the Restatement and any Transition Period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years.

(e) **"Committee"** shall mean the Remuneration Committee of the Board.

(f) "***Covered Executive***" shall mean each current and former Executive Officer of the Company.

(g) "***Erroneously Awarded Compensation***" shall mean the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive Compensation that otherwise would have been Received had it been determined based on the restated amounts, and computed without regard to any taxes paid by the Covered Executive in respect of the Erroneously Awarded Compensation. For Incentive Compensation based on stock price or total shareholder return, where the amount of erroneously awarded Incentive Compensation is not subject to mathematical recalculation directly from the information in a Restatement:

i. The calculation of Erroneously Awarded Compensation shall be based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive Compensation was Received; and

ii. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange.

(h) "***Exchange***" shall mean the Nasdaq Stock Market.

(i) "***Executive Officer***" shall mean the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries shall be deemed executive officers of the Company if they perform such policy making functions for the Company.

(j) "***Financial Reporting Measures***" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures, including, without limitation, stock price and total shareholder return. Financial reporting measures may include "non-GAAP financial measures" as well as other measures, metrics and ratios that are not GAAP measures. For the avoidance of doubt, a financial reporting measure need not be presented in the Company's financial statements or included in a filing with the SEC.

(k) "***Fiscal Year***" shall mean the Company's fiscal year; provided that a Transition Period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months will be deemed a completed fiscal year.

(l) "***Incentive Compensation***" shall mean any compensation (whether cash or equity-based) that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

(m) "***Listing Rule***" shall have the meaning set forth in Section 1 of this Policy.

(n) "***Received***" shall mean, with respect to any Incentive Compensation, actual or deemed receipt, and Incentive Compensation shall be deemed received in the Company's Fiscal Year during which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if payment, grant or vesting of the Incentive Compensation occurs after the end of that period.

(o) "***Restatement***" shall mean an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the Company's previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. The date that the Company is required to prepare an accounting restatement is the earlier to occur of: (i) the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement; or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement. The Company's obligation to recover Erroneously Awarded Compensation is not dependent on whether the Company files a restated financial statement. A change to the Company's financial statement that does not represent an error correction is not a Restatement, including without limitation: (i) retrospective application of a change in accounting principle; (ii) retrospective revision to reportable segment information due to a change in the structure of the Company's internal organization; (iii) retrospective reclassification due to a discontinued operation; (iv) retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; and (v) retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

(o) ***"SEC***" shall mean the U.S. Securities and Exchange Commission.

(p) ***Transition Period***" shall mean any transition period that results from a change in the Company's Fiscal Year within or immediately following the three completed Fiscal Years immediately preceding the Company's requirement to prepare a Restatement.

Policy Adopted on: 02-OCT-2023