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

FORM 20-F

(Mark One)

☐ **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, 2022
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**

Date of event requiring this shell company report

Commission File Number 001-39992

Immunocore Holdings plc

(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)
England and Wales
(Jurisdiction of incorporation or organization)
92 Park Drive
Milton Park
Abingdon, Oxfordshire OX14 4RY
United Kingdom
(Address of principal executive offices)
Bahija Jallal, Ph.D.
Chief Executive Officer
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Milton Park
Abingdon, Oxfordshire OX14 4RY
United Kingdom
Tel: +44 1235 438600
Email: ir@immunocore.com
(Name, Telephone, Email and/or Facsimile number and Address of Company Contact Person)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value £0.002 per share	IMCR	The Nasdaq Stock Market LLC
Ordinary share, nominal value £0.002 per share*	*	The Nasdaq Stock Market LLC*

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

Securities registered or to be registered pursuant to Section 12(g) of the Act. None
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 £0.002 per share: 48,088,346 shares outstanding as of December 31, 2022.

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 by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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

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GENERAL INFORMATION

Unless context otherwise requires, all references in this Annual Report on Form 20-F, or Annual Report, to "Immunocore," the "Company," "we," "us" and "our" refer to Immunocore Holdings plc and, where appropriate, its consolidated subsidiaries.

KIMMTRAK® is our registered trademark. This Annual Report includes trademarks, tradenames and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks, tradenames and service marks referred to in this Annual Report appear without the ®, ™ and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks, tradenames and service marks to the fullest extent under applicable law. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of us by, these other parties.

PRESENTATION OF FINANCIAL INFORMATION

Our financial statements in this Annual Report were prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of our financial statements were prepared in accordance with U.S. GAAP.

Our financial information is presented in pounds sterling. For the convenience of the reader, in this Annual Report, unless otherwise indicated, translations from pounds sterling into U.S. dollars were made at the rate of £1.00 to $1.2077 on December 31, 2022. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of pounds sterling at the dates indicated or any other date. All references in this Annual Report to "$" mean U.S. dollars and all references to "£" and "GBP" mean pounds sterling.

We have historically conducted our business through Immunocore Limited, and therefore, our historical consolidated statements presented the consolidated results of operations of Immunocore Limited. Following the completion of our corporate reorganization and initial public offering in February 2021, our consolidated financial statements present the consolidated financial results of operations of Immunocore Holdings plc.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties. 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 and opinions contained in this Annual Report are based upon information available to us as of the date of this Annual Report and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements include, but are not limited to, statements about:

- the therapeutic potential and expected clinical benefits of KIMMTRAK, including the ability of KIMMTRAK(tebentafusp-tebn) to transform the treatment of metastatic uveal melanoma, or mUM, for patients and extended overall survival benefit;
- the safety, efficacy and clinical progress of our various clinical programs, including those for IMC-F106C and IMC-M113V;
- our ability to continue to generate revenues, which is dependent upon maintaining significant market acceptance among physicians, patients and healthcare payers;
- our ability to maintain regulatory approval of KIMMTRAK (tebentafusp-tebn) for mUM, in the United States, European Union and other territories, as well as our ability to obtain and maintain regulatory approval in additional jurisdictions, and the timing thereof;
- our expectations regarding the continued commercialization and marketing of KIMMTRAK for mUM, including expanding into and the related timing of reaching patients in additional territories;
- our ability to build a sustainable pipeline of new medicine candidates, including but not limited to future generations of KIMMTRAK and additional product candidates identified and developed using our IMMTAX platform;

- our ability to successfully execute our sales and marketing strategy of KIMMTRAK in the United States, Europe and elsewhere, including continuing to successfully recruit and retain sales and marketing personnel and to successfully build the market for our medicines
- our expectations about the willingness of healthcare providers to recommend KIMMTRAK to people with mUM;
- the rate and degree of market acceptance of our product candidates among physicians, patients, patient advocacy groups, third-party payors and the medical community and our ability and our distribution and marketing partners' ability to obtain coverage and adequate reimbursement and pricing for, our medicines from government and third-party payers and risks relating to the success of our patient assistance programs;
- the initiation, timing, progress and results of our ongoing clinical trials and any planned clinical trials, including the expansion arms of such trials, for tebentafusp in advanced melanoma, IMF-F106C, IMC-I109V and IMC-M113V, and our research and development programs, including delays or disruptions in clinical trials, non-clinical experiments and investigational new drug application-enabling studies;
- our estimates regarding the period of time for which our current capital resources will be sufficient to fund our continued operations, our future expenses, including the impact thereon of rising inflation, fluctuating exchange rates and other macroeconomic factors, and our future revenues and our needs for and ability to obtain additional financing;
- our expectations regarding timing of regulatory filings for, or our ability to obtain regulatory approval of, our product candidates other than KIMMTRAK;
- our ability to obtain accelerated approval for current and future product candidates from the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other comparable regulatory authorities in other jurisdictions;
- our ability to identify and develop additional product candidates using our ImmTAX platform;
- our expectations regarding business disruptions affecting the initiation, patient enrollment, clinical trial site monitoring, development and operation of our current and proposed clinical trials, including as a result of a public health emergency, such as the coronavirus 2019, or COVID-19, pandemic, or other global and macroeconomic factors, such as the war in Ukraine, global geopolitical tensions, supply chain disruptions, rising interest rates and rising inflation;
- our business strategies and goals;
- our plans to collaborate, or statements regarding our current collaborations, including with Genentech, and our ability to find future partners and collaborators;
- the performance of our third-party suppliers and manufacturers,
- our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our product candidates and our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others;
- our expectations regarding competition with respect to KIMMTRAK or any of our other current or future product candidates, as well as innovations by current and future competitors in our industry;
- our expectations regarding regulatory developments in the United States and other countries, including potential changes in healthcare laws and regulations;
- our financial performance and our ability to effectively manage our anticipated growth;
- our ability to identify, recruit and retain qualified employees, including key commercial or management personnel; and
- whether we are classified as a PFIC for current and future periods;

You should refer to the section titled "Item 3.D Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

PART I

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

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.

An investment in our American Depositary Shares, or ADSs, involves a high degree of risk. You should carefully consider the risks described below, and all other information appearing elsewhere in this Annual Report, including our consolidated financial statements and the related notes hereto, before making an investment decision regarding our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us may also adversely affect our business.

Summary Risk Factors

Our business is subject to a number of risks and uncertainties. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors" in Part I, Item 3.D. of this Annual Report. Set forth below is a summary list of the principal risk factors as of the date of the filing this Annual Report:

- We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- Our ability to continue to generate revenues from KIMMTRAK and any future approved product candidates is subject to their consideration as effective drugs with advantages over other therapies, and their timely attaining and maintaining significant market acceptance among physicians, patients and healthcare payers.
- Our revenues from KIMMTRAK may be significantly reduced by both existing and future legislation for drug pricing reforms requiring the payment of rebates.
- Our future prospects are highly dependent on our ability to continue to successfully develop and execute our commercialization strategy for KIMMTRAK. Failure to do so would adversely impact our financial condition and prospects.
- We will require substantial additional funding to achieve our business goals. If we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts.

- We are heavily dependent on the success of our ImmTAX platform to identify and develop product candidates. If we or our collaborators are unable to successfully develop and commercialize our platforms or experience significant delays in doing so, our business may be harmed.
- We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.
- We may be unable to successfully complete additional large-scale, pivotal clinical trials for any product candidates we develop after KIMMTRAK.
- Our product candidates utilize a novel mechanism of action and involve novel targets which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.
- Clinical product development involves a lengthy and expensive process, with an uncertain outcome.
- Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful; interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change materially.
- We are subject to manufacturing and supply chain risks that could substantially increase our costs and limit supply of our products and components used in the preparation and administration of our product and product candidates. If we, or our third party manufacturers, fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.
- Reports of adverse events or safety concerns involving KIMMTRAK or our product candidates could delay or prevent us from obtaining or maintaining regulatory approvals or could negatively impact sales of our products or the prospects for our product candidates.
- For existing KIMMTRAK approvals, and if we obtain further regulatory approvals to market KIMMTRAK and any other future approved products, we will remain subject to extensive ongoing regulatory obligations and oversight, including post-approval requirements, that could result in significant additional expense and could negatively impact our ability to commercialize our current and any future approved products.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, industry standards and other obligations related to internal controls, healthcare sector compliance, anti-bribery and anti-corruption, data privacy and security (including security incidents) could harm our business.
- If we are unable to adequately protect our proprietary technology or obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products or if the scope of the protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property or proprietary rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.
- The FDA and other local regulators' approval pathways can be difficult to predict and whether, for example, further unanticipated clinical trials are required, will depend on the data obtained in our ongoing clinical trials.
- Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain and motivate qualified personnel.
- Our existing collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.
- As a company based and operating partly outside of the United States, we are subject to economic, political, regulatory and other risks associated with international operations.

Risks Related to Our Financial Position and Need for Capital

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

While we are a commercial-stage biotechnology company, we have incurred net losses in each year since our inception. Our losses were £41.2 million, £131.5 million and £74.1 million for the years ended December 31, 2022, 2021 and 2020, respectively. We had an accumulated deficit of £261.3 million as of December 31, 2022. We have funded our operations to date primarily with proceeds from private placements of our ordinary and preferred shares, payments from our collaboration partners, KIMMTRAK revenue, debt financing, our initial public offering ("IPO") and subsequent private investment in Immunocore Holdings Plc (the "PIPE").

While we have received regulatory approval for KIMMTRAK for mUM in the United States, the European Union, and certain other significant jurisdictions in 2022, we do not have approvals for any other indications or in any other jurisdictions for KIMMTRAK, or have approvals for our other product candidates. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Since inception, we have focused substantially all of our efforts and financial resources on developing our drug discovery platform and research and development of our product candidates. We have not obtained regulatory approvals for any of our product candidates other than KIMMTRAK, and there is no assurance that we will obtain further approvals in the future for KIMMTRAK in additional territories or any of our other product candidates. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future.

These losses will adversely impact our shareholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- further commercialize KIMMTRAK and any future product candidate for which we may obtain marketing approval in the United States and expanded territories and countries;
- continue our ongoing and planned development of our clinical stage programs and our preclinical pipeline assets;
- initiate pre-clinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek regulatory approvals for our existing and potential future product candidates that successfully complete clinical trials;
- build a portfolio of product candidates through the discovery, development, or acquisition or in-license of drugs, product candidates or technologies;
- maintain, protect, enforce and expand our intellectual property portfolio;
- acquire or in-license other product candidates, intellectual property and technologies;
- hire additional clinical, regulatory, scientific and sales and marketing personnel;
- add operational, financial and management information systems and personnel, including personnel to support commercial development of KIMMTRAK, our product development and planned future commercialization efforts of existing and future product candidates; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

To become and remain profitable, we must succeed in developing and commercializing further products that generate significant revenue. This will require us to be successful in a range of challenging activities, including continuing to market and sell KIMMTRAK and any future products for which we may obtain regulatory approval, our global regulatory submissions for any existing or future product candidates that we may pursue, obtaining regulatory approval, procuring commercial-scale manufacturing, as well as discovering or acquiring and then developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond our expectations if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory authorities to perform studies in addition to those we currently expect, if issues associated with KIMMTRAK arise following FDA approval, or if there are any delays in the initiation and completion of our clinical trials or the development of tebentafusp or any future product candidates.

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

Our future prospects are highly dependent on our ability to continue to successfully develop and execute our commercialization strategies for KIMMTRAK and any future products for which we may obtain regulatory approval. Failure to do so would adversely impact our financial condition and prospects.

We focus substantial resources on the commercialization of KIMMTRAK and will have to focus substantial resources on the commercialization of any product for which we may obtain regulatory approval in the future. Our ability to generate significant medicine revenues and to achieve commercial success in the near-term will initially depend on our ability to continue to commercialize KIMMTRAK.

We are focusing a significant portion of our commercial activities and resources on KIMMTRAK, and we believe our ability to grow our long-term revenues, and a significant portion of the value of our company, relates to our ability to successfully commercialize KIMMTRAK in the United States and Europe. While we have established commercial teams, we expect to develop these teams further and otherwise continue to develop commercialization strategies in order to continue to successfully commercialize KIMMTRAK in the longer term. There are many factors that could cause commercialization of KIMMTRAK to be unsuccessful, including many that are outside our control. For example, the mUM patient population could be lower than estimated, patient and physician acceptance and adoption of KIMMTRAK could change, and physicians' willingness to prescribe or patients' willingness to take KIMMTRAK could change, each of which could limit the commercial potential of KIMMTRAK. Thus, there is uncertainty regarding the full commercial potential of KIMMTRAK. If the continued commercialization of KIMMTRAK became less successful or was perceived as disappointing, the price of our ADSs could decline significantly and long-term success of the medicine and our company could be harmed.

Our ability to continue to generate revenues from KIMMTRAK is subject to attaining and maintaining continued market acceptance among physicians, patients and healthcare payers.

KIMMTRAK, and other product candidates that we may develop or acquire, may not attain or maintain market acceptance among physicians, patients, healthcare payers or the medical community, even if they receive marketing approval by relevant authorities. We believe that the degree of continued market acceptance and our ability to continue to generate revenues from KIMMTRAK will depend on a number of factors, including:

- timing of competitive medicines;
- continued efficacy and safety of KIMMTRAK;
- continued projected growth of the markets in which KIMMTRAK competes;
- the extent to which physicians diagnose and treat the conditions that KIMMTRAK is approved to treat;
- prevalence and severity of any side effects;
- if and when we are able to obtain regulatory approvals for additional indications for KIMMTRAK;
- continued acceptance by patients, physicians and applicable specialists;
- availability of, and ability to maintain, coverage and adequate reimbursement and pricing from government and other third-party payers;
- potential or perceived advantages or disadvantages of KIMMTRAK over alternative treatments, including cost of treatment and relative convenience and ease of administration;
- strength of sales, marketing and distribution support;
- the price of KIMMTRAK, both in absolute terms and relative to alternative treatments;
- impact of past and limitation of future medicine price increases;
- our ability to maintain a continuous supply of KIMMTRAK for commercial sale;
- the effect of current and future healthcare laws;
- disruptions caused by health pandemics or epidemics, such as the COVID-19 pandemic, including the extent to which physicians and patients delay visits or writing or filling prescriptions for KIMMTRAK;
- the performance of third-party distribution partners, over which we have limited control; and
- medicine labeling or medicine insert requirements of the FDA or other regulatory authorities

Our ability to grow KIMMTRAK sales will be affected by the success of our sales, access, marketing and medical strategies. If KIMMTRAK or any other products that we may seek approval for, or acquire, fail to attain, or fail to maintain, market acceptance, we may not be able to generate significant revenue to sustain profitability, which would have a material adverse effect on our business, results of operations, financial condition and prospects (including, possibly, the value of our ADSs).

Our revenues from KIMMTRAK may be reduced by both enacted and proposed legislation for drug pricing reforms requiring the payment of rebates.

Effective January 1, 2023, the 2021 Infrastructure Investment and Jobs Act requires certain manufacturers to refund the government for discarded amounts of certain drugs covered under Medicare Part B (which could include KIMMTRAK) from single use containers. The Centers for Medicare & Medicaid Services ("CMS") has finalized most of the regulations required by this law. Without further action, the final rule would characterize the dead loss volume that exceeds an applicable percentage in small vial drug administration as wastage and thus trigger a corresponding rebate. We are concerned that this requirement conflicts with FDA guidance providing for accurate and efficient administration of medicines produced in small vials and have outlined our concerns for CMS. CMS is considering a framework for reviewing products with unique circumstances along with potential increased percentages that might be appropriate for each circumstance. In furtherance of this, CMS has requested additional information from the public about drugs with unique circumstances and expressed its intention to revisit this applicable percentage issue through further rulemaking. We believe KIMMTRAK has unique circumstances to warrant an exemption or increased percentage threshold. However, at this time, the process and criteria for unique circumstances remain unclear. If not adequately addressed in future rulemaking, or if the government does not otherwise consider KIMMTRAK to be a unique circumstance warranting an exemption or increased percentage threshold, our revenue in the United States could be impacted from the fourth quarter of 2023 and continuing in subsequent years.

Additional drug pricing legislation has or may be proposed in further countries, which may also reduce our future revenues if such laws are made effective in those countries.

We will require substantial additional funding to achieve our business goals. If we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts.

Developing biopharmaceutical products is expensive and time-consuming, and we expect to require substantial additional capital to conduct research, pre-clinical testing and human studies, establish pilot scale and commercial scale manufacturing processes and facilities, and establish and develop quality control, regulatory, marketing, sales and administrative capabilities to support our existing programs and pursue potential additional programs. We are also responsible for the payments to third parties of expenses that may include milestone payments, license maintenance fees and royalties, including in connection with certain agreements with academic institutions or other companies with respect to the in-licensing or acquisition of their intellectual property rights. Because the outcome of any pre-clinical or clinical development and regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of any existing or future product candidates. In addition, global macroeconomic factors, such as supply chain disruptions and rising inflation, may increase these expenses beyond what we currently anticipate. In recent months, inflation has begun to impact our costs more identifiably, and we anticipate this could increase our expenses in 2023 and future years.

As of December 31,2022, we had working capital (defined as total current assets less total current liabilities) of £308.8 million and cash and cash equivalents of £332.5 million. We expect that our existing cash and cash equivalents with the inclusion of expected revenue for KIMMTRAK will provide sufficient funds to continue to meet our liabilities as they fall due into 2026. However, it is possible that our revenue may be lower than our estimates, which could have a material adverse effect on our financial condition. In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations or license and development agreements. Any additional fundraising efforts for us may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates that we may identify and pursue. Moreover, such financing may result in dilution to our shareholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our future funding requirements will depend on many factors, including, but not limited to:

- our ability to continue to execute our commercialization strategies for KIMMTRAK and, if approved, our other product candidates;
- progress, timing, scope and costs of our clinical trials, including the ability to timely initiate clinical sites, enroll subjects and manufacture soluble bispecific TCR product candidates for our ongoing, planned and potential future clinical trials, including our clinical trials of IMC-F106C (PRAME) in multiple solid tumors, IMC-I109V targeting hepatitis b virus, or HBV; and IMC-M113V targeting human immunosuppression virus, or HIV;
- time and costs required to perform research and development to identify and characterize new product candidates from our research programs;
- the time and cost necessary to pursue regulatory authorizations and approvals that may be required by regulatory authorities to execute clinical trials or commercialize our products;
- our ability to have clinical and commercial products successfully manufactured consistent with FDA, EMA and other authorities' regulations;
- amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;

- sales and marketing costs associated with commercializing our products, if approved, including the cost and timing of scaling our marketing and sales capabilities;
- cost of building, staffing and validating our manufacturing processes, which may include capital expenditure;
- terms and timing of any revenue we may receive under existing or future collaborations;
- costs of operating as a public company;
- time and cost necessary to respond to technological, regulatory, political and market developments;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the impact of global and macroeconomic factors, including heightened inflation;
- costs, associated with, and terms and timing of, any future any potential acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish; and
- inability of clinical sites to enroll patients as healthcare capacities are required to cope with natural disasters, epidemics or other health system emergencies, such as the COVID-19 pandemic.

A change in the outcome of any of these or other variables with respect to the development, regulatory approval and commercialization of any of our current and future product candidates could significantly change the costs and timing associated with the development and commercialization of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Additional funds may not be available when we need them, on terms that are acceptable, or at all, particularly in light of recently worsening macroeconomic conditions, including rising interest rates and volatility in the capital markets. If adequate funds are not available to us on a timely basis, we may be required to delay, limit or terminate one or more research or development programs or the commercialization of any product candidates or be unable to expand operations or otherwise capitalize on business opportunities, as desired, which could materially affect our business, prospects, financial condition and results of operations.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or cause us to relinquish valuable rights.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity, convertible debt securities or other equity-based derivative securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as holder of ADSs. Any indebtedness we incur would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our shareholders. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs to decline and existing shareholders may not agree with our financing plans or the terms of such financings. If we raise additional funds through strategic partnerships, collaborations, and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies or our product candidates, or grant licenses on terms unfavorable to us.

Risks Related to KIMMTRAK and the Development of Our Product Candidates

In order to increase adoption and sales of KIMMTRAK, we will need to continue developing our commercial organization as well as recruit and retain qualified field representatives.

In order to continue our commercialization of KIMMTRAK, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our medicines and any additional medicines we may acquire will be expensive and time-consuming. We also cannot be certain that we will be able to continue to successfully develop this capability.

In addition, none of the members of our sales force have promoted any medicine for the treatment of mUM prior to the launch of KIMMTRAK. We are required to expend significant time and resources to train our sales force to be credible and able to educate physicians on the benefits of prescribing and pharmacists dispensing KIMMTRAK. Furthermore, we must train our sales force to ensure that a consistent and appropriate message about KIMMTRAK is being delivered to our potential customers. We may experience turnover of the sales representatives that we hired or will hire, requiring us to train new sales representatives. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate physicians about the benefits of KIMMTRAK and their proper administration and label indication, as well as our patient assistance programs, our efforts to successfully commercialize KIMMTRAK could be put in jeopardy, which could have a material adverse effect on our financial condition, share price and operations.

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

We received approval from the FDA and EC for KIMMTRAK for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM in 2022. We estimate that there are approximately 1,000 mUM patients per annum in the United States and Western Europe who test positive for HLA-A*02:01 and might benefit from KIMMTRAK as a monotherapy.

We are evaluating the safety and tolerability of IMC-F106C in Phase 1/2 dose escalation trials in patients with advanced or metastatic solid tumors who express PRAME and test positive for HLA-A*02:01. We estimate that, across all solid tumors, the annual number of patients worldwide who test positive for HLA-A*02:01 and can potentially benefit from our IMC-F106C programs is up to 150,000. There is no assurance, however, as to what percentage of this population ultimately might benefit from monotherapy.

We are evaluating the safety and tolerability of IMC-M113V in a Phase 1 clinical trial in patients with chronic HIV who are virally suppressed on anti-retroviral c therapy. We estimate that there are more than one million HIV patients globally who test positive for HLA-A*02:01. There is no assurance, however, as to what percentage of this population might benefit from this therapy.

We are evaluating the safety and tolerability of IMC-I109V in a Phase 1 clinical trial in patients with chronic HBV who are non-cirrhotic, hepatitis B e-Antigen negative, and virally suppressed on chronic nucleot(s)ide analogue therapy. We estimate that there are more than one million chronic HBV patients globally who test positive for HLA-A*02:01.

The total addressable market opportunity for KIMMTRAK and our programs will ultimately depend upon, among other things, acceptance by the medical community and patient access, product pricing and reimbursement as well as expansion into additional markets. The number of patients with cancers, solid tumors, HIV, and chronic HBV and test positive for HLA-A*02:01 may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business.

We are heavily dependent on the success of our ImmTAX platform to identify and develop product candidates. If we or our collaborators are unable to successfully develop and commercialize our platforms or experience significant delays in doing so, our business may be harmed.

We are heavily dependent on the success of our ImmTAX platform technology, KIMMTRAK and the product candidates currently in our core programs. Our ImmTAC, ImmTAV and ImmTAAI platforms were developed from the foundation of our ImmTAX platform and are our primary platform technologies. Our commercial prospects will be heavily dependent on product candidates identified and developed using our ImmTAX platform. To date, we have invested substantially all of our efforts and financial resources to identify, acquire intellectual property for, and develop our ImmTAX platform technology and our programs, including conducting pre-clinical studies and early-stage clinical trials, and providing general and administrative support for these operations.

We may not be successful in our efforts to further develop our ImmTAX platform technology and current product candidates. With the exception of KIMMTRAK, which has been approved by the FDA, EC, and a limited number of comparable regulatory authorities, we are not permitted to market or promote any of our product candidates until we receive regulatory approval from the FDA, EMA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all.

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

We obtained marketing approval for KIMMTRAK in the United States, Europe and certain other territories in 2022. We may not be able to continue to effectively market, sell and distribute KIMMTRAK. We have invested, and expect to continue to invest, significant financial and management resources to further develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that tebentafusp will be approved in a territory. We utilize a hybrid model that includes in-house and contracted resources in the United States and Europe, and we have engaged third parties and may engage additional third parties to provide these services. We have entered into agreements with Syneos Health, Inc., or Syneos, Medison Pharma, and other third parties, to develop our commercial infrastructure for the commercial launch and continued sale of KIMMTRAK, including to potentially retain, train and deploy a direct sales force, but we have limited experience operating or managing a third-party sales force as a company. There can be no assurance that the capabilities of the Syneos sales organization or other third parties will be more effective than an internally developed sales organization. In addition, Syneos can terminate our agreement under certain circumstances. If Syneos or other third parties fail to hire, train, and retain qualified sales personnel, market our product successfully or on a cost-effective basis or otherwise terminates our relationship, our ability to generate revenue will be limited and we will need to identify and retain an alternative organization or develop our own sales and marketing capability. This could involve significant delays and costs, including the diversion of our management's attention from other activities. We may also need to retain additional consultants or external service providers to assist us in sales, marketing and distribution functions, and may be unsuccessful in retaining such services on acceptable financial terms or at all.

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

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

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

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

Health epidemics or pandemics could materially adversely impact our business, including the commercialization of KIMMTRAK, our supply chain, our pre-clinical studies and our clinical trials, our liquidity and access to capital markets and our business development activities, as well as the business or operations of our CROs or other third parties with whom we conduct business.

Our business could be adversely affected by health epidemics or pandemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. We experienced significant impacts from the COVID-19 pandemic and could experience similar or additional impacts from COVID-19 or other health epidemics or pandemics in the future.

In response to these public health directives and orders, we implemented work-from-home policies to support the community efforts to reduce the transmission of COVID-19 and protect employees, complying with guidance from federal, state/provincial or municipal government and health authorities. We also implemented a number of measures to ensure employee safety and business continuity.

The effects of executive orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines (for example, our timeline for tebentafusp), the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations have occurred and could occur in the future, related to COVID-19 or other infectious diseases and could impact personnel at third-party manufacturing facilities in the United Kingdom, United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

The continued effects of the COVID-19 pandemic or other future health epidemics or pandemics may also further negatively impact our clinical trials and the operations or our CROs or CMOs in the future, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials, including patients that may not be able or willing to comply with clinical trial protocols such as weekly dosing regimens if quarantines impede patient movement or interrupt healthcare services;
- delays or difficulties in clinical site initiation, including difficulties in recruiting and retaining clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of risks of exposure to disease, being forced to quarantine or being unable to visit clinical trial locations or otherwise comply with clinical trial protocols;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the epidemic or pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, including because they, as healthcare providers, may have heightened exposure to disease, which would adversely impact our clinical trial operations;
- interruption of our clinical supply chain or key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state/provincial or municipal governments, employers and others; and
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

For our clinical trials that we expect to conduct at sites outside the United States, particularly in countries which are experiencing or in the future experience heightened impact from COVID-19 or other future pandemics, in addition to the risks listed above, we may also experience the following adverse impacts:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our clinical trials;
- changes in federal, state/provincial or municipal regulations as part of a response to the COVID-19 or other outbreak of disease which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA to accept data from clinical trials in these affected geographies.

The COVID-19 pandemic has impacted, and it or other epidemics or pandemics may in the future, impact our business and clinical trials, and such impact will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence, infectiousness and severity of new variants, travel restrictions and social distancing in the United Kingdom, United States, and other countries, business closures or business disruptions and the effectiveness of actions taken in the United Kingdom, United States, and other countries to contain and treat the disease. The ultimate impact of the COVID-19 pandemic or a similar epidemic is highly uncertain and subject to change. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business.

Even though KIMMTRAK has received approval from the FDA, EC, and certain comparable regulatory authorities in other jurisdictions, and even if tebentafusp receives approval in additional countries, or if any of our other product candidates receives marketing approval, these may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for continued commercial success.

Even though KIMMTRAK has received FDA and EC approval, and even if we obtain approvals from the FDA, the EMA or other comparable regulatory agencies and are able to initiate commercialization of our other product candidates, the product candidate may not achieve or maintain market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not become or remain commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- hospitals and cancer treatment centers establishing the infrastructure required for the administration of the product candidate;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects, including CRS, for which KIMMTRAK has a boxed warning recommending at least 16 hours of patient monitoring after each of the first three infusions, and as clinically indicated thereafter;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or the EMA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the pricing of our products and the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time, including if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. Because we expect sales of KIMMTRAK and our other product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find or maintain market acceptance would harm our business and could require us to seek additional financing.

We may be unable to successfully complete additional large-scale, pivotal clinical trials for any product candidates we develop after KIMMTRAK.

We may be unable to successfully complete additional large-scale, pivotal clinical trials for any product candidates we develop after KIMMTRAK. We cannot be sure that issues will not arise that require us to suspend or terminate our clinical trials. Guidance we have received from the FDA or other regulatory authorities on clinical trial design is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. Successful completion of our clinical trials is a prerequisite to submitting a Biologics License Application, or BLA, to the FDA and a Marketing Authorization Application, or MAA, to the EMA, for each product candidate and, consequently, the ultimate approval and commercial marketing of each product candidate. We do not know whether any of our future clinical trials will begin on time or ever be completed on schedule, if at all.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product candidates utilize a novel mechanism of action and involve novel targets which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.

Our product candidates utilize novel mechanisms of action and involve novel targets which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects. Our ImmTAX platform uses advanced computational models in tight integration with our structural biology, protein engineering, affinity maturation and binding efficacy capabilities to predict and design the compounds that will achieve the most desirable characteristics, including potency, selectivity, bioavailability, and drug-like properties. A disruption in any of these capabilities may have significant adverse effects in our abilities to expand our ImmTAX platform, and we cannot predict whether we will continue to have access to these capabilities in the future to support our ImmTAX platform. In addition, there can be no assurance that we will be able to rapidly identify, design and synthesize the necessary compounds or that these or other problems related to the development of this novel mechanism will not arise in the future, which may cause significant delays or raise problems we may not be able to resolve.

Regulatory approval of novel product candidates such as ours can be more expensive, riskier and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of our mechanism of action may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more difficult to find, hire and retain personnel for research, development and manufacturing positions. Because our soluble bispecific T cell receptors, or TCRs, utilize a novel mechanism of action and involve novel targets, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our pre-clinical studies and clinical trials. Any such events could adversely impact our business prospects, financial condition and results of operations.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. For example, we develop various protein models and make predictions as to how molecules might target antigens, with subsequent validation efforts in our labs and labs of our CROs. There can be no assurance that we will find potential additional targets using this approach, that any such targets will be tractable, or that such clinical validations will be successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome.

While we plan to pursue additional regulatory approvals, it is uncertain whether tebentafusp will receive further marketing approval beyond the approval which KIMMTRAK has received in the United States, the European Union, Canada and other territories. Furthermore, it is impossible to predict when or if tebentafusp for the treatment of advanced melanoma, IMC-F106C, IMC-I109V, IMC-M113V, IMC-P115C, IMC-T119C, or IMC-R117C, or any of our 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 pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of pre-clinical 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. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Our pre-clinical studies and future clinical trials may not be successful. From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials 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. Preliminary or top-line 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, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We also rely, and expect to continue to rely in part on, outside vendors (for example, independent contractors and CROs) to conduct, supervise or monitor some or all aspects of clinical trials involving our products. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

We currently rely on, and expect to continue to rely in part on, CMOs to manufacture our products for clinical trials. If they fail to commence or complete, or experiences delays in, manufacturing our products and product candidates, our planned clinical trials will be delayed, which will adversely affect our stock price and our ability to conduct our business as currently planned.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in the European Union and other territories. Before we can commercialize further product candidates, we must obtain marketing approval. Currently, the majority of our product candidates are in development, and we have not received approval to market any of our product candidates from regulatory authorities, with the exception of KIMMTRAK. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States, the European Union and other territories, is expensive and often takes many years. If the FDA, EMA or a comparable foreign regulatory authority requires that we perform additional pre-clinical or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Furthermore, our ability to enroll patients may continue to be delayed by the COVID-19 pandemic and it is not possible to know the extent and scope of such delays at this point.

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

Even if we were to obtain approval for further product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

Positive results from early pre-clinical studies of our product candidates are not necessarily predictive of the results of later pre-clinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive results from our earlier pre-clinical studies of our product candidates in our later pre-clinical studies and future clinical trials, we may be unable to successfully develop, obtain regulatory for and commercialize our product candidates.

Any positive results from our pre-clinical studies of our product candidates may not necessarily be predictive of the results from required later pre-clinical studies and clinical trials. Similarly, even if we are able to complete our planned pre-clinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such pre-clinical studies and clinical trials of our product candidates may not be replicated in subsequent pre-clinical studies or clinical trial results. In addition, positive results in later stage clinical trials of one of our product candidates in an indication may not be predictive of the safety or efficacy of our other product candidates in other indications, even if they employ a similar mechanism of action.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in pre-clinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval.

Interim, "top-line" 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 may publish interim, "top-line" or preliminary data from our planned 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. Preliminary or "top-line" 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, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our ADSs to fluctuate significantly.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience delays in completing our pre-clinical studies and initiating or completing clinical trials, and we may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional pre-clinical studies or clinical trials or we may decide to abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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 our product candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant delays in pre-clinical studies or clinical trials, including those caused by the COVID-19 pandemic, also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any delays in our pre-clinical or future clinical development programs may harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our 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, EMA, or similar regulatory authorities. In particular, because we will be deploying our drug discovery platform across a broad target space, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Furthermore, our ability to enroll patients may be significantly delayed by new or ongoing public health crises, such as those we experienced as a result of the COVID-19 pandemic and could again in the future.

In addition to the competitive trial environment, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their cancer is either severe enough or not too advanced to include them in a study. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. Further, if we are required to develop companion diagnostics and are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek participation in the FDA's expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise to seek to accelerate clinical development and regulatory timelines. Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; 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 (*e.g.*, of the impact of the COVID-19 pandemic).

Our planned clinical trials or those of our future collaborators may reveal significant adverse events not seen in our pre-clinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive pre-clinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and 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.

We may develop future product candidates, in combination with one or more cancer therapies. The uncertainty resulting from the use of our product candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials.

As is the case with many treatments for cancer, infectious diseases and autoimmune diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

We are at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities.

For example, in 2020, we received notice from the FDA of a partial clinical hold on our IMC-F106C clinical trial after the second patient (with baseline elevated risk factors for pulmonary embolus) experienced a fatal adverse event of respiratory failure due to multiple pulmonary emboli 24 hours after receiving the first dose (0.3 mcg). In accordance with our own internal guidelines, we put our clinical trial on hold to investigate this unexplained death and informed the FDA. The FDA subsequently put our clinical trial on a partial clinical hold and allowed us the option to continue dosing the first patient. After autopsy, including expert review, and other investigations, the primary investigator concluded that the cause of death was respiratory failure and not related to study drug. We modified the trial protocol to add a lower dose cohort and additional screening and on-treatment precautions. The FDA accepted our changes and removed the partial clinical hold enabling the trial to continue. However, if in the future we are delayed in addressing, or unable to address, any FDA concerns, we could be delayed, or prevented, from conducting our clinical trials.

Our 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, EMA or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Because of our planned dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. 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.

For example, our oncology clinical trials include cancer patients who are very sick and whose health is deteriorating, and we expect that additional clinical trials of our other product candidates will include similar patients with deteriorating health. In clinical trials conducted by other companies involving CAR T cells, TCR T or T cell redirecting bispecifics, the most prominent acute toxicities included symptoms thought to be associated with cytokine release syndrome, or CRS, such as fever, low blood pressure and kidney dysfunction. KIMMTRAK has a boxed warning regarding CRS, recommending patient monitoring for at least 16 hours following the first three infusions, and as clinically indicated thereafter. It is possible that some of these patients may experience similar adverse side effects as were observed in clinical trials conducted by other companies and academic institutions, and that additional patients may die during our clinical trials for various reasons, including as a result of receiving our product candidates, because the patient's disease is too advanced, or because the patient experiences medical problems that may not be related to our product candidate. Even if the deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidate.

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

Our product candidates may have serious and potentially fatal cross-reactivity to other peptides or protein sequences within the body.

Our product candidates may recognize and bind to a peptide unrelated to the target antigen to which it is designed to bind. If this peptide is expressed within normal tissues, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse effects. Detection of any cross-reactivity may halt or delay any ongoing clinical trials for any TCR-based product candidate and prevent or delay regulatory approval. Unknown cross-reactivity of the TCR binding domain to related proteins could also occur. We have also developed a pre-clinical screening process to identify cross-reactivity of the TCR binders. Any cross-reactivity that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization.

We intend to develop our tebentafusp, IMC-F106C and other programs, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop our tebentafusp, IMC-F106C and other programs, and may develop future product candidates, for use in combination with one or more currently approved cancer therapies. We entered into an agreement with Sanofi in 2022 under which Sanofi will develop tebentafsup in combination with SAR444245, non-alpha IL-2, for the potential treatment of patients with metastatic cutaneous melanoma. In addition, we have begun enrollment in multiple combination arms of our IMC-F106C Phase 1 clinical trial, including evaluation of IMC-F106C in combination with standards of care including checkpoint inhibitors, chemotherapy and tebentafusp. Even if any product candidate we, or our collaboration partners, develop, was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our IMC-F106C programs, or any other future product candidates, in combination with one or more other cancer, infectious disease or autoimmune disease therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our IMC-F106C and other programs, or any product candidate we develop in combination with any such unapproved cancer, infectious disease or autoimmune therapies, that do not ultimately obtain marketing approval.

If the FDA, EMA or similar foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our or any product candidate we develop, we may be unable to obtain approval of or market our IMC-F106C and other programs, or any product candidate we develop.

If we do not achieve our projected development and commercialization goals within the timeframes we announce and expect, the commercialization of our product candidates or any future product candidates may be delayed, and our business will be harmed.

For planning purposes, we estimate the timing of achieving various scientific, clinical, regulatory, and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, regulatory submissions or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of clinical trials, announcement of trial data, receipt of regulatory approval, or the commercial launch of a product. The achievement of many of these milestones may be affected by factors outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achieving the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs, and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, EMA and comparable foreign regulatory authorities, and the timing thereof;
- other actions, decisions, or rules issued by regulators;
- our ability to access sufficient, reliable, and affordable supplies of materials used in the manufacture of our product candidates;
- our ability to manufacture and supply clinical trial materials to our clinical sites on a timely basis;
- the efforts of our collaborators with respect to the commercialization of our approved products, if any; and
- the securing of, costs related to, and timing issues associated with, commercial product manufacturing, as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our lead product candidate and any other current or future product candidates may be delayed, and our business, results of operations, financial condition, and prospects may be adversely affected.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs and our attractiveness as a commercial partner and may ultimately have an impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular proprietary molecules in our library, product candidates or therapeutic areas are subject to change over time, and these decisions may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates, abandon products that we have devoted significant resources toward in favor of other product candidates, or misread trends in the biopharmaceutical industry, in particular for our lead product candidate, our business, financial condition and results of operations could be materially adversely affected.

We conduct clinical trials for our product candidates outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials.

We conduct clinical trials outside the United States including in Australia, New Zealand, Europe and Asia, and are likely to continue to do so in these or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole 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 United States population and United States 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 an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies 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 or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

A variety of risks associated with conducting research and clinical trials in multiple countries and marketing our product candidates internationally could materially adversely affect our business.

Clinical trials are currently being conducted in multiple countries throughout the world, and we plan to globally develop our current and future product candidates. Accordingly, we expect that we 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;
- differing standards for the conduct of clinical trials;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States or elsewhere and shipping the product candidate to patients in other countries;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in foreign economies and markets, particularly in light of recently worsening global macroeconomic conditions;
- 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 Kingdom or the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977, as amended, the U.K. Bribery Act 2010, or comparable foreign regulations;
- challenges enforcing or protecting 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 or the United Kingdom;
- the impacts Brexit may have with respect to the cross-border acknowledgment of clinical trial results and marketing authorizations as well as recruitment of scientific personnel;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including the Ukraine war, other wars and acts of terrorism, and the outbreak of and international responses to global health crises such as the COVID-19 pandemic.

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

Risks Related to the Commercialization of Our Product Candidates

If we fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

KIMMTRAK and our product candidates are biologics and the process of manufacturing our products is complex, highly regulated and subject to multiple risks. We may encounter difficulties in production, particularly with respect to process development, quality control, upscaling or scaling-out of our manufacturing capabilities. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Before we can begin commercial manufacture of our products, regulatory authorities must approve marketing applications that identify manufacturing facilities operated by us or third-party manufacturers that have passed regulatory inspection and manufacturing processes that are acceptable to the regulatory authorities. Any failure to follow current Good Manufacturing Practice, or cGMP, or other regulatory requirements or any delay, interruption or other issues that arise in the manufacture, fill and finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of drug product for our clinical trials or the termination of or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. In addition, our pharmaceutical manufacturing facilities are continuously subject to scheduled and unannounced inspection by the FDA, and other comparable EU and other international regulatory authorities, before and after product approval, to monitor and ensure compliance with cGMP and other regulations. Our manufacturing facility in the United States has been approved by the FDA, the EC and health agencies in other countries for the manufacture of KIMMTRAK. In addition, our third-party manufacturers' facilities involved with the manufacture of KIMMTRAK or our product candidates have also been inspected and approved by various regulatory authorities. Although we are not involved in the day-to-day operations of our contract manufacturers, we are ultimately responsible for ensuring that our products are manufactured in accordance with cGMP regulations.

Due to the complexity of the processes used to manufacture our products and product candidates, we may be unable to continue to pass or initially pass federal or international regulatory inspections in a cost-effective manner. For the same reason, any potential third-party manufacturer of our products or our product candidates may be unable to comply with cGMP regulations in a cost-effective manner and may be unable to initially or continue to pass a federal or international regulatory inspection.

Our TCR bispecific product candidates that have been produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical trials or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates.

A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, suspension, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, or FCA, corporate integrity agreements, consent decrees, or withdrawal of product approval. For example, our IMC-C103C program was temporarily placed on partial clinical hold in 2020 due to insufficient specifications on a drug release assay in the corresponding IND.

If we, or third-party manufacturers with whom we contract, are unable to comply with manufacturing regulations, we may be subject to delay of approval of our product candidates, warning or untitled letters, fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our business, financial condition, results of operations and growth prospects

If we are unable to successfully develop and maintain manufacturing processes for KIMMTRAK or our product candidates, or unable to produce sufficient quantities at acceptable costs, we may be unable to support a clinical trial or be forced to terminate a program, or if we are unable to produce sufficient quantities of our products at acceptable costs, we may be unable to meet commercial demand, lose potential revenue, have reduced margins or be forced to terminate a program.

Due to the complexity of manufacturing KIMMTRAK and our product candidates, we may not be able to manufacture sufficientquantities. Our inability to produce enough of our product candidate at acceptable costs may result in the delay or termination of development programs. With respect to our commercial portfolio, we may not be able to manufacture KIMMTRAK successfully with a commercially viable process or at a scale large enough to support their respective commercial markets or at acceptable margins.
The development of commercially viable manufacturing processes typically is very difficult to achieve and is often very expensive and may require extended periods of time. Changes in manufacturing processes (including manufacturing cell lines), equipment or facilities (including moving manufacturing from one of our facilities to another one of our facilities or a third-party facility, or from a third-party facility to one of our facilities) may require us to complete clinical trials to receive regulatory approval of any manufacturing modifications.

Even a developed manufacturing process can encounter difficulties. Problems may arise during manufacturing for a variety of reasons, including human error, mechanical breakdowns, problems with raw materials and cell banks, malfunctions of internal information technology systems, and other events that cannot always be prevented or anticipated. Many of the processes include biological systems, which add significant complexity, as compared to chemical synthesis. We expect that, from time to time, consistent with biotechnology industry expectations, certain production lots will fail to produce product that meets our quality control release acceptance criteria. To date, our historical failure rates for KIMMTRAK have been within our expectations, which are based on industry norms. If the failure rate increased substantially, we could experience increased costs, lost revenue, damage to customer relations, time and expense investigating the cause and, depending upon the cause, similar losses with respect to other lots or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

In order to produce product within our time and cost parameters, we must continue to produce product within our expected success rate and yield expectations. Because of the complexity of our manufacturing processes, it may be difficult or impossible for us to determine the cause of any particular lot failure and we must effectively take corrective action in response to any failure in a timely manner.

We currently rely on third parties for portions of the manufacture of each of our commercial products. If those manufacturers are unwilling or unable to fulfill their contractual obligations or satisfy demand outside of or in excess of the contractual obligations, we may be unable to meet demand for these products or sell these products at all and we may lose potential revenue. Further, the availability of suitable contract manufacturing capacity at scheduled or optimum times is not certain.

In addition, our manufacturing processes subject us to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of hazardous materials and wastes resulting from their use. We incur significant costs in complying with these laws and regulations.

We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.

The biotechnology industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to acquire or in-license novel therapeutics that could make the product candidates that we develop obsolete. 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 or other proprietary 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, tolerability, reliability, convenience of use, price and reimbursement.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of therapeutics to address unmet needs in cancer including: Adaptimmune Therapeutics plc, or Adaptimmune, Immatics Biotechnologies GmbH, or Immatics (alone and in collaboration with Bristol Myers Squibb), Adaptive Biotechnologies Corporation, or Adaptive, pure MHC, LLC, BioNTech SE, Genentech, Matterhorn, Anocca, Enara Bio and Regeneron, who are also seeking to identify peptide HLA targets and develop product candidates; Adaptimmune, T-Knife GmbH, Adaptive, 3T Biosciences, Inc., MediGene, Regeneron Pharmaceuticals, Inc., or Regeneron, Gilead Sciences, Inc., bluebird Bio, Inc., or bluebird bio, Takara Bio Inc., Bristol-Myers Squibb Company, GSK, Kite Pharma, Lion TCR, TCR Cure, Corregene Biotechnology Co. LTD, and Tscan who are developing TCR-based cell therapies; Immatics, Regeneron, F. Hoffmann-La Roche Ltd, Amgen, Inc., Genmab, Inc., Molecular Partners, 3T Biosciences, Inc., and CDR-Life Inc. are developing CD3-based TCR bispecific compounds or TCR mimetic antibodies.

We are aware of various companies and academic institutions that are developing TCR transduced cell therapies against a range of pHLA targets, some of which may overlap with product candidates in our pipeline such as PRAME. Specifically in regards to PRAME, we are aware that Immatics and Medigene are both conducting Phase 1 clinical trials of PRAME-directed cellular therapies and Immatics also have communicated plans for Phase 1 development of a PRAME TCRxCD3 approach.

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, it may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the impairment of our business reputation;
- the withdrawal of clinical trial participants;
- costs due to related litigation;
- the distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We believe our product liability insurance coverage is sufficient in light of our current commercial and clinical programs; however, 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 intend to expand our insurance coverage each time we commercialize an additional product; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could adversely affect our results of operations and business.

Patients with the diseases targeted by certain of our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Our Dependence on Third Parties

Our existing therapeutic collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have relatively limited capabilities for drug development and have limited experience of carrying out sales, marketing and distribution activities for KIMMTRAK. We have entered into collaborations with other companies that we believe can provide similar capabilities, including for example with Genentech and Sanofi. Our collaborations have previously provided us with important funding for our development programs and technology platforms, and we could receive additional funding under our collaborations in the future. Our existing therapeutic collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or 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 products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; this may also happen if the collaborators' development of competing products is substantially faster than our development timelines;
- collaborators may not further develop product candidates developed by us or co-developed with us under the collaboration;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators have certain defined rights to change or expand the scope of development programs during the course of the collaboration. This may lead to additional research work for us that may be time-consuming and expensive. Such work may compete with our own development programs and may delay timelines to market or proof-of-concept for our product candidates. If development programs under the collaboration turn out to be more costly and time-consuming, such unanticipated costs and work could likewise compete with our internal development programs;

- collaborators may not properly maintain, enforce or defend our intellectual property or proprietary information or may use them in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability, and collaborators may also allege that we are liable for potential infringement, misappropriation or other violations of third-party intellectual property or proprietary rights during the research and development work for the collaboration;

- certain collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. For example, certain of our collaboration and license agreements may be terminated for convenience upon the completion of a specified notice period; and

- collaborators may discontinue the development of product candidates within the collaboration, for example if they consider the results achieved so far or the product candidates not promising enough or if their development strategies change.

If our therapeutic collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our program collaborators.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators.

For some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that reduced the number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Subject to certain specified exceptions, each of our existing therapeutic collaborations contains an exclusivity restriction on our engaging in activities that are the subject of the collaboration with third parties for specified periods of time.

We rely on CROs and other third parties to conduct our Phase 1, Phase 2 and Phase 3 pivotal clinical trials and expect to rely on CROs and other third parties to conduct future clinical trials, as well as investigator-sponsored clinical trials of our product candidates. If these CROs and other third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely and expect to continue to rely on CROs, medical institutions, clinical investigators, contract laboratories and other third parties to conduct or otherwise support clinical trials for our product candidates, including our Phase 2/3 advanced melanoma tebentafusp trial, our Phase 1/2 clinical trial of IMC-F106C, and our Phase 1 clinical trial of IMC-I109V. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We rely and expect to continue to rely heavily on CROs, medical institutions, clinical investigators, contract laboratories and other third parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We, our principal investigators and our CROs are required to comply with regulations, including Good Clinical Practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, 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, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we designed our Phase 2/3 advanced melanoma trial for tebentafusp, our Phase 1/2 clinical trial of IMC-F106C, and our Phase 1 clinical trials of IMC-I109V and IMC-M113V, and intend to design the future clinical trials for our product candidates, we expect that CROs will conduct all of our clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;

- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development program materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs 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, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our product candidates for pre-clinical development, clinical testing, and commercial supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we currently have any plans to establish, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for pre-clinical development and clinical testing, and the commercial manufacture of our products. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third -party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation or unauthorized disclosure of our proprietary information, including our trade secrets and know-how; and

- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

The third parties upon whom we rely for the supply of the active pharmaceutical ingredient used in our product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients, or API, used in our product candidates are supplied to us from single-source suppliers. 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 API for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We do not currently have arrangements in place for a redundant or second-source supply of any such API in the event any of our current suppliers of such API cease their operations for any reason. We are also unable to predict how changing global and macroeconomic conditions such as public health crises (including the COVID-19 pandemic), the war in Ukraine, global geopolitical tension and rising inflation will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API prior to submission of a BLA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers 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 suppliers for the API used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier 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 API used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API 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.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Where we license technology from a third party, the prosecution, maintenance, enforcement and defense of the patent or other intellectual property or proprietary rights licensed from such third party may be controlled by the third party, which may impact the scope of patent or other protection.

Where we license patent rights, technology or other intellectual property or proprietary rights from a third party, control of such third-party rights may vest in the licensor, particularly where the license is non-exclusive or field-restricted. This may mean that we are not able to control or affect the scope of the claims of any relevant third-party patent or other intellectual property protection or have control over the preparation, filing, prosecution, maintenance, enforcement and defense of such patents and patent applications. Therefore, we cannot be certain that such patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject to such licensed rights could be adversely affected. Where a licensor brings an enforcement action with respect to licensed patents or other intellectual property, this could negatively impact our business or result in additional restrictions being imposed on the license we have and the scope of such license, or result in invalidation or limitation of the scope of the licensed patents or other intellectual property rights. In addition, should we wish to enforce the relevant patent or other intellectual property rights against a third person, we may be reliant on consent from the relevant licensor or the cooperation of the licensor. The licensor may refuse to bring such action and leave us unable to restrict competitor entry into the market. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we or our third-party suppliers use hazardous, non-hazardous, biological or other materials 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, potentially infectious material and genetically modified cells. We and our suppliers are subject to federal, state and local laws and regulations in the United Kingdom and United States governing the use, manufacture, storage, handling and disposal of such hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, and that we and our suppliers have all necessary permits, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from hazardous chemical or biological 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 have insurance in place for liabilities arising from handling biological and hazardous substances, but it may not or may not fully cover all costs from such accidents. 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 impact our business, prospects, financial condition or results of operations.

Risks Related to Intellectual Property

If we are unable to adequately protect our proprietary technology or obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products or if the scope of the protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our product candidates and our core technologies, including our novel target discovery technology, our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our current or future pending patent applications will issue or will mature into issued patents that include claims with a scope sufficient to protect tebentafusp, IMC-F106C, IMC-I109V, IMC-M113V, IMC-P115C, IMC-T119C, IMC-R117C, or any other current or future product candidates or technologies, in whole or in part, or effectively prevent others from commercializing competing product candidates and technologies. While we own issued patents relating to tebentafusp and pending patent applications relating to our other product candidates, including IMC-F106C, IMC-I109V, IMC-M113V, IMC-P115C, IMC-T119C and IMC-R117C, we do not own or in-license any issued patents relating to such other product candidates, and we can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States and countries of the European Union, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates, including generic versions of such products.

Furthermore, certain of our patents and technology were funded in part by investments from non-profit third parties, including the Bill & Melinda Gates Foundation, or the Gates Foundation. We are required to fulfill certain contractual obligations with respect to products created using such grant funding, including making certain products available at an affordable price in a list of clearly defined low and lower-middle income countries. For more information, see “Item 4B. Business overview—Our Collaborations and License Agreements—Gates Collaboration.”

Other parties may have developed technologies that are related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive issued patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same methods or formulations or the same subject matter. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our pending patent applications or any patent application we may license, or that we were the first to file for patent protection of such inventions. In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to most of the pending patent applications covering our product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office, or USPTO, or its global equivalents, are often significantly narrowed by the time they issue, if they issue at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we may license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or any patent we may license may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. We may become involved in opposition, derivation, re-examination, revocation, *inter partes* review, post-grant review, interference or other proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights.

Competitors or other third parties may claim that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Third parties may also claim that we are infringing, misappropriating or otherwise violating their patents or other intellectual property rights and that we therefore cannot practice our technology as claimed under our patents, if issued. Competitors and other third parties may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor or other third party could claim that our patents, if issued, are not valid for a number of reasons. If a patent office or court agrees, we would lose our rights to those challenged patents, in whole or in part.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, without payment to us, or could limit the duration of the patent protection covering our technology and product candidates. Such challenges may also result in our inability to manufacture or commercialize our product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such proceedings also may result in substantial cost and require significant time and attention from our scientists and management.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products or technology similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. In-licensed patents and patent applications may also be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their interest to other parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Even if unchallenged, our patent portfolio may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents or any patents we may license by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and renewal fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates and technologies, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how, proprietary information and continuing technological innovation to develop and maintain our competitive position. With respect to the building of our ImmTAX platform, we consider trade secrets and know-how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees, CROs and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of trade secrets and other confidential information is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, CROs and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secret protection as a result. In addition, 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 technology and processes. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, some courts, especially outside the United States, are sometimes less willing to protect trade secrets. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach.

Our trade secrets could otherwise become known, obtained or independently discovered by our competitors or other third parties, who could purchase our products and product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. 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, or those to whom they communicate such information, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property or proprietary 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 and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We are subject to, and may in the future become party to or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference, post-grant review, *inter partes* review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the European Patent Office, or EPO. Our competitors or other third parties may assert infringement claims against us, alleging that our products or technologies are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies have filed, and continue to file, patent applications related to soluble, bispecific TCRs. Some of these patent applications have already been allowed or issued, and others may issue in the future. Since these areas are competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates, or the practice of our technology. If a patent holder believes our product or product candidate infringes on its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

Even if we believe that such claims are without merit, there is no assurance that a court or patent office would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. We may also attempt to obtain a license even in the absence of an action or finding of infringement. In either case, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have wilfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. If we lose a foreign lawsuit alleging our infringement, misappropriation of other violation of a competitor's patents or other intellectual property or proprietary rights, we could be prevented from marketing our products in one or more foreign countries. 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 damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets or other confidential information of our competitors or other third parties or are in breach of non-competition or non-solicitation agreements with our competitors or other third parties, or claims asserting ownership of what we regard as our own intellectual property.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, 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, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing our product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Competitors and other third parties may infringe, misappropriate, challenge the validity of or otherwise violate our patents and other intellectual property rights. We may become involved in opposition, derivation, re-examination, revocation, *inter partes* review, post-grant review, interference or other proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. For example, our European patents may be involved in opposition proceedings at the European Patent Office, challenging the validity of those patents. Opposition proceedings may involve issues including, but not limited to, priority, patentability of the claims involved, and certain procedural formalities. As a result of the opposition proceedings, the European Patent Office's Opposition Division, or the Opposition Division, can revoke a patent, maintain the patent as granted, or maintain the patent in an amended form. Decisions made by the Opposition Division can be appealed to the European Patent Office's Appeal Board. Challenges to our patents, including in such opposition proceedings, may result in loss of patent rights, exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the scope and duration of the patent protection of our ImmTAX platform technology and product candidates. For more information, see "Item 8.A Consolidated Statements and Other Financial Information—Legal Proceedings."

Additionally, our patents or the patents of our licensing or collaboration partners may in the future become, involved in inventorship or priority disputes, and our ability to commercialize our product candidates could be adversely affected if we do not obtain a license to any patents material to the development of our product candidates. We may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our platform technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

To counter infringement or unauthorized use, we or our licensing or collaboration partners may be required to file infringement claims. A court may disagree with such allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that the applicable patents or other intellectual property do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe, misappropriate or otherwise violate their intellectual property or that a patent or other intellectual property right asserted against them is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render any patents that may issue invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our future patents, should they issue, but that could nevertheless be determined to render our patents invalid.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property litigation and proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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 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. 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 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 greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating, or from successfully challenging, our intellectual property rights. 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.

We may not be able to effectively enforce our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain jurisdictions, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the patent laws of some foreign jurisdictions do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement, misappropriation or other violation of our patents and other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension and data exclusivity for any 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 product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term 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 term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we are not able to obtain a license, or not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially. Even if we are able to obtain a license, it may be non-exclusive, which may allow our competitors or other third parties access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These companies may have a competitive advantage over us due to their size, capital 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. In cases where we are unable to procure sufficient rights to third-party intellectual property rights, we might need to cease use of the compositions or methods covered by such third-party intellectual property rights and/or develop alternative approaches that do not infringe, misappropriate or otherwise violate such intellectual property rights. This could entail additional costs and development delays, and the development of such alternatives may not be feasible. Any of the foregoing could prevent us from developing or commercializing one or more of our product candidates, or force us to modify such product candidates, or to cease some aspect of our business operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our current and any future collaboration and license agreements impose, or we expect will impose, various development, diligence, commercialization, payment, and other obligations on us. In spite of our efforts, a collaborator or licensor might conclude that we have materially breached our obligations under such agreement and seek to terminate the agreement, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. If these agreements are terminated, or if the underlying patent or other intellectual property rights licensed thereunder fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical or similar to ours 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.

Moreover, disputes may arise regarding intellectual property subject to a collaboration or licensing agreement, including:

- the scope of rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the counterparty that is not subject to the agreement;
- the sublicensing of patent and other intellectual or proprietary rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our counterparty and us and our partners; and
- the priority of invention of patented technology.

These agreements 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 have licensed prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law in 2011, could increase those uncertainties and costs.

The Leahy-Smith Act 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 and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. For example, the Leahy-Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent with the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. 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 patent 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. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement or defense of our or our collaboration or licensing partners' issued patents.

In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. 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. This will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Therefore, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce rights in our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any existing patents and patents that we may obtain in the future.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we own or license now or in the future;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license now or in the future;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights or any intellectual property rights we may license;
- it is possible that our present or future pending patent applications (whether owned or licensed) will not lead to issued patents;
- it is possible that there are or will be prior public disclosures that could invalidate our or our licensors' or collaboration partners' patents;
- issued patents that we hold rights to may fail to provide us with any competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;

- the ownership, validity or enforceability of our patents or patent applications may be challenged by third parties;

- the patents or pending or future applications of others, if issued, may harm our business; and

- 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 intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering our product candidates or technologies could be found invalid or unenforceable if challenged in court or in administrative proceedings.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or technologies, should such a patent issue, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions *(e.g.,* opposition proceedings). An adverse determination in any of the foregoing proceedings could result in the revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or technologies. Such a loss of patent protection could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If our trademarks and trade names are not adequately protected, then this may impede our ability to build and sustain name recognition in our markets of interest and our business may be adversely affected.

We may rely on trademarks and trade names to protect our business. If our trademarks and trade names are not adequately protected, this may impede our ability to build and sustain name recognition in our markets of interest and our business may be adversely affected. We may not be able to protect our rights to these trademarks and trade names, which we need to support name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark oppositions or infringement claims brought by owners of other registered or unregistered trademarks or trade names that incorporate elements which are identical or similar to our trademarks or trade names. For example, our U.S. trademark application for IMMTAX is currently subject to an opposition filed by Immatics Biotechnologies GmbH, or Immatics, and we have brought counterclaims against three of Immatics's U.S. registered trademarks for IMMATICS. In addition, Immatics have filed invalidation actions against UK and EU trademark registration for IMMTAX. If we are unsuccessful in defending this opposition, we may be required to change our branding for our ImmTAX platform which could cause us to incur substantial costs and impede our ability to build and sustain name recognition for such platform. For more information on the opposition proceeding see "Item 8.A Consolidated Statements and Other Financial Information." Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on effective use of our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Risks Related to Government Regulation

The FDA regulatory pathways can be difficult to predict and whether, for example, further unanticipated clinical trials are required, will depend on the data obtained in our ongoing clinical trials.

The regulatory approval pathway and the amount of time it takes us to obtain regulatory approvals for our product candidates will depend on the data that are obtained in our ongoing clinical trials and any future clinical trials, including future registrational or pivotal clinical trials. We may attempt to seek approval on a per indication basis for our product candidates on the basis of a single pivotal trial or on the basis of data from one or more uncontrolled trials. While the FDA requires in most cases two adequate and well-controlled pivotal clinical trials to demonstrate the efficacy of a product candidate, a single trial with strong confirmatory evidence may be sufficient in instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and if confirmation of the result in a second trial would be practically or ethically impossible. In rare cancer indications with very limited treatment options, a large and/or controlled trial is often not feasible and thus data from smaller and even uncontrolled trials may be sufficient for regulatory approval. Depending on the data we obtain, the FDA or other regulatory authorities may require additional clinical trials to be carried out or further patients to be treated prior to the granting of any regulatory approval for marketing of our product candidates. It is difficult for us to predict with such a novel technology exactly what will be required by the regulatory authorities in order to take our product candidates to market or the timeframes under which the relevant regulatory approvals can be obtained.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. For example, clinical trials may be required in pediatric populations before any marketing approval can be obtained, which can be time-consuming and costly. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and foreign regulatory authorities also have substantial discretion in the drug and biologics approval processes. The number and types of pre-clinical programs and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, and there may be varying interpretations of data obtained from pre-clinical programs or clinical trials, either of which may cause delays or limitations in the approval or the decision not to approve an application. In addition, approval of our product candidates could be delayed or refused for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe, pure, potent and have a favorable risk/benefit profile for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical programs or clinical trials;
- data collected from clinical trials of product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- manufacturing processes or facilities or those of the third-party manufacturers we use may not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

It is possible that no product candidates will ever obtain the appropriate regulatory approvals necessary to be commercialized. Any delay in obtaining, or failure to obtain, required approvals would materially adversely affect our ability to generate revenue from the particular product candidate, which would result in significant harm to our business.

Even though we have received regulatory approval for KIMMTRAK, and even if we receive regulatory approval for any of our other product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

We are subject to extensive ongoing obligations and continued regulatory review with respect to KIMMTRAK, such as continued adverse event reporting requirements. Any problems with a product or any violation of ongoing regulatory obligations could result in restrictions on the applicable product, including the withdrawal of the applicable product from the market.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. Later discovery of previously unknown problems with a product, 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, regulatory action, delays in regulatory timelines and additional costs to us.

Failure to comply with applicable FDA and other regulatory requirements may subject us to administrative or judicially imposed sanctions, including:

- issuance of Form FDA 483 notices or Warning Letters by the FDA or other regulatory agencies;
- imposition of fines and other civil penalties;
- criminal prosecutions;
- injunctions, suspensions or revocations of regulatory approvals;
- suspension of any ongoing clinical trials;
- total or partial suspension of manufacturing;
- delays in commercialization;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us;
- refusals to permit drugs to be imported into or exported from the United States;
- restrictions on operations, including costly new manufacturing requirements;
- product recalls or seizures; and
- requirements to conduct post-marketing studies or clinical trials.

The policies of the FDA and other regulatory agencies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or of KIMMTRAK in any additional indications or territories, or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we or our collaborators might not be permitted to market our current or any future approved products and our business would suffer.

Reports of adverse events or safety concerns involving KIMMTRAK or our product candidates could delay or prevent us from obtaining or maintaining regulatory approvals or could negatively impact sales of our products or the prospects for our product candidates.

Reports of adverse events or safety concerns involving our products could interrupt, delay or halt clinical trials of our products. In addition, reports of adverse events or safety concerns involving our products could result in regulatory authorities requiring that we update the applicable product's prescribing information, or limiting, denying or withdrawing approval of our products for any or all indications, including previously approved indications. There are no assurances that patients receiving our products will not experience serious adverse events, including fatal events, in the future, whether the serious adverse events are disclosed in the prescribing information or are newly reported. Further, there are no assurances that patients receiving our products with co-morbid diseases not previously studied, will not experience new or different serious adverse events in the future.

The prescribing information for KIMMTRAK includes warnings and precautions for various toxicities, as well as a boxed warning related to the risk of cytokine release syndrome, or CRS. We may be required to update the prescribing information for our products, including boxed warnings, limitations of use, contraindications, warnings and precautions, and adverse reactions, based on reports of adverse events or safety concerns, or implement a Risk Evaluation and Mitigation Strategy, or REMS. Side effects and toxicities associated with our products could affect the willingness of physicians to prescribe, and patients to utilize, our products and thus harm commercial sales of our products. Implementation of a REMS could advantage products that compete with ours or make it more difficult or expensive for us to distribute our products.

Likewise, reports of adverse events or safety concerns involving our product candidates could interrupt, delay or halt clinical trials of our product candidates, or could result in our or our collaborators' inability to obtain regulatory approvals of our product candidates. Additional and/or unexpected safety events could be observed in these or other trials that could delay or prevent us from advancing the clinical development of, or obtaining regulatory approvals for, our products and product candidates or require us to alter the approved labeling of our products, and may adversely affect our business, results of operations and prospects.

Concerns regarding the safety of our products or product candidates as a result of undesirable side effects identified during clinical testing or otherwise could cause the FDA to order us to cease further development or commercialization of our products or the product candidates. Undesirable side effects caused by our products or product candidates could also result in denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, the requirement of additional trials, implementation of a REMS or the inclusion of unfavorable information in our product labeling, and in turn delay or prevent us from commercializing the applicable product or product candidate. In addition, actual or potential drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates or result in potential product liability claims. Any of these events could prevent us from developing or commercializing the applicable product or product candidate, and could significantly harm our business, results of operations and prospects.

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

If any of our 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 approved prescription drug products. 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. If we are found to have promoted such off-label uses, we may become subject to significant liability. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of regulated products for off-label uses and has enjoined several companies from engaging in off-label promotion. The FDA and other regulatory agencies have also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations and actions; litigation; fines and penalties; disruptions to our business operations; reputational harm; loss of revenue and profits; loss of customers and sales; and otherwise adversely affect our business and prospects.

In the ordinary course of business, we process personal data and other sensitive information (including proprietary and confidential business data, trade secrets, intellectual property, clinical trial participant data, and sensitive third-party data). We are subject to data privacy and security obligations such as various laws, regulations, guidance, industry standards, external and internal policies, contracts and other obligations that govern the processing of personal data by us and on our behalf. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective legal frameworks. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparation for and compliance with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our business including our information technologies, systems and practices and to those of any third parties that process personal data on our behalf. Although we strive to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations. If we (or third parties upon we rely) fail, or are perceived to have failed, to address and comply with data privacy and security obligations, we could face significant consequences. These consequences may include but are not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar consequences); litigation (including class-related claims); additional reporting requirements and oversight; bans on processing personal data; orders to destroy and not to use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation and our business and financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, our clinical trial activities); inability to process personal data; inability to operate in specific jurisdictions; limitations in our ability to develop and commercialize our products; time and other resource expenditures; adverse publicity; and revisions to our operations.

Globally, virtually every jurisdiction in which we operate has established its own data privacy and security frameworks.

In particular, as a company established in the United Kingdom, our processing of personal data is subject to the United Kingdom's implementation of the European Union's General Data Protection Regulation ("UK GDPR"); it is also, or may also become, in certain circumstances subject to the European Union's own General Data Protection Regulation ("EU GDPR"). Each of these regulations requires stringent standards of data privacy and security concerning personal data and potentially significant sanctions. For example, companies may face: temporary or definitive bans on processing of personal data and other corrective actions; fines of up to 17.5 million pounds sterling under the UK GDPR / 20 million Euros under the EU GDPR, or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data that is processed subject to the UK GDPR and/or EU GDPR, or certain other data privacy and security regimes, to the United States or other countries due to limitations on cross-border data flows and/or actual or *de facto* data localization requirements. In particular, the UK GDPR and EU GDPR significantly restrict the transfer of personal data to the United States and other countries whose privacy laws are considered 'inadequate' for the purposes of either or both of those regulations, as they may apply. Other jurisdictions relevant to our operations may similarly implement, or adopt stringent interpretations of, their own data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data to the United States in compliance with the UK GDPR and EU GDPR, such as the United Kingdom's 'International Data Transfer Agreement' and the European Commission's 'Standard Contractual Clauses', all these mechanisms are subject to legal challenges, and there is no assurance that we can always satisfy or rely on these measures to lawfully effect cross-border transfers of personal data where required. If there is no lawful manner for us to effect cross-border transfers of personal data in compliance with the UK GDPR, EU GDPR and/or other applicable data privacy and security obligations, as applicable, or if the requirements for a compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate certain parts of our operations, increased exposure to regulatory actions, substantial fines and penalties, the inability to work with certain collaborators, partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside the European Economic Area ("EEA") for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activist groups. Similarly, following 'Brexit', we can rely upon the European Commission's adequacy decision in favor of the UK under the EU GDPR, which allows most transfers of personal data from the EEA to the United Kingdom to continue without cross-border transfer-specific restrictions until June 27, 2025. If that adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the United Kingdom will require a valid 'transfer mechanism', which could significantly impact our ability to receive personal data from third parties (including partners, collaborators, principal investigators and trial sites) who are subject to the EU GDPR.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws (including data breach notification laws, personal data privacy laws and consumer protection laws). For example, the California Consumer Privacy Act of 2018 ("CCPA") imposes obligations on businesses to which it applies. These obligations include but are not limited to providing specific disclosures in privacy notices and affording California residents with certain rights related to their personal data. The CCPA allows for statutory fines for non-compliance (up to $7,500 per violation). Other states have similarly enacted data privacy laws. If we become subject to new data privacy or security laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors).

Additionally, regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, establish privacy and security standards that limit the use and disclosure of individually identifiable health information and protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of such information and ensure the confidentiality, integrity and availability of electronic protected health information. These provisions may apply to our business or that of third parties upon whom we rely (such as our clinical trial sites, collaborators, service providers, contractors or consultants). Determining whether such health information has been handled in compliance with applicable obligations can be complex and may be subject to changing interpretation. If we are unable to protect properly the privacy and security of such information, we could be found to have violated our statutory, contractual and other obligations.

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

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. 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 may intend to charge for our products will also be subject to approval.

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 engage third parties 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. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of 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.

We intend to 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 pre-clinical 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 therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics 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 therapeutic candidates.

We are subject to the U.K. Bribery Act 2010, or the Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations. Violations of such laws and regulations could subject us to liability.

Our operations are subject to anti-corruption laws, including the Bribery Act, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and other anti-corruption laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. In addition, the FCPA 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. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union governing our international operations, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. Exports of our products and product candidates must be made in compliance with these laws and regulations. In addition, these laws may restrict or prohibit altogether the provision or supply of certain of our products and product candidates to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions, unless there are license exceptions that apply or specific licenses are obtained.

As disclosed elsewhere in this Annual Report, we conducted an internal investigation in the summer and fall of 2020 as a result of receiving a whistleblower complaint alleging employee misconduct and other improper activities related to a kickback scheme involving an employee and two third-party vendors between 2018 and 2020. Our audit committee led the investigation utilizing outside counsel, during which the named employee resigned. After the investigation, we terminated the one remaining open contract with the third-party vendors and issued proceedings in October 2020 against the involved parties. The amount in question was estimated to be in the range of £1.1 million to £1.8 million, and we recovered our estimated losses of £1.8 million from the employee and third-party vendors in December 2020. In the course of auditing our 2019 financial statements for our initial public offering, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting relating to our procurement processes and application of delegation of authority approval limits due to insufficient risk assessment procedures. Since then, we enhanced our overall control environment, including adding finance and accounting personnel to drive and implement required additional processes and procurement controls, implementing improvements in software relating to approvals of purchase orders and contracts, adding additional layers of review of contracts and journal entries and delegation of contract authority limits. We also further developed and documented our accounting policies and financial reporting procedures, including ongoing executive management review and audit committee oversight. We remediated the material weakness as of December 31, 2020. While we have policies and procedures to address compliance with anti-corruption laws and Trade Control laws, we cannot assure you that these measures will be completely effective in ensuring our compliance in the future with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements and Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Because we are organized under the laws of England and Wales with principal executive offices in the United Kingdom and have a U.S. subsidiary and operations in the United States, we are subject to U.S. laws that regulate foreign investments in U.S. businesses and real estate as well as those that regulate access by foreign persons to technology developed and produced in the United States. These laws include section 721 of the Defense Production Act of 1950, as amended, and its implementing regulations at 31 C.F.R. Parts 800 and 802, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, as implemented by the Export Administration Regulations, and through additional U.S. Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies", yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export, re-export, or transfer of our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance with U.S. law; and threatening monetary fines and other penalties if we do not.

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. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek Orphan Drug Designation for certain of our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we have obtained Orphan Drug Designation from the FDA for tebentafusp in uveal melanoma, and we may also seek Orphan Drug Designation for certain of our other product candidates in the future which could be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. 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.

As part of our business strategy, in Europe, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, granted Orphan Drug Designation for tebentafusp in uveal melanoma. We may also seek Orphan Drug Designation for certain of our other product candidates in the future to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in European Union would be sufficient to justify the necessary investment in developing the drug. In the European Union, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the European Union. The European Union exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even when and if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, 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. Moreover, 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 if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if another drug with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

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

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval.

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 therapies considered for approval under conventional FDA 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 such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions, and legislative bodies may enact new policies, including unfavorable pricing restrictions, that may adversely affect the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

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 current or future 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 regulations, statutes or the interpretation of existing 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.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear what effect any such challenges or the healthcare reform measures of the Biden administration will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect until 2031, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012 among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There 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 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. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Further, the IRA, among other things: (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

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 healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for KIMMTRAK and our product candidates, if approved, or put pressure on our product pricing.

We expect that additional state and federal 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, which could result in reduced demand for our current or future product candidates or additional pricing pressures. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic or future epidemics or pandemics.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and adequate reimbursement for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. 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;

- the federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act, or FCA, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; 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 in order to have committed a violation;

- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests of such physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be 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, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We may not be able to file applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or applicable competent authorities may not permit us to proceed.

We plan to submit investigational new drug applications, or INDs, for additional product candidates to the FDA in the future. We also plan to submit applications to start clinical trials of additional product candidates outside the United States to the national competent authorities (for example, a clinical trial authorization, or CTA, to Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom).

The filing of INDs to the FDA and the filing of applications outside the United States is dependent on additional data that have to be generated to support such regulatory filings. Hence, these filings may be delayed if the tests to generate those data show unexpected results or if technical issues arise in generating those data in the first place.

We cannot be sure that submission of an IND, IND amendment or CTA will result in the FDA or any other competent authority outside the United States allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. The manufacturing and pre-clinical safety and efficacy testing requirements of both ImmTAC® and ImmTAAI® remain emerging and evolving fields. Accordingly, we expect chemistry, manufacturing and control related topics, including product specification, as well as pre-clinical safety testing, will be a focus of IND reviews, which may delay the allowance of INDs by the FDA or CTA approval by other competent authorities outside the United States.

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 and radioactive 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.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA 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.

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

Risks Relating to our Business Operations, Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of Dr. Bahija Jallal, Chief Executive Officer, Brian Di Donato, our Chief Financial Officer, and Dr. David Berman, our Head of Research and Development, as well as the other principal members of our management, scientific, clinical and commercial team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

In particular, we have experienced competitive hiring environments in our three locations: Oxfordshire, England where we are headquartered, Pennsylvania and Maryland. We may also experience further competition as a result of Brexit. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

We have incurred and may continue to incur increased costs in offering and maintaining competitive salaries to attract the personnel required to execute our strategy, and these costs could be significantly further impacted by the effects of rising global inflation.

We expect to continue to expand our development, commercial and regulatory capabilities and have recently developed sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2022, we had 408 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we continue to function and grow as a public company and in the areas of product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

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

We are exposed to the risk that our employees, principal investigators, CROs, partners, vendors and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

For example, in the summer and fall of 2020, we conducted an internal investigation as a result of receiving a whistleblower complaint alleging employee misconduct and other improper activities related to a kickback scheme involving an employee and two third-party vendors between 2018 and 2020. Our audit committee led the investigation utilizing outside counsel, during which the named employee resigned. After the investigation, we terminated the one remaining open contract with the third-party vendors and issued proceedings in October 2020 against the involved parties. We recovered our estimated losses of £1.8 million from the employee and third-party vendors in December 2020. In the course of auditing our 2019 financial statements for our initial public offering, we identified a material weakness in our internal control over financial reporting, relating to our procurement processes and application of delegation of authority approval limits due to insufficient risk assessment procedures. Since then, we enhanced our overall control environment, including adding finance and accounting personnel to drive and implement required additional processes and procurement controls, implementing improvements in software relating to approvals of purchase orders and contracts, adding additional layers of review of contracts and journal entries and delegation of contract authority limits. We also further developed and documented our accounting policies and financial reporting procedures, including ongoing executive management review and audit committee oversight. We remediated the material weakness as of December 31, 2020.

We have adopted a Code of Business Conduct and Ethics applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity 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 comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, additional reporting obligations and oversight, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our indebtedness may adversely affect our business, including by limiting our flexibility to operate our business and adversely affecting our financial health and competitive position.

On November 8, 2022, we entered into a loan agreement with investment funds managed by Pharmakon Advisors, LP ("Pharmakon"), or the Loan Agreement ("Pharmakon Loan Agreement"), that is secured by a lien covering substantially all of our assets, including intellectual property, providing for term loans to the Group in an aggregate principal amount of up to $100 million to be funded in two tranches. The first tranche, in the amount of $50 million, bears interest at a fixed rate of 9.75% and will mature on November 8, 2028. We used the proceeds from the first tranche, together with cash on hand, to repay in full our existing $50 million loan from Oxford Finance LLC, which was terminated upon such repayment. As of December 31, 2022, the outstanding principal balance under the Loan Agreement was $50.0 million. An additional $50.0 million is available to us at our option, subject to certain conditions precedent. The Loan Agreement contains customary covenants and events of default applicable to us.

In addition, the Loan Agreement contains, and any agreements evidencing or governing other future indebtedness may contain, certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things:

- convey, sell, lease, transfer, assign, dispose of or otherwise make cash payments consisting of all or any part of our business or property;
- effect certain changes in our business, management, ownership or business locations;
- merge or consolidate with, or acquire all or substantially all of the capital stock or assets of, any other company;
- create, incur, assume or be liable for any additional indebtedness, or create, incur, allow or permit to exist any additional liens;
- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of our capital stock;
- make certain investments; and
- enter into transactions with our affiliates.

While we have not previously breached and are not currently in breach of these or any of the other covenants contained in our credit agreement, there can be no assurance that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, our lender may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to it that secure such indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

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

Our operations and those of our third-party suppliers and collaborators could be subject to earthquakes, fire, explosion, power shortages, telecommunications failures, water shortages, floods, hurricanes or other extreme weather conditions, medical epidemics or pandemics, armed conflicts and geopolitical tension, acts of terrorism, labor disputes or other business interruptions, or other natural or man-made accidents or incidents. Any of the foregoing may result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, and may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event.

Although we have limited business interruption insurance policies in place, any interruption could come with high costs for us, as salaries and loan payments would usually continue. Moreover, any interruption could seriously harm our ability to timely proceed with any clinical programs or to supply product candidates for use in our clinical programs or during commercialization. For example, the ongoing COVID-19 pandemic has, at times, caused an interruption in our clinical trial activities. Specifically, we had to reduce our business activities including those in the laboratory according to governmental orders in the United States as well as in the United Kingdom. Additionally, supply chains disruptions may continue to impact our research activities. Moreover, due to the Russia and Ukraine conflict, the United States, United Kingdom, European Union, and other nations announced various sanctions against Russia and Belarus. The war in Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, the European Union, and other countries have created global security concerns and geopolitical tension that could have a lasting impact on regional and global economies, any or all of which could disrupt our supply chain, adversely affect our ability to conduct ongoing and future clinical trials of our product candidates, and adversely affect our ability to commercialise our products (subject to regulatory approval) in this region and have wider implications globally that could impact our business outside of this region. For example, ongoing military conflict will likely impact our ability to conduct clinical trials in Ukraine, Russia and potentially in other Eastern European countries, and may prevent us from continuing follow-up for patients previously enrolled or enrolling patients in future trials at sites in these countries, and may also prevent us from commercialising our products (subject to regulatory approval) in this region. This could negatively impact the anticipated timing and completion of future clinical trials and/or analyses of future clinical results, and negatively impact our plans to commercialise our product (subject to regulatory approval) in this region, which could harm our business.

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

In the ordinary course of business, we collect, store, use, transmit, disclose and otherwise process proprietary, confidential and sensitive data (including personal data such as health-related data), intellectual property and trade secrets. We may rely upon third-party service providers and technologies to operate critical business systems to process such information in a variety of contexts (including, without limitation, third-party providers of cloud-based infrastructure, personnel email and other functions). Our ability to monitor these third parties' information security practices is limited and these third parties may not have adequate information security measures in place.

We and the third parties upon whom we rely face a variety of evolving threats including but not limited to breakdown; breach; interruption or damage from computer viruses; computer hackers; malicious code (such as worms); social-engineering attacks (including phishing attacks); personnel error or malfeasance; theft or misuse; denial-of-service attacks; sophisticated nation-state and nation-state-supported actors; malware (including as a result of advanced persistent threat intrusions); denial-of-service attacks (such as credential stuffing); ransomware attacks; software bugs; server malfunctions; software and hardware failures; natural disasters; fires; floods; terrorism; war; telecommunication and electrical failures; and other compromise. Despite our security practices, there is a risk that we may be subject to phishing and other cyberattacks in the future. Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. The COVID-19 pandemic and our remote workforce increases risks to our information technology systems and data as more of our personnel work from remote locations and use network connections outside of our control. Any of the previously identified or similar threats could cause a security breach or other interruption. A security breach or other interruption could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. A security breach or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our goods and otherwise operate our business. For example, the loss of clinical trial data from completed or future clinical trials 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 manufacturing of our product candidates and any future 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.

The risk of security breaches has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by threat actors change frequently, may not be recognized until launched, and can originate from a wide variety of sources. While we have implemented security measures designed to protect our information technology systems and data, there can be no assurance that these measures will be effective. We have not always been able in the past to protect against security breaches (for example, we incurred two minor phishing attacks in 2018 and 2019).We may expend significant resources and modify our business activities (including our clinical trial activities) in an effort to protect against security breaches. Certain data privacy and security obligations may require us to implement and maintain specific security measures (including industry-standard or reasonable security measures) to protect our information technology systems and data.

To the extent that any disruption or security breach were to occur (or be perceived to have occurred), we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary expenditures; financial loss; harm to our competitive position; delays to the further development and commercialization of our product candidates or any future product candidates; and other similar harms. Security breaches and attendant consequences may cause customers to stop using our goods; limit our ability to conduct clinical trials; and otherwise negatively impact our business. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach (under applicable privacy and security obligations) to counterparties, data subjects, regulators or others could be material. The failure to comply with such notification obligations could lead to adverse consequences.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

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

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company or product, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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

We do not carry insurance for all categories of risks that our business may encounter, and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. Required coverage limits for such insurances are difficult to predict and may not be sufficient. If potential losses exceed our insurance coverage, our financial condition would be adversely affected. 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. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop. Additionally, operating as a public company will make it more expensive for us to obtain director and officer liability insurance. As a result, it may be more difficult to attract and retain qualified individuals to serve on our board of directors or the board committees.

Risks Related to Our International Operations

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

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

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property and proprietary rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;

- changes in non-U.S. currency exchange rates of the pound sterling, U.S. dollar, euro and currency controls;
- changes in a specific country's or region's political or economic environment, including the longer-term implications of Brexit;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our share option schemes or equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Moreover, due to the Russia-Ukraine conflict, the United States, United Kingdom, European Union, and other nations announced various sanctions against Russia and Belarus. The military conflict and the retaliatory measures that have been taken, or could be taken in the future, by the United States, United Kingdom, European Union, and other countries have created global security concerns and global geopolitical tension that could result have a lasting impact on regional and global economies, any or all of which could disrupt our supply chain, adversely affect our ability to conduct ongoing and future clinical trials of our product candidates, and adversely affect our ability to commercialize our products (subject to regulatory approval) in this region and have wider implications globally that could impact our business outside of this region.

The United Kingdom's withdrawal from the European Union may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Our principal office space is located in the United Kingdom. The United Kingdom formally exited the European Union, commonly referred to as Brexit, on January 31, 2020. Under the terms of its departure, the United Kingdom entered a transition period, or the Transition Period, during which it continued to follow all European Union rules. The Transition Period ended on December 31, 2020. On December 30, 2020, the United Kingdom and European Union signed the Trade and Cooperation Agreement, which includes an agreement on free trade between the two parties, which provisionally applied from January 1, 2021, and formally entered into force on May 1, 2021.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and will continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom and the European Union. For example, following the Transition Period, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorizations and our products will therefore require a separate marketing authorization to allow us to market such products in Great Britain. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from or delay us commercializing our product candidates in the United Kingdom and/or the EEA and restrict our ability to generate revenue and achieve and sustain profitability. In the short term, there is ongoing disruption to import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU customs agencies that may delay time-sensitive shipments and may negatively impact our product supply chain. In addition, there are non-tariff costs to such trade that did not exist prior to the expiry of the Transition Period. Orphan designation in Great Britain following Brexit is, unlike in the EU, not available pre-marketing authorization. Applications for orphan designation in Great Britain (or the United Kingdom, if there is not a prior centralized marketing authorisation in the EU) are now made at the same time as an application for marketing authorization. The criteria to be granted orphan designation are essentially identical to those in the EU but based on the prevalence of the condition in Great Britain as opposed to prevalence in the EU. It is therefore possible that conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the Transition Period are or would no longer be and that conditions that were not currently designated as orphan conditions in the European Union will be designated as such in Great Britain.

The Retained EU Law (Revocation and Reform) Bill 2022, which is currently progressing through the United Kingdom Parliament seeks to allow the Government of the United Kingdom to repeal or replace certain European Union Law that was incorporated into the law of the United Kingdom, effective as of the end of the Transition Period. Repealing or replacing such European Union Law would be likely cause further uncertainty.

As a result of Brexit or otherwise, other European countries may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union will have and how such withdrawal will affect us, and the full extent to which our business could be adversely affected.

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

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the pound sterling and the U.S. dollar, may adversely affect us. Although the majority of our employees, offices and research facilities are based in the United Kingdom, we source some of our research and development, manufacturing, consulting and other services from the United States and the European Union. Further, significant current and future revenue is and may continue to be derived from abroad, including the United States, European Union and further territories. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the euro, and other currencies, which may impact our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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

An active trading market for our ADSs may not continue to develop or be sustained.

Prior to our initial public offering in February 2021, there was no public trading market for our ordinary shares or ADSs. Although our ADSs are listed on The Nasdaq Global Select Market, we cannot assure you that an active trading market for our ADSs will continue to develop or be sustained. If an active market for our ADSs does not continue to develop or is not sustained, it may be difficult to for investors to sell ADSs without depressing the market price for the ADSs or to sell the ADSs at all. You may not be able to sell your ADSs quickly or at the market price if trading in our ADSs is not active.

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

We completed our initial public offering in February 2021. From February 4, 2021 to January 31, 2023, the closing price of our ADSs ranged from a high of $65.08 to a low of $18.94 per ADS. The trading price of our ADSs has and is likely to continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Annual Report, these factors include but not limited to:

- our failure to successfully execute our commercialization strategy with respect to KIMMTRAK;
- actions or announcements by third-party or government payers with respect to coverage and reimbursement of KIMMTRAK;
- adverse regulatory decisions, or our ability to obtain regulatory approval of, tebentafusp in other jurisdictions, or any of our other product candidates;
- adverse results or delays in pre-clinical studies or clinical trials;
- reports of adverse events in products similar or perceived to be similar to those we are developing or clinical trials of such products;

- an inability to obtain additional funding on favorable terms or at all, including as a result of recently worsening macroeconomic conditions;
- failure by us to successfully develop and commercialize our product candidates;
- failure by us to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us to identify additional product candidates for our pipeline;
- failure by us or our licensors and strategic partners to prosecute, maintain, protect or enforce our intellectual property and proprietary rights;
- disputes or other developments relating to intellectual and other proprietary rights, including litigation
- matters and our ability to obtain patent and other intellectual property protection for our technologies;
- changes in laws or regulations applicable to future products;
- an inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- the introduction of new products, services or technologies by our competitors;
- failure by us to meet or exceed financial projections we may provide to the public;
- failure by us to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate commercial supply for any approved product or inability to do so at acceptable prices;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic partner or our competitors;
- inability to comply with our debt covenants and to make payments as they become due;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or shareholder litigation;
- changes in the market valuations of similar companies;
- general economic, industry, political and market conditions, including, but not limited to, the war in Ukraine, ongoing impacts of COVID-19, global geopolitical tension, rising inflation and interest rates, supply chain disruptions, and volatility in the capital markets;
- sales of our ADSs or ordinary shares by us or our shareholders in the future;
- the trading volume of our ADSs; and
- other events or factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their ADSs and may otherwise negatively affect the liquidity of our ADSs. In addition, the stock market in general, and the securities of biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors, including impacts thereon of the war in Ukraine, COVID-19, and global geopolitical tension, as well as rising inflation and interest rates, supply chain disruptions, and volatility in the capital markets, may negatively affect the market price of our ADSs, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause the price of our ADSs to decline rapidly and unexpectedly. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and a diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our ADS price and trading volume could decline.

The trading market for our ADSs is influenced, in part, on the research and reports that securities or industry analysts publish about us or our business. As a newly public company, we have only limited research coverage by equity research analysts. Securities or industry analysts may elect not to provide research coverage of our ADSs, and such lack of research coverage may adversely impact the market price of our ADSs. Even if we have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our ADSs could decline if one or more equity research analysts downgrade our ADSs or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our ADSs could decrease, which in turn could cause the trading price or trading volume of our ADSs to decline.

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

As of December 31, 2022, our executive officers, directors and current beneficial owners of five percent or more of our ordinary shares and their respective affiliates beneficially owned, in the aggregate, approximately 40% of our outstanding ordinary shares (including ordinary shares in the form of ADSs). The voting power of this group may increase to the extent any shareholders holding non-voting ordinary shares convert their non-voting ordinary shares into ordinary shares.

As a result, depending on the level of attendance at our general meetings of shareholders, these persons, acting together, would be able to significantly influence all matters requiring approval by our shareholders, including the election, re-election and removal of directors, any merger, scheme of arrangement, or sale of all or substantially all of our assets, or other significant corporate transactions, and amendments to our articles of association.

In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our ADSs by:

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

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

We may be required to repurchase for cash all, or to facilitate the purchase by a third party of all, the shares of our company held by the Bill & Melinda Gates Foundation if we default under the global access commitments agreement, which could have an adverse impact on us and limit our ability to make distributions to our shareholders.

We entered into a global access commitments agreement with our shareholder, the Bill & Melinda Gates Foundation, or the Gates Foundation, in September 2017, which was amended and restated in March 2020 and February 2021, pursuant to which we are required to take certain actions to support the Gates Foundation's mission. In the event that we are in breach of certain provisions of the global access commitments agreement, following a cure period, we may be required to repurchase for cash all, or to facilitate the purchase by a third party of all, the securities of our company held by the Gates Foundation at certain terms that may not be favorable to us. This would also include the ADSs acquired in the concurrent private placement, if any. If this occurs, cash used for this purpose may, adversely affect our liquidity, cause us to reduce expenditures in other areas of our business, or curtail our growth plans. If we do not have sufficient cash on hand to purchase the securities, we could have to seek financing alternatives in order to meet our obligations, and there is no certainty that financing would be available on reasonable terms or at all. For the period that we are unable to repurchase the securities held by the Gates Foundation or arrange for a third party to purchase such securities, we would not likely be allowed to pay dividends, repurchase the securities of any other shareholder or otherwise make any other distribution to any of our shareholders in connection with their securities. Therefore, meeting this purchase obligation, if necessary, could have a material adverse effect on our business and financial results. For more information on the Gates Foundation's withdrawal rights, see "Item 4B. Business overview—Our Collaborations and License Agreements—Gates Collaboration."

The sale of a substantial number of our ADSs in the public market could cause the market price of our ADSs to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our ADSs in the public market, or the perception that these sales might occur, could depress the market price of our ADSs and could impair our ability to raise capital through the sale of additional equity securities.

We have filed a registration statement on Form S-8 under the Securities Act to register ordinary shares subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, as well as, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

We have registered approximately 9.3 million of our ordinary shares for resale by certain holders of our ordinary shares pursuant to registration rights agreements with such holders. Additionally, as of December 31, 2022, the holders of an aggregate of approximately 5.2 million of our ordinary shares, or their transferees, have rights, subject to conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders, as well as to cooperate in certain public offerings of such ordinary shares. Upon registration, these shares are, or will be, as applicable, available to be freely sold in the public market subject, in the case of our affiliates, to the restrictions of Rule 144 under the Securities Act. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

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

Holders of the ADSs do not have the same rights as our shareholders and in accordance with the provisions of the deposit agreement, will not be able to exercise voting rights attaching to the ordinary shares represented by the ADSs on an individual basis. The depositary or its nominee will act as the representative for the holders of the ADSs and will exercise the voting rights attached to the ordinary shares represented by the ADSs. Holders of our ADSs may not receive voting materials in time to instruct the depositary to vote, and it is possible that they, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise voting rights and may lack recourse if their ADSs are not voted as requested. In addition, holders of our ADSs will not be able to call a shareholders' meeting. See "Item 12.D American Depositary Shares."

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."

We are entitled to amend the deposit agreement and to change the rights of ADS holders under the terms of such agreement, or to terminate the deposit agreement, without the prior consent of the ADS holders.

We are entitled to amend the deposit agreement and to change the rights of the ADS holders under the terms of such agreement, without the prior consent of the ADS holders. We and the depositary may agree to amend the deposit agreement in any way we decide is necessary or advantageous to us or to the depositary. Amendments may reflect, among other things, operational changes in the ADS program, legal developments affecting ADSs or changes in the terms of our business relationship with the depositary. In the event that the terms of an amendment are materially disadvantageous to ADS holders, ADS holders will only receive 30 days' advance notice of the amendment, and no prior consent of the ADS holders is required under the deposit agreement. Furthermore, we may decide to direct the depositary to terminate the ADS facility at any time for any reason. For example, terminations may occur when we decide to list our ordinary shares on a non-U.S. securities exchange and determine not to continue to sponsor an ADS facility or when we become the subject of a takeover or a going-private transaction. If the ADS facility will terminate, ADS holders will receive at least 30 days' prior notice, but no prior consent is required from them. Under the circumstances that we decide to make an amendment to the deposit agreement that is disadvantageous to ADS holders or terminate the deposit agreement, the ADS holders may choose to sell their ADSs or surrender their ADSs and become direct holders of the underlying ordinary shares, but will have no right to any compensation whatsoever.

ADSs 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 the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, holders and beneficial owners 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 the 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. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

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 any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

Moreover, as the jury trial waiver relates to claims arising out of or relating to the ADSs or the deposit agreement, we believe that, as a matter of construction of the clause, the waiver would likely to continue to apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to claims arising before the cancellation of the ADSs and the withdrawal of the ordinary shares, and the waiver would most likely not apply to ADS holders who subsequently withdraw the ordinary shares represented by ADSs from the ADS facility with respect to claims arising after the withdrawal. However, to our knowledge, there has been no case law on the applicability of the jury trial waiver to ADS holders who withdraw the ordinary shares represented by the ADSs from the ADS facility.

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

The depositary for the 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 will 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 the 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.

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

Under current English law, a company's accumulated realized profits must exceed its accumulated realized losses (on a non-consolidated basis) before dividends can be declared and paid. Therefore, we must have distributable profits before declaring and paying a dividend. In addition, as a public limited company incorporated in England and Wales, we will only be able to make a distribution if the amount of our net assets is not less than the aggregate of our called-up share capital and undistributable reserves and if, and to the extent that, the distribution does not reduce the amount of those assets to less than that aggregate.

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

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

We are incorporated under English law and have our registered office in England. Certain members of our board of directors and senior management 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 securities laws of the United States.

The United States and the United Kingdom 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 United Kingdom. In addition, uncertainty exists as to whether U.K. courts would entertain original actions brought in the United Kingdom against us or our directors or senior management predicated upon the securities laws of the United States or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of the United Kingdom 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 an English court gives judgment for the sum payable under a U.S. judgment, the English judgment will be enforceable by methods generally available for this purpose. These methods generally permit the English court discretion to prescribe the manner of enforcement.

As a result, U.S. investors may not be able to enforce against us or our senior management, board of directors or certain experts named herein who are residents of the United Kingdom or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to you unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than U.S. public companies.

We are a "foreign private issuer," as defined in the SEC rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we will file an annual report on Form 20-F within four months of the close of each fiscal year ended December 31 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. However, because of the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States.

While we are a foreign private issuer, we are not subject to certain Nasdaq corporate governance rules applicable to public companies organized in the United States.

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

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

Furthermore, English law does not have a regulatory regime for the solicitation of proxies applicable to us, thus our practice varies from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies. In addition, we have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice will vary from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. In addition, while we have adopted a code of business conduct and ethics, English law does not require us to publicly disclose waivers from this code that have been approved by our board within four business days. We expect to report any such waivers in the subsequent Annual Report on Form 20-F. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

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

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to Nasdaq listed U.S. companies. Because we are a foreign private issuer, however, our audit committee is not subject to additional requirements applicable to Nasdaq listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer, subject to certain phase-in requirements permitted by Rule 10A-3 of the Exchange Act.

We have incurred significant costs as a public company, and operating as a public company also places significant demands upon our management.

As a public company listed in the United States, 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 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on publicly traded companies of effective disclosure and financial controls and corporate governance practices. Our 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, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

We previously identified a material weakness in our internal control over financial reporting, which has since been remediated. We may discover additional material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, which may impair our ability to produce timely and accurate financial statements or prevent fraud. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs

Section 404(a) of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, requires that beginning with this Annual Report, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. As a large accelerated filer, under Section 404(b) of the Sarbanes-Oxley Act our independent registered public accounting firm is required to issue an annual report that addresses the effectiveness of our internal control over financial reporting.

In the course of auditing our 2019 financial statements for our initial public offering, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting.

In the summer and fall of 2020, we conducted an internal investigation as a result of receiving a whistleblower complaint alleging employee misconduct and other improper activities related to a kickback scheme involving an employee and two third-party vendors between 2018 and 2020. Our audit committee led the investigation utilizing outside counsel, during which the named employee resigned. After the investigation, we terminated the one remaining open contract with the third-party vendors and issued proceedings in October 2020 against the involved parties. We recovered our estimated losses of £1.8 million from the employee and the third-party vendors in December 2020. In the course of auditing our 2019 financial statements for our initial public offering, we and our independent registered public accounting firm identified a material weakness relating to our procurement processes and application of delegation of authority approval limits due to insufficient risk assessment procedures. We determined that our internal controls did not operate effectively to prevent or timely detect unauthorized contracts and purchase orders. This resulted in the inability to prevent and timely detect these fraudulent activities. We remediated the material weakness as of December 31, 2020.

While we remediated our prior material weakness, we may identify additional material weaknesses or otherwise fail to maintain proper and effective internal controls. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs.

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

If a U.S. holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group, if any. Because our group includes U.S. subsidiaries, our current non-U.S. subsidiaries and any future newly formed or acquired non-U.S. subsidiaries will be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with controlled foreign corporation reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the controlled foreign corporation rules of the Internal Revenue Code of 1986, as amended, or the Code. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs. Based on our analysis, we believe that we did not meet the definition of a controlled foreign corporation under Section 957(a) of the Code in 2022.

If we are a passive foreign investment company, or PFIC, for any taxable year, there could be adverse U.S. federal income tax consequences to U.S. investors.

Under the Code, we will be a PFIC, for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the value of our assets (generally determined in the basis of a weighted quarterly average) consists of assets that produce, or are held for the production of, passive income (including cash). For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. Cash and cash-equivalents are passive assets for these purposes. 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. investor holds our shares, the U.S. investor may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements.

Based on our analysis of our activities and the composition of our income and assets, we believe that we were not a PFIC for our taxable year ending December 31, 2022. However, 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, there can be no assurance that we will not be treated as a PFIC for the current or any future taxable year. In addition, for our current and future taxable years, the total value of our assets (including goodwill) for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Accordingly, if our market capitalization declines while we hold a substantial amount of cash and cash-equivalents for any taxable year we may be a PFIC for that taxable year. Under the income test, our status as a PFIC depends on the composition of our income for the relevant taxable year which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how we spend the cash we raise in any offering. We have only recently begun to generate product revenues and therefore we may be a PFIC for any taxable year in which we do not generate sufficient amounts of active income to offset our passive financing income. Therefore, we cannot express an expectation regarding our PFIC status for the current or any future taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service, or IRS, will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for any prior, current or future taxable year.

For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, as well as certain elections that may be available to U.S. investors, see "Item 10.E Taxation—Material United States Federal Income Considerations for U.S. Holders."

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 U.K. tax legislation.

As a U.K. incorporated and tax resident entity, we are subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since inception and therefore have not paid any U.K. corporation tax. As of December 31, 2022, we had cumulative carryforward tax losses of £241 million. Subject to any relevant utilization criteria and restrictions (including the Corporate Income Loss Restriction and the Corporate Capital Loss Restriction that, broadly, restrict the amount of carried forward losses that can be utilized to 50% of group profits or gains arising above £5.0 million per tax year), we expect these to be eligible for carry forward and utilization against future operating profits.

As a company that carries out extensive research and development activities, or R&D, we seek to benefit from the U.K. research and development tax relief programs, being the Small and Medium-sized Enterprises R&D tax relief program, or SME Program, and, for certain specific categories of expenditure, the Research and Development Expenditure Credit program, or RDEC Program. The tax reliefs we have obtained under these programs have generated a meaningful proportion of our cash flow, amounting to £40.3 million and £12.4 million in the accounting periods ending December 31, 2020 and December 31, 2021, respectively. We further received £9.9 million in January 2023, relating to R&D activities in the year ended December 31, 2021. We anticipate receiving tax credits relating to the year ended December 31, 2022 later in 2023.

While the SME Program has been particularly beneficial to us, as under such program the trading losses that arise from our qualifying R&D activities can be surrendered for a cash rebate of up to 33.35% of qualifying expenditure, amendments to the U.K. R&D tax credit regime have recently been enacted, or proposed. These amendments (amongst other things) (i) will reduce the cash rebate that may be claimed under the SME Program to 18.6% of qualifying expenditure, and (ii) may (unless limited exceptions apply) introduce restrictions on the tax relief that can be claimed for expenditure incurred on sub-contracted R&D activities or externally provided workers, where such sub-contracted activities are not carried out in the U.K. or such workers are not subject to U.K. payroll taxes. These amendments are expected to take effect from April 2023. In addition, the U.K. Government has recently launched a consultation on its proposal to merge the SME Program and the RDEC Program into a single scheme with effect from April 2024; if such proposal is implemented, it may be the case that we are no longer able to make claims in respect of sub-contracted R&D activities, and that different (and potentially lower) caps are imposed on the amount of tax relief that we can claim. These and other potential future changes to the U.K. R&D tax relief programs may mean we no longer qualify. or have a material impact on the extent to which we can make claims.

We may benefit in the future from the United Kingdom's "patent box" regime, which allows certain profits attributable to revenues from patented products (and other qualifying income) to be taxed at an effective rate of 10% by giving an additional tax deduction. We are the exclusive licensee or owner of several patent applications which, if issued, would cover our product candidates, and accordingly, future upfront fees, milestone fees, product revenues and royalties could be eligible for this deduction. When taken in combination with the enhanced relief available on our R&D expenditures, we expect a long-term rate of corporation tax lower than the statutory to apply to us. If, however, there are unexpected adverse changes to the U.K. R&D tax credit regime or the "patent box" regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments then our business, results of operations and financial condition may be adversely affected. This may impact our ongoing requirement for investment and the timeframes within which additional investment is required.

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 income tax returns in multiple jurisdictions. Our consolidated effective income tax rate, and the tax treatment of our ADSs and ordinary shares, 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 or being implemented at national (including the Inflation Reduction Act in the United States) or international level (such as those related to the Organisation for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project (including "BEPS 2.0"), the European Commission's state aid investigations and other initiatives); the practices of tax authorities in jurisdictions in which we operate; 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, or the stamp duty or stamp duty reserve tax treatment of our ADSs or ordinary shares.

A bill is currently proceeding through the UK parliament (the Retained EU Law (Revocation and Reform) Bill) which provides for the revocation of EU laws and rights which, notwithstanding Brexit, currently remain effective in the UK, except where the UK Government and/or parliament take active steps to preserve the EU law position within UK law. Certain aspects of the stamp duty and stamp duty reserve tax treatment of our ordinary shares and ADSs are based on EU law which could be affected by this Bill. Accordingly, if this Bill is enacted, and steps are not taken by the UK Government and/or parliament to preserve the current position, this could, in particular, result in a charge to stamp duty reserve tax on the issuance of new ADSs, at the rate of 1.5% of the issue price, potentially with effect from December 31, 2023, which would represent an additional cost if we seek to raise further capital in this way.

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 increase the estimated tax liability that we have expensed to date and paid or accrued on our statement of financial position, and otherwise 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, His Majesty's Revenue & Customs, or HMRC, the IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, 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. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. 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.

Shareholder protections found in provisions under the U.K. City Code on Takeovers and Mergers, or the Takeover Code, will not apply if our place of management and control remains outside the United Kingdom.

On February 1, 2021, Immunocore Holdings Limited was re-registered as a public limited company with the name Immunocore Holdings plc. Depending on meeting the jurisdictional criteria, the Takeover Code can be applicable to public limited companies incorporated in England and Wales. 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 currently not 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 are regulated and conducted. The following is a brief summary of some of the most important rules of the Takeover Code:

- In connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is "the subject of rumor or speculation" or there is an "untoward movement" in the company's share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about its review of a potential offer.

- When a person or group of persons acting in concert (a) acquires, whether by a series of transactions over a period of time or not, interests in shares carrying 30% or more of the voting rights of a company (which percentage is treated by the Takeover Code as the level at which effective control is obtained) or (b) acquires an interest in any other shares which increases the percentage of shares carrying voting rights in which they are interested when they are already interested in shares which carry not less than 30% of the voting rights but do not hold shares carrying more than 50% of such voting rights, they must make a cash offer to all other shareholders at the highest price paid by them or any person acting in concert with them in the 12 months before the offer was announced.

- When interests in shares carrying 10% or more of the voting rights of a class have been acquired by an offeror (i.e., a bidder) and any person acting in concert with it in the offer period (i.e., before the shares subject to the offer have been acquired) or within the previous 12 months, the offer must be in cash or be accompanied by a cash alternative for all shareholders of that class at the highest price paid by the offeror or any person acting in concert with them in that period. Further, if an offeror or any person acting in concert with them acquires any interest in shares during the offer period, the offer for the shares must be in cash or accompanied by a cash alternative at a price at least equal to the price paid for such shares during the offer period.

- If after an announcement is made, 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.

- The board of directors of the offeree company must appoint a competent independent adviser 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 adviser 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 advisers.

- 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 and detailed 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 English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the U.K. Companies Act, or the Companies Act, and by our articles of association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. See "Item 10.B Memorandum and Articles of Association—Differences in Corporate Law" in this Annual Report for a description of the principal differences between the provisions of the Companies Act applicable to us and, for example, the Delaware General Corporation Law relating to shareholders' rights and protections.

The principal differences include the following:

- under our articles of association, any resolution put to the vote of a general meeting must be decided exclusively on a poll. Under English law, it would be possible for our articles of association to be amended such that each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings;

- 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 rights to subscribe for, or to convert securities into, 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 of association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the articles of association. 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/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 voting for approval;

- under English law and our articles of association, 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; and

- the quorum requirement for a shareholders' meeting is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized representative. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

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

On February 1, 2021, Immunocore Holdings Limited was re-registered as a public limited company with the name Immunocore Holdings plc. English law provides that a board of directors may only allot shares (or rights to subscribe for or convert any security into shares) with the prior authorization of shareholders, such authorization stating the aggregate nominal amount of shares that it covers and being valid for a maximum period of five years, each as specified in the articles of association or relevant shareholder resolution. At a general meeting of shareholders held on February 3, 2021, we obtained authority from our shareholders to allot new shares or to grant rights to subscribe for or to convert any security into shares in the company up to a maximum aggregate nominal amount of £150,000 for a period of five years from the date of such general meeting of shareholders, which authorization will need to be renewed upon expiration (i.e., at least every five years) but may be sought more frequently for additional five-year terms (or any shorter period).

English law also generally provides shareholders with preemptive rights when new shares are issued for cash. However, it is possible for the articles of association, or for shareholders to pass a special resolution at a general meeting, being a resolution passed by at least 75% of the votes cast, to disapply preemptive rights. Such a disapplication of preemptive rights may be for a maximum period of up to five years from the date of adoption of the articles of association, if the disapplication is contained in the articles of association, or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution but not longer than the duration of the authority to allot shares to which the disapplication relates. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years). At a general meeting of shareholders held on February 3, 2021, we obtained authority from our shareholders to disapply preemptive rights for a period of five years from the date of such general meeting of shareholders which disapplication 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 prohibits a public company from repurchasing its own shares without the prior approval of shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, and other formalities. Such approval may be for a maximum period of up to five years. See "Item 10.B Memorandum and Articles of Association."

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

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

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

Item 4. Information on the Company.

A. History and development of the company.

Immunocore Holdings plc was incorporated on January 7, 2021. On February 9, 2021, we completed our IPO, and we have been a publicly listed company for over two years.

We were originally incorporated under the laws of England and Wales in December 2007 as a private company with limited liability called Immunocore Limited. Immunocore Holdings Limited was incorporated on January 7, 2021 as a private limited company under the laws of England and Wales with nominal assets and liabilities for the purpose of becoming the holding company of Immunocore Limited and consummating the corporate reorganization. On January 22, 2021, each holder of series A preferred shares, series B preferred shares, series C preferred shares, G1 shares, G2 shares and ordinary shares in Immunocore Limited sold and transferred their shares to Immunocore Holdings Limited (now Immunocore Holdings plc) in exchange for receiving 100 shares of the same class in Immunocore Holdings Limited. We refer to this as our "Share Exchange". Immediately following the Share Exchange, the holders of shares in Immunocore Limited held shares in Immunocore Holdings plc of the same class and in the same proportions as their holding in Immunocore Limited, except for that they each held 100 times as many shares. Immunocore Limited became a wholly-owned subsidiary of Immunocore Holdings plc as a result of the Share Exchange. Following the Share Exchange, Immunocore Limited undertook a reorganization of its share capital to re-designate its series A preferred shares, series B preferred shares, series C preferred shares, G1 shares and G2 shares into a single class of ordinary shares. Subsequent to the Share Exchange, Immunocore Limited reduced its share capital by way of the cancellation of all amounts standing to the credit of Immunocore Limited's share premium account and the cancellation of 6,414,412 ordinary shares resulting from the reorganization of capital referred to above pursuant to Part 17 of the Companies Act in order to create distributable reserves. On February 1, 2021, Immunocore Holdings Limited re-registered as a public limited company and was re-named Immunocore Holdings plc.

On February 9, 2021, immediately prior to the completion of our initial public offering, the different classes of our issued share capital were converted into a single class of ordinary shares (and a class of deferred shares and a class of non-voting ordinary shares) on a 20 to 1 basis, and we completed our initial public offering on the Nasdaq Global Select Market. Our ADSs are traded under the symbol IMCR. Our ordinary shares are not listed. Our registered office in the United Kingdom is located at 92 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY, United Kingdom, and the telephone number of our registered office is +44 (0)1235 438600.

Our agent for service of process in the United States is Immunocore, LLC, Six Tower Bridge, Suite 200, 181 Washington Street, Conshohocken, Pennsylvania 19428.

Our actual capital expenditures for the years ended December 31, 2022, 2021 and 2020 amounted to £1.8 million, £1.0 million and £3.1 million, respectively. These capital expenditures primarily consisted of property, plant and equipment, leasehold improvements, lab equipment and computer equipment and software in the United Kingdom.

The SEC maintains an Internet site that contains reports, proxy information statements and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov. Our website address is www.immunocore.com. Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this document. We have included our website address in this document solely as an inactive textual reference.

B. Business overview.

We are a commercial-stage biotechnology company pioneering the development of a novel class of TCR bispecific immunotherapies called ImmTAX –**I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **X** disease – designed to treat a broad range of diseases, including cancer, infectious and autoimmune. Leveraging our proprietary, flexible, off-the-shelf ImmTAX platform, we are developing a deep pipeline in multiple therapeutic areas, including four clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune conditions and multiple earlier pre-clinical programs.

In January and April 2022, we received approval from the U.S. Food and Drug Administration, or FDA, and European Commission, or EC, respectively, for our lead product candidate, KIMMTRAK, for the treatment of unresectable or metastatic uveal melanoma, or mUM. We then received approval in June 2022 from the UK's Medicines and Healthcare products Regulatory Agency, or MHRA, the Australian Therapeutic Goods Administration, or TGA, and Health Canada. KIMMTRAK is now approved in over 30 countries and we have commercially launched in the United States, Germany and France, among other territories, with further commercial launches underway in additional territories where we have received approval. The Company plans to launch KIMMTRAK in additional countries, if approved in those countries, in 2023-2024.

KIMMTRAK is the lead product from our ImmTAX platform and is the first approved new therapy in uveal melanoma in four decades. To date, we have dosed over 1,000 cancer patients with KIMMTRAK, tebentafusp, and our other ImmTAX product candidates, which we believe is the largest clinical data set of any T cell engager bispecific in a solid tumor and any TCR therapeutic. Our clinical programs are being conducted with patients with a broad range of cancers including melanoma, lung, gastric and ovarian, among others. We believe that these other ImmTAX product candidates have the potential to address other tumor types with larger addressable patient populations and significant unmet need.

KIMMTRAK is manufactured at facilities located in Denmark and Germany. We are supporting the appropriate use of KIMMTRAK in the United States and Europe through a well-equipped and fit-for-purpose trained commercial team that includes medical, sales, and value access team members. We utilize a hybrid model that includes in-house and contracted resources in the United States and Europe. To support our commercial efforts, we have entered into an exclusive multi-regional agreement with Medison to help seek regulatory authorization and commercialize Immunocore's KIMMTRAK in Canada, Australia, New Zealand, Israel, Central and Eastern Europe, South and Central America, and the Caribbean.

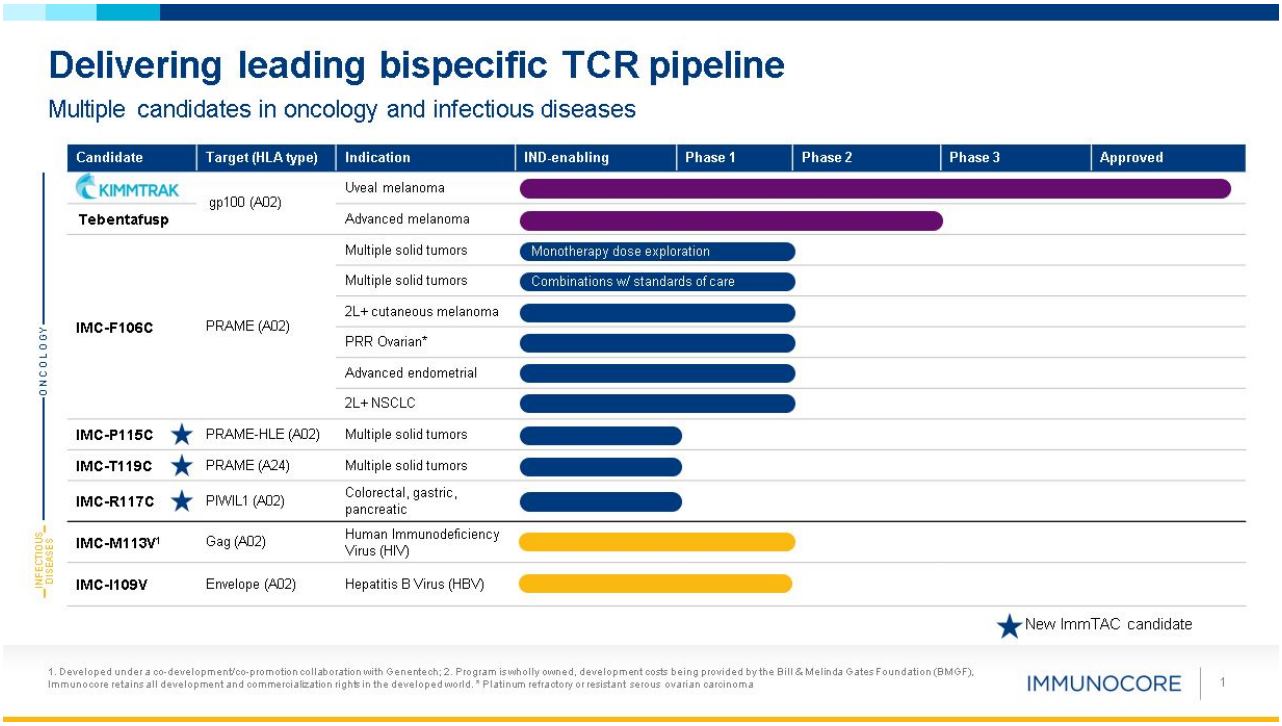
Our clinical programs are being conducted with patients with a broad range of cancers including melanoma, lung, gastric and ovarian, among others. We are progressing two clinical stage programs within our ImmTAC (**I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **C**ancer) platform, including KIMMTRAK, and an additional three ImmTAC molecules approaching targeted IND submission in the next eighteen months. We believe our other ImmTAC product candidates have the potential to address other tumor types with larger addressable patient populations and significant unmet need, and we are studying the application of our ImmTAX platform to infectious diseases and autoimmune conditions.

Unlike antibody targeted immunotherapies that have a relatively small target pool, our approach relies on the power of T cell receptors, or TCRs, which are naturally occurring receptors found on the surface of T cells that have the ability to target nearly all of the human proteome. Natural TCRs give T cells the ability to scan for abnormalities in nearly any cell in the body that are presented as protein fragments, or antigens, by human leukocyte antigen, or HLA, on the cell surface. Our ImmTAX platform builds upon these natural TCRs to engineer soluble targeted and high-affinity TCRs. By engineering these TCRs through our ImmTAX platform, we are developing off-the-shelf, bispecific therapeutics, which are able to precisely target a wide range of proteins uniquely expressed by unhealthy and abnormal cells that cannot be targeted by current antibody-based immunotherapies.

Our ImmTAX bispecific therapeutics couple the targeting power of these engineered TCRs on one end with the other end displaying pre-optimized effector functions, which have the ability to drive a desired immune response at the site of the disease. This combination is designed to provide us with significant flexibility as we are able to engineer and tailor our ImmTAX therapeutics to target proteins that are specific to the disease we are trying to treat and then modulate the corresponding immune response by either boosting or inhibiting the immune system.

Our Pipeline

We are currently leveraging our ImmTAX platform within three therapeutic areas: cancer, infectious diseases, and autoimmune conditions. We have named each of these platforms according to their therapeutic area to distinguish the type of target recognized by the TCR targeting system and the selected effector function. Our current pipeline includes four clinical stage assets as well as three ImmTAC molecules approaching targeted IND submission in the next eighteen months, and numerous pre-clinical programs. While our most advanced clinical programs are focused on developing treatments for oncology, we believe our ImmTAX platform is versatile, and will also allow us to develop therapeutics with significant advantages in the treatment of infectious diseases and autoimmune conditions. Our current pipeline is represented in the diagram below.



Our ImmTAC Platform (Oncology)

Within our ImmTAC (**I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **C**ancer) platform, we have two clinical stage programs, three ImmTAC molecules approaching targeted IND submission in the next eighteen months, and additional pre-clinical programs, focusing on the treatment of solid tumors with high unmet medical needs. Our ImmTAC product candidates are bispecific, soluble TCR molecules featuring an antigen-specific targeting module based on our high-affinity, highly specific TCR system and our proprietary cluster of differentiation 3 effector module for T cell recruitment, engagement and activation.

Our ImmTAC programs include:

- **KIMMTRAK** (tebentafusp-tebn), our ImmTAC molecule targeting an HLA-A*02:01 gp100 antigen, is our first approved product. The FDA and the EC have approved KIMMTRAK (tebentafusp-tebn and tebentafusp, respectively) for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM. The UK's MHRA, Health Canada, and the Australian Government Department of Health's TGA have each approved KIMMTRAK for the treatment of HLA-A*02:01-positive adult patients with mUM. KIMMTRAK is now approved in over 30 countries and we have commercially launched in the United States, Germany and France, among other territories, with further commercial launches underway in additional territories where we have received approval.

- **Tebentafusp** is also being developed for the treatment of advanced melanoma. In June 2022, we presented updated clinical data from our Phase 1b clinical trial of tebentafusp in metastatic cutaneous melanoma (mCM) in an oral presentation at the 2022 ASCO Annual Meeting. In mCM patients who progressed on prior anti-PD(L)1, tebentafusp with durvalumab continues to demonstrate promising overall survival (OS) (1-yr ~75%) compared to recent benchmarks (1-yr ~55%). We are currently screening patients in a randomized Phase 2/3 clinical trial of tebentafusp monotherapy or with an anti-PD(L)1 therapy. This trial will enroll patients with advanced melanoma, excluding only uveal melanoma, that have progressed on an anti-PD1, received prior ipilimumab and, if applicable, received a tyrosine kinase inhibitor (TKI).

- **IMC-F106C**, our ImmTAC molecule targeting an optimal HLA-A*02 PRAME antigen is currently being evaluated in a first-in-human, Phase 1/2 dose escalation clinical trial in patients with multiple solid tumor cancers. The initial Phase 1 data from the dose escalation study of IMC-F106C, the first PRAME x CD3 ImmTAC bispecific protein, was presented at the 2022 European Society for Medical Oncology (ESMO) Congress. Durable RECIST responses and reduction in circulating tumor DNA (ctNDA) were observed across multiple solid tumors. The Company's planned global expansion of the clinical trial footprint for PRAME-A02 studies is underway, with additional patients now being recruited into the Phase 1/2 monotherapy (cutaneous melanoma, ovarian, non-small cell lung cancer, and endometrial) and combination expansion arms in order to understand the breadth of clinical activity across multiple tumor types. The Company expects to report data from the monotherapy and combination arms by the first half of 2024.

- **IMC-T119C,** our ImmTAC molecule targeting an optimal HLA-A*24 PRAME antigen was announced as part of our pipeline in January 2023 with planned IND submission in 2024. In order to expand the potential of TCR therapy targeting PRAME, the Company is developing IMC-T119C, a first-in-class ImmTAC product candidate targeting a PRAME peptide presented by HLA-A24. HLA-24 is an HLA-type that is estimated to be present in 60% of people in Japan and 15-20% in Western populations.

- **IMC-P115C**, our half-life extended ImmTAC molecule targeting an optimal HLA-A*02 PRAME antigen was announced as part of our pipeline in January 2023 with planned IND submission in 2024. This ImmTAC candidate was designed with the aim of improving patient convenience. IMC-P115C targets the same PRAME-A02 peptide and uses the same CD3 end and TCR specificity as IMC-F106C.

- **IMC-R117C**, our ImmTAC molecule targeting an optimal HLA-A*02 PIWIL1 antigen was announced as part of our pipeline in January 2023 with planned IND submission in the fourth quarter of 2023. PIWIL1 is believed to play a role in tumor progression and is expressed across a range of tumors including colorectal, which is historically insensitive to immune checkpoints, as well as gastro-esophageal, and pancreatic cancer. PIWIL1 is also reported to be a negative prognostic marker. The Company believes IMC-R117C is the first PIWIL1 targeted immunotherapy.

As we have elected in February 2023 to withdraw from co-funding with Genentech the MAGE-A4 HLA-A02 program, IMC-C103C, Genentech shall acquire an exclusive worldwide license to the MAGE-A4 HLA-A02 soluble TCR bispecific therapeutic candidate compounds and shall be fully responsible for all further development and commercialization of such candidate compounds, at its expense. The licenses granted to Genentech do not include any rights to (i) affinity-enhanced TCRs or (ii) TCR therapeutic compounds, in each case (i) and (ii) that are directed to targets other than MAGE-A4.

Our ImmTAV Platform (Infectious Diseases)

Using our ImmTAV (**I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **V**irus) platform, we have advanced our first program into the clinic. Our ImmTAV product candidates are bispecific soluble TCR molecules featuring our ImmTAX TCR-based targeting system with high specificity for low-expression viral antigens, combined with the proprietary anti-CD3 effector module for T cell engagement and activation that has been evidenced by our clinical oncology pipeline. We are seeking to develop therapeutics that can provide a functional cure to chronic viral disease and are focusing initially on hepatitis B virus, or HBV, and human immunosuppression virus, or HIV.

Our ImmTAV programs include:

- **IMC-M113V**, our ImmTAV molecule targeting a human immunosuppression virus, or HIV, gag antigen bispecific TCR molecule, expected to be evaluated in a Phase 1 clinical trial for which we are currently enrolling patients. Our goal is to develop a functional cure for HIV. Initial Phase 1 safety and pharmacodynamic activity data from the single ascending dose portion of the study was presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in 2023. IMC-M113V was well tolerated at doses where the Company observed biomarkers of T cell engagement. The Company has started enrolling people living with HIV in the multiple ascending dose (MAD) part of the trial, to identify a safe and tolerable dosing schedule that could lead to reduction in the viral reservoir and control of HIV after stopping antiretroviral therapies (ART), or functional cure.

- **IMC-I109V**, our ImmTAV molecule targeting a conserved hepatitis B virus, or HBV, envelope antigen, is currently being evaluated in a Phase 1 clinical trial in patients with chronic HBV who are non-cirrhotic, hepatitis B e-Antigen negative, and virally suppressed on chronic nucleot(s)ide analogue therapy. Our goal is to develop a functional cure for HBV. We reported initial data from our trial in June 2022, observing a transient decrease in the HBV surface antigen, as well as transient elevations in alanine transaminase ("ALT") and cytokines. The Company is enrolling patients in the single ascending dose (SAD) portion of the study.

Our ImmTAAI Platform (Autoimmune Diseases)

While our ImmTAC and ImmTAV platforms attempt to provide therapeutic benefit by driving an immune response against targeted cells, our ImmTAAI (**I**mmune **m**odulating **m**onoclonal **T**CRs **A**gainst **A**utoImmune disease) platform leverages our ImmTAX platform to generate product candidates designed to provide precision targeted immunosuppression for the treatment of autoimmune diseases. Our ImmTAAI product candidates are designed to target organs, tissues or immune cells and deliver an immune suppressive effector function. We have optimized two immune system modulating effector functions to provide local T cell inhibition, which we believe may limit any adverse effects originating from systemic immune suppression. We believe we can use our ImmTAAI platform to develop a portfolio of product candidates to treat autoimmune indications with a high unmet medical need and provide significant benefit to patients.

Our 2023-2024 Strategic Priorities

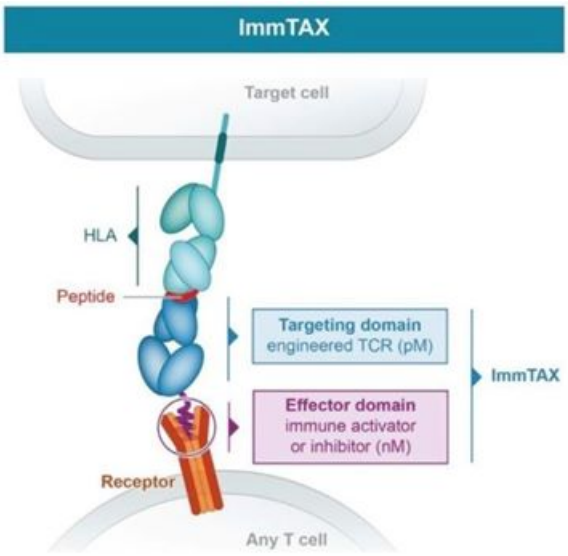
Our strategic priorities for 2023-2024 include to:

- Continue global expansion of KIMMTRAK in metastatic uveal melanoma;
- Expand global site footprint in order to accelerate trial enrollment for PRAME-A02 monotherapy and combination Phase 1/2, with data update planned by the first half of 2024;
- Submit IND for three newly announced ImmTAC Candidates: IMC-R117C (PIWIL1), IMC-P115C (PRAME-A02-HLE), and IMC-T119C (PRAME-A24); and
- Enroll patients in the MAD portion of the IMC-M113V HIV Phase 1 trial to identify safety and anti-viral activity.

Overview of ImmTAX Platform

Our therapeutic platform takes advantage of human TCRs through engineering of novel therapies known as Immune mobilizing monoclonal TCRs Against X disease, or ImmTAX. Our ImmTAX product candidates are bispecific therapies that are comprised of two key elements—a TCR targeting system and an effector function—that, when combined, are designed to give our platform significant flexibility to treat a range of diseases.

Specifically, our optimized ImmTAX bispecifics couple a high-affinity TCR targeting system with a range of effector functions tailored for the specific disease being addressed. TCRs are naturally found on the surface of T cells and are programmed to scan for abnormalities in the body through binding protein fragments presented by HLA on the surface of other cells. We have been able to build upon the activity of natural TCRs to develop high-affinity TCRs, which allow for a precise targeting by our therapeutics of unhealthy and abnormal cells. Our TCR targeting system can be customized to target almost any protein within the human proteome, thereby increasing the potential for an on-target immune response. We accomplish this by identifying proteins that are specific to a disease, and customizing the TCR domain of our ImmTAX molecules to target the HLA fragment presented by that specific protein. Below is a depiction of how our ImmTAX molecules combine a TCR targeting domain with a range of effector functions that can either activate or turn off the immune system (e.g., anti-CD3 or PD1 agonist).



The non-targeting component of our ImmTAX molecules is an effector antibody fragment designed to mimic the body's natural mechanisms for modulating the immune system, thereby allowing us to develop product candidates which are designed to generate a range of immune responses depending on the disease that is being treated. For example, for diseases such as cancer or infectious disease where an enhanced immune response is required, certain effectors can be applied to drive a potent immune response recruiting any T cell to attack the targeted cell. Alternatively, for certain autoimmune disorders where establishing control of an aberrant immune response is required, certain other effectors can be used to mimic the body's natural control mechanisms.

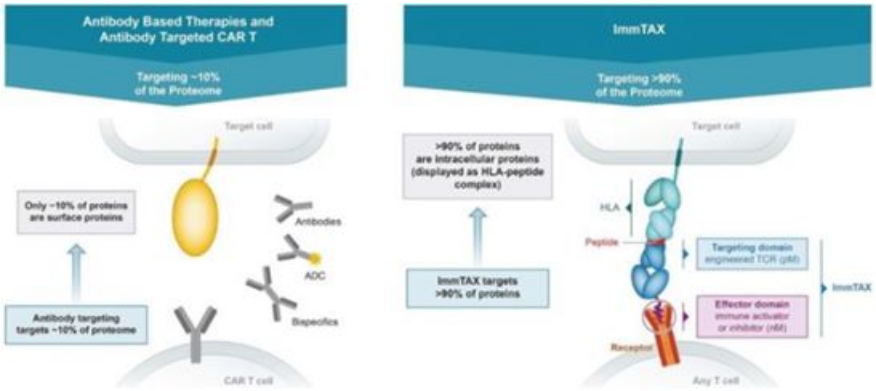
We believe the flexibility of our approach will allow us to develop therapeutics designed to treat a broad range of diseases. While we have focused our initial efforts on oncology, we are broadening our development efforts to infectious diseases and autoimmune conditions. We have named each of these platforms according to their therapeutic area to distinguish the type of target recognized by the TCR targeting system and the selected effector function:

- ImmTAC - **I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **C**ancer
- ImmTAV - **I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **V**iruses
- ImmTAAI - **I**mmune **m**odulating **m**onoclonal **T**CRs **A**gainst **A**uto**I**mmune disease

Advantages of our ImmTAX Platform

Our ImmTAX platform enables us to combine a high-affinity TCR targeting system with a range of immune-activating effector domains resulting in what we believe is a highly tailored and flexible approach to treat a broad range of diseases with a number of potential advantages, which are described below:

Ability to access significantly larger pool of cellular targets compared to currently approved therapies. Currently approved antibody-targeted therapies are limited to cell surface protein targets, a subset that makes up approximately 10% of the human proteome. Our ImmTAX platform has the potential to access a significantly larger pool of cellular targets when compared to antibody-targeted therapies, given their ability to target intracellular proteins, thereby expanding the total addressable therapeutic landscape. By using TCRs specific to HLA complexes, our ImmTAX platform allows for the selection of targets expressed by indications for which there are no currently effective antibody targets. Additionally, our platform benefits from the ability to select targets with very high levels of differential expression between healthy and diseased cells, thereby allowing clinical doses to be increased with manageable toxicity. The targeting advantage of our platform versus antibody-targeted therapies is shown below.



Ability to engineer ImmTAX with million-fold greater affinity and enhanced specificity allows for precise cellular targeting. Natural TCRs have binding half-lives measured in seconds and broad specificity profiles. Our processes are unique in our ability to consistently engineer TCRs with million-fold improvements in affinity over natural TCRs while simultaneously improving specificity. We believe this proprietary engineering technology will allow us to develop therapeutics that have antibody-like binding properties with high specificity and target binding half-lives measured in hours to days. These properties are designed to enable low doses of drug required and prolonged binding to cell targets. Additionally, the high specificity and affinity of ImmTAX give them the ability to bind to targets that are present with extremely low density across the cell surface.

Ability to address a broad range of disease types by leveraging a variety of precise effector domains to drive a specific immune response Affinity enhanced TCRs are coupled in a modular fashion to one of our pre-optimized immune-modulatory effectors to fine tune the characteristics of the therapy specific to the biology factors for a disease indication. By optimizing factors such as potency, therapeutic index and clearance characteristics, we aim to maximize potential clinical benefit. Using this modular approach, we are developing immune activating therapies for both cancer and infectious diseases which are designed to potently and specifically eliminate TCR targeted cells through redirection of non-exhausted polyclonal T cells. For autoimmune diseases, we employ an effector function that provides potent immunosuppression at the tissue or cellular level, with the goal of minimizing harmful systemic immunosuppression.

Sales and Marketing

We have launched KIMMTRAK in the United States, Germany, France and a number of other countries, and we are focused on driving increasing awareness and adoption of KIMMTRAK as a treatment for mUM amongst mUM patients and their healthcare providers. Our focus is to utilize our commercial capabilities to continue to meet patient demand in our major markets, and to launch in further markets in 2023. A breakdown of net product revenue from the sale of KIMMTRAK and net pre-product revenue from the sale of tebentafusp as part of a compassionate use and early access program is presented by region based on the location of the customer below.

	2022	2021	2020
	£ '000	£ '000	£ '000
United States	80,448	—	—
Europe	35,490	3,010	—
Rest of World	871	—	—
Total revenue from the sale of therapies	**116,809**	**3,010**	**—**

We utilize a hybrid model, partnering in-house personnel with other field-based personnel providers. Under our strategic partnership with Syneos Health, Inc., or Syneos. Syneos are responsible for sales, field market access, patient and provider education and customer support in a number of territories. We also utilize Medison Pharma Ltd ("Medison") under our multi-regional distribution agreement in other territories. In November, the Company and Medison amended and restated their exclusive distribution agreement for KIMMTRAK originally entered into in September 2021. Medison is the exclusive distribution partner for KIMMTRAK in Canada, Australia, New Zealand, Israel, Central and Eastern Europe, and South and Central America, and the Caribbean.

Reimbursement

Coverage in the United States, Europe and other territories

In the United States, it is essential to obtain third-party payor coverage policies, coding mechanisms, and adequate payment to expand market acceptance and adoption of KIMMTRAK as a treatment for mUM. During 2022, we approached the U.S. commercial third-party payor community in order to establish coverage for KIMMTRAK.

We have performed similar processes in Europe, where reimbursement arrangements were established for commercial supply in Germany, and continued in France (under our early access and commercial programs) in 2022, prior to further negotiation of pricing in these countries, which is expected to occur in 2023.

In order to maximize KIMMTRAK sales, we expect to continue to establish and further develop our reimbursement mechanisms and pricing negotiation processes for KIMMTRAK in other European countries and territories outside Europe in 2023 and beyond.

Manufacturing and Drug Supply

Our Chemistry, Manufacturing and Controls, or CMC, group conducts studies in molecular bioengineering, process development, analytical assay development, product characterization, formulation development and stability studies in support of Good Manufacturing Practice, or cGMP, -compliant manufacturing.

We do not currently own or operate cGMP-compliant manufacturing facilities for the production of clinical or commercial ImmTAX product candidates; however, we extensively outsource to microbial contract manufacturing organizations, or CMOs, for both drug substance and drug product production and have a successful cGMP-compliant manufacturing history of production of cGMP batches. We develop the upstream fermentation and downstream purification processes, as well as developing the analytical assays for quality control batch release testing and stability studies in-house and then transfer the technology and know-how to the CMOs to establish, scale-up, validation and manufacturing. This outsourced approach to manufacturing requires the CMOs to establish master and working cell banks, ImmTAX reference standards and produce the cGMP-compliant drug substance, and/or cGMP-compliant drug product. We conduct quality and technical audits of the CMOs to monitor the manufacturing operations and ensure compliance with the mutually agreed process operations and cGMP-regulations.

For KIMMTRAK, we currently contract with the following well-established third-party manufacturers:

- AGC Biologics A/S, headquartered in Copenhagen, Denmark; and
- Baxter Oncology GmbH, headquartered in Halle/Westfalen, Germany

Our manufacturers have recently manufactured triplicate Process Performance Qualification, or PPQ, batches, commercial large-scale manufacturing consistency batches of drug substance and drug product of KIMMTRAK, and we believe the quantities will be sufficient for commercial launch and initial commercial supply. AGC Biologics A/S and Baxter Oncology GmbH are positioned to provide longer term commercial manufacture of KIMMTRAK, with the storage, global distribution, packaging and labeling operations being provided by Deutsche Post DHL Group, or DHL and Integrated Commercialization Solutions, LLC, a division of AmerisourceBergen Corporation in the United States.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies and intense competition. We believe that our approach, strategy, TCR experience and ultimately, our ImmTAX platform provide us with competitive advantages. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or with their collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in 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.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of therapeutics to address unmet needs in cancer including: Adaptimmune Therapeutics plc, or Adaptimmune, Inc., Immatics Biotechnologies GmbH, or Immatics (alone and in collaboration with Bristol Myers Squibb), Adaptive Biotechnologies Corporation, or Adaptive, pure MHC, LLC, BioNTech SE, Genentech, Matterhorn, Anocca, Enara Bio and Regeneron, who are also seeking to identify peptide HLA targets and develop product candidates; Adaptimmune, T-Knife GmbH, Adaptive, 3T Biosciences, Inc., MediGene, Regeneron Pharmaceuticals, Inc., or Regeneron, bluebird Bio, Inc., or bluebird bio, Takara Bio Inc., Bristol-Myers Squibb Company, GSK, Kite Pharma, Lion TCR, TCR Cure, Corregene Biotechnology Co. LTD, and TScan who are developing TCR-based cell therapies; Immatics, Regeneron, F. Hoffmann-La Roche Ltd, Amgen, Inc., Genmab, Inc., Molecular Partners, 3T Biosciences, Inc., and CDR-Life Inc., are developing CD3-based TCR bispecific compounds or TCR mimetic antibodies.

We are aware of various companies and academic institutions that are developing TCR transduced cell therapies against a range of pHLA targets, some of which may overlap with product candidates in our pipeline such as PRAME. Specifically in regards to PRAME, we are aware that Immatics and Medigene are both conducting Phase 1 clinical trials of PRAME-directed cellular therapies and Immatics also have communicated plans for Phase 1 development of a PRAME TCRxCD3 bispecific approach.

Oncology

Any ImmTAC product candidates that we successfully develop and commercialize for oncology indications may compete with existing products and new products that may become available in the future. There is intense competition in the field of oncology from multiple different treatment modalities and new approaches are continually emerging.

While KIMMTRAK recently received regulatory approval from the FDA and marketing authorization from the EMA, Delcath Systems, Inc. is conducting a single-arm pivotal trial in metastatic uveal melanoma to evaluate a procedure that delivers a high dose of melphalan to the liver via percutaneous hepatic perfusion. This system is currently marketed in Europe as a CE Marked device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). We are aware of several other companies with product candidates in clinical development for the treatment of metastatic uveal melanoma, none of which have yet progressed to pivotal trial testing.

HIV

There are now over 30 antiretroviral medications in six drug classes approved for the treatment of HIV. Antiretroviral therapy (ART) consists of treatment with a combination of two or three agents targeting different stages of the virus life cycle. If started early, ART provides a normal lifespan, prevents immunodeficiency and stops the spread of HIV. However, treatment does not provide a cure and must be taken continuously for life to prevent relapse. Furthermore, there is no effective vaccine to prevent HIV.

Chronic HBV

There are numerous antiviral therapies approved by the FDA for the treatment of chronic HBV infections. These treatments consist of life-long antiviral therapy to suppress virus replication. This can slow the progression of liver cirrhosis and reduce the incidence of liver cancer, but most patients do not achieve functional cure. There are also FDA-approved vaccinations that provide effective prophylaxis against HBV, although they do not reverse or cure the disease in people who have already contracted the virus.

Intellectual Property

We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including by seeking, maintaining, enforcing and defending patent rights for our therapeutics and platform, whether developed internally or licensed from third parties. Our success will depend on our ability to obtain and maintain patent and other protection including data/market exclusivity for our soluble TCR bispecific therapeutic product, product candidates and platform technology, preserve the confidentiality of our know-how and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties. For more information, please see “Item 3.D Risk Factors—Risks Related to Intellectual Property.”

We seek to protect our proprietary position by filing patent applications in territories that are commercially important for our soluble TCR bispecific therapeutic product, product candidates and technology platform technologies, generally including but not limited to the United States, Europe, Australia, Brazil, Canada, China, India, Israel, Japan, Mexico, New Zealand, South Africa and South Korea. We also rely on data exclusivity, market exclusivity and patent term extensions where available, including any relevant exclusivity through supplementary protection certificates and orphan or pediatric drug designation.

As of December 31, 2022, our global portfolio comprises approximately 600 patents and pending applications, including 25 issued US patents and more than 300 ex-US patents. The majority of our patents and patent applications are solely owned. The portfolio encompasses solely owned patents and patent applications directed to our commercial TCR product (KIMMTRAK) and further product candidates (including IMC-F106C, IMC-M113V and IMC-I109V), our platform technology used to identify and generate our therapeutic candidates, novel targets, formulations and methods of treatment. A minor proportion of the portfolio, comprising certain older platform IP, is jointly owned in equal share with Adaptimmune. We control the prosecution of the jointly owned patents and patent applications, and we have rights under the joint patents as required to develop and commercialize our therapeutics. For more information on our assignment and exclusive license agreement with Adaptimmune, see "Item 4.B Business overview—Our Collaborations and License Agreements—Assignment and Exclusive License Agreement with Adaptimmune Limited."

We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage.

We have not in-licensed any issued patents relating to our product or product candidates.

KIMMTRAK (Tebentafusp)

As of December 31, 2022, we own granted patents and patent applications covering the composition of matter of our commercial product KIMMTRAK (tebentafusp). The patents include claims that cover the specific sequence of KIMMTRAK, as well as claims that cover TCR variants with similar biological properties. Granted patents have been obtained in major territories including two in the United States and 28 in foreign jurisdictions, including Europe (including United Kingdom, France, Germany, Italy, Spain, Ireland, Denmark and the Netherlands), Australia, Canada, China, Hong Kong, Japan, Mexico, Eurasia and South Africa. These granted patents are expected to expire in 2030. Applications for patent term extension and/or supplementary protection certificates have been filed in several jurisdictions including the United States, which, if granted, could extend protection by up to 5 years to 2035. Further patent families have been filed including to cover the label dosing regimen, formulation, and methods of treatment. If granted these applications would extend protection up to 2042.

ImmTAX pipeline

As of December 31, 2022, we solely own patent families covering the composition of matter of each of our oncology and infectious disease pipeline candidates, including issued US patents covering the composition of matter of our PRAME (IMC-F106C) candidates. In each case, claims of the patent or patent application are directed to the engineered soluble TCR bispecific therapeutic candidate and to TCR variants with similar biological properties. The issued US patents for IMC-F106C are expected to expire in 2038, excluding any additional term for patent term adjustments or patent term extensions. Further patent applications have been filed relating to dosing regimens for IMC-F106C.

Our ImmTAX platform

As of December 31, 2022, we solely own a number of patents and patent applications related to our ImmTAX platform. The oldest patent families relating to our ImmTAX TCR bispecific format will expire starting in 2030. We have filed further platform patent families relating to TCR bispecifics with improved therapeutic properties, including formats with extended in vivo half-life and improved anti-CD3 effector functions, as well as therapeutic formats for the treatment of autoimmune indications. Such pending patent applications, if granted, are expected to expire between 2039 and 2040, excluding any additional term for patent term adjustments or patent term extensions.

We jointly own in 50% equal share with Adaptimmune platform patent families relating to methods and tools for selecting TCRs in the early pipeline. The latest of these will expire in 2036.

HLA target peptide patent applications

As of December 31, 2022, we own a number of patent families relating to novel HLA-restricted peptide targets and their use. Such patents and pending patent applications, if granted, are expected to expire between 2036 and 2037, excluding any additional term for patent term adjustments or patent term extensions.

Patent term

Typically, we file our priority applications at the U.K. Intellectual Property Office, or UKIPO, and/or at the U.S. Patent and TrademarkOffice, or USPTO. This is followed 12 months later by the filing of a patent application under the PCT claiming priority from the initial application(s), and/or national applications. Further data can be added to the application during the priority year and the resulting patent term is calculated from the PCT filing date. This strategy allows us to obtain an early priority date while additional experimental data are generated. At the end of the PCT period, generally two and a half years from the priority date, separate patent applications can be pursued in any of the 157 PCT member states. Our PCT patent applications are not eligible to become issued patents until, among other things, we file national stage patent applications within such PCT period in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose any patent protection on the inventions disclosed in such patent applications. For all patent applications, we determine claiming strategy and territory coverage on a case-by-case basis. Advice of counsel and alignment with overarching business objectives is always considered. We regularly reassess the value of the patents and patent applications in our portfolio.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed patent applications, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. For more information on patent term extension, see "Item 4.B Business overview—Government Regulation—Patent Term Restoration and Extension." As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our owned pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated, narrowed, held unenforceable, infringed or circumvented. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. See "Item 3.D Risk Factors—Risks Related to Intellectual Property."

Trade secrets

In addition to patent protections, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements and invention assignment agreements with our collaborators and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties. Furthermore, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors and other third parties. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, please see "Item 3.D Risk Factors — Risks Related to Intellectual Property."

Third-party rights

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our product candidates or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our current or future product candidates may have an adverse impact on us. For more information, please see "Item 3.D Risk Factors—Risks Related to Intellectual Property."

Trademarks

As of December 31, 2022, our trademark portfolio contains registrations or registration applications for our commercial product KIMMTRAK as well as for IMMUNOCORE, IMMTAX, IMMTAC, IMMTAV and IMMTAAI in the United States and in certain foreign jurisdictions.

Our Collaborations and License Agreements

Genentech Collaboration

In June 2013, we entered into a research collaboration and license agreement, or the 2013 Genentech Agreement, with Genentech, Inc., or Genentech, and F. Hoffmann-La Roche Ltd, or Roche, pursuant to which we along with Genentech and Roche agreed to collaborate in the development, manufacture and ultimately, commercialization of soluble TCR bispecific therapeutic candidate compounds. Under the 2013 Genentech Agreement, Genentech paid us an initial upfront payment of $20 million in exchange for exclusive licenses to two of our targets, MAGE-A4 as well as an undisclosed target.

In September 2016, following achievement of formal nomination of the pre-clinical candidate compound, we and Genentech amended the 2013 Genentech Agreement. The 2016 Genentech Amendment provided that we regained control of the initial two programs, and Genentech granted us an exclusive worldwide license to use its background intellectual property rights to advance such programs. We had sole responsibility for the development, manufacture and commercialization of the soluble TCR bispecific therapeutic compounds of the targets at our own expense, and were required to use diligent efforts to achieve commercialization of at least one therapeutic compound for each of the programs. In exchange for the rights granted to us, Genentech would be able to earn future development and commercial milestones of up to approximately $167 million and tiered royalty payments between a mid-single-digit and low-teens percentage on net sales of such compounds. Genentech also obtained a right of first negotiation in respect of the programs, should we seek to license the rights to develop and/or commercialize either program to a third party.

In November 2018, Genentech exercised its right of first negotiation with respect to our IMC-C103C program. We received an aggregate of $100 million from Genentech, consisting of an initial upfront payment of $50 million and $50 million paid upon an IND filing for the first clinical trial of the product candidate compound, in exchange for granting Genentech rights to co-develop/co-promote our IMC-C103C program.

In November 2018, in response to Genentech's exercise of its right of first negotiation in regards to our IMC-C103C program, we entered into a new license and collaboration agreement, or the 2018 Genentech Agreement, pursuant to which we and Genentech agreed to collaborate in the development and commercialization of certain compounds targeting MAGE-A4, specifically pHLA-A2. Under the 2018 Genentech Agreement, we granted Genentech a co-exclusive worldwide license to our intellectual property rights in MAGE-A4 soluble TCR bispecific therapeutic candidate compounds to advance the development and commercialization of such compounds as contemplated under the 2018 Genentech Agreement. We were responsible for development of the IMC-C103C program through the completion of the Phase 1 clinical trial, with costs being shared equally between us and Genentech, and we were required to use diligent efforts with respect to our development and commercialization obligations.

In February 2023, Genentech accepted our proposal to cease co-funding the development of MAGE-A4 HLA-A02 targeted programs, except for our equal share of the wind-down costs of the IMC-C103C Phase 1 clinical trial. The clinical trial with IMC-C103C is nearing completion and we do not plan to enroll additional patients. We are eligible to receive development and commercial milestone payments plus royalties from Genentech on any sales of MAGE-A4 HLA-A02 targeted products arising under the Genentech agreement. Royalties are payable while there is a jointly owned or solely owned valid patent claim covering the soluble TCR bispecific therapeutic product in the country in which the relevant TCR therapeutic product is being sold, which, if applicable patent applications are granted, is expected to be at least 2037 for IMC-C103C, and, in each case, for a minimum of 10 years from the first commercial sale of the relevant soluble TCR bispecific therapeutic product. As we have elected in February 2023 to withdraw from co-funding with Genentech the MAGE-A4 HLA-A02 program, IMC-C103C, Genentech shall acquire an exclusive worldwide license to the MAGE-A4 HLA-A02 soluble TCR bispecific therapeutic candidate compounds and shall be fully responsible for all further development and commercialization of such candidate compounds, at its expense. The licenses granted to Genentech do not include any rights to (i) affinity-enhanced TCRs or (ii) TCR therapeutic compounds, in each case (i) and (ii) that are directed to targets other than MAGE-A4.

Under the 2018 Genentech Agreement, Genentech also obtained a right of first negotiation in respect of other TCR therapeutic candidate compounds that target MAGE-A4 by binding to an antigen other than HLA-A02, should we discover any such therapeutic candidate compounds and seek to license the rights to a third party during the term of the 2018 Genentech Agreement.

The 2018 Genentech Agreement is effective until all payment obligations expire. Both parties have rights to terminate the 2018 Genentech Agreement for uncured material breach upon 90 days' written notice or immediately upon insolvency of the other party. Genentech has additional rights to terminate the 2018 Genentech Agreement for convenience on provision of 90 days' notice to us. We also have rights to terminate any license where Genentech ceases development or withdraws from the market any licensed compound in specified circumstances. Following termination of the 2018 Genentech Agreement by either party, a formal negotiation process exists under which we can agree to commercially reasonable terms with Genentech for us to continue development and commercialization of the terminated assets.

GSK Collaboration

In 2022, our collaboration and license agreement, or the GSK Agreement, with GlaxoSmithKline Intellectual Property Development Ltd, or GSK, was terminated, and no further revenue is expected from GSK. GSK has no further rights to targets under the GSK Agreement.

We originally entered into the GSK Agreement pursuant to which we and GSK agreed to collaborate in the development of soluble TCR bispecific therapeutic compounds, for up to four targets, in June 2013, and we received payments totalling £22.9 million in upfront payments and early development milestones under the agreement.

Lilly Collaboration

In 2022, our development and license agreement, referred to, as subsequently amended, as the Lilly Collaboration, with Eli Lilly and Company, or Lilly, was terminated and no further revenue is expected from Lilly. Lilly has no further rights to targets under the Lilly Collaboration.

We originally entered into the Lilly Collaboration in July 2014, pursuant to which we and Lilly agreed to collaborate in the development, manufacture and commercialization of soluble TCR bispecific therapeutic compounds for up to three targets. We received an upfront fee payment of $45 million.

Gates Collaboration

In September 2017, we entered into a $40 million convertible loan agreement and a global access agreement with the Gates Foundation, pursuant to which we agreed to develop, manufacture and commercialize soluble TCR bispecific therapeutic candidates targeted to neglected diseases, primarily tuberculosis and HIV, with the potential to treat people at an affordable price in developing countries. In March 2020, we and the Gates Foundation amended and restated the global access agreement, or the Gates Agreement, pursuant to which we are required to take certain actions to support the mission of the Gates Foundation. The Gates Agreement was further amended in February 2021. The initial tranche of $25 million was directed to the development of product candidates for the treatment of tuberculosis or HIV, and converted into equity as part of our series B preferred share financing. In connection with our entry into a subscription agreement with the Gates Foundation, we terminated the outstanding convertible loan note purchase agreement with the Gates Foundation by deed of termination, as the Gates Foundation instead subscribed for the remaining amount of the loan ($15 million) as part of a concurrent private placement in connection with our initial public offering.

Pursuant to the terms of the Gates Agreement, the Gates Foundation has the ability to request additional product development work for the development of product candidates for the treatment of malaria and human papillomavirus, with the terms of any such work to be negotiated in good faith between us and the Gates Foundation.

We are required to use diligent efforts to complete agreed upon research plans for tuberculosis and HIV. While we delivered a potential product candidate for the treatment of tuberculosis, under a program within the Gates Agreement, leveraging our universal HLA-E capabilities, the governing committee selected instead a potential HIV product candidate for GMP manufacture and for evaluation in a Phase 1 clinical trial. If requested by the Gates Foundation, we will be required to continue further development of the HIV program through commercialization of a final product with the terms of any such work to be negotiated in good faith between us and the Gates Foundation.

In the event of certain defaults by us under the Gates Agreement, the Gates Foundation has a right to sell (or require a buy-back by us of) any of the equity securities held by the Gates Foundation. In such an event, if within 12 months after such redemption or sale, we experience a change in control or an initial public offering at a valuation of more than 150% of the valuation used for the redemption or the sale of the shares, we have agreed to pay the Gates Foundation compensation equal to the excess of what it would have received in such transaction if it still held its shares at the time of such initial public offering or a change of control over what it received in the sale or redemption of its shares.

Under the terms of the Gates Agreement, we have full control over the development, commercialization and pricing of the Gates Foundation funded programs in developed countries. Within a defined list of developing countries, we have an obligation to abide by the Gates Foundation global access principles, which includes pricing restrictions and a requirement that we use diligent efforts to make funded products available in such countries. We also grant the Gates Foundation certain non-exclusive, perpetual, royalty-free licenses under our intellectual property and products developed using funds from the Gates Foundation for the benefit of people in identified developing countries. These licenses would only be exercised in certain defined default events, including where we are unwilling or unable to continue with the development of a program or where we are in breach of certain obligations under the Gates Agreement (including the global access commitments). Under the terms of the Gates Agreement, the Gates Foundation can request that we work on further neglected diseases (excluding hepatitis, oncology or autoimmune diseases) provided acceptable terms can be reached. We also have an obligation to make available certain research tools on a royalty-free basis to certain entities supported by the Gates Foundation and other third parties and certain obligations relating to publishing of scientific results of our work.

Gadeta Collaboration

In December 2022, we entered into a Collaboration, Option and License Agreement (the "Gadeta Collaboration") with Gadeta B.V. ("Gadeta"). Under the agreement, we and Gadeta will collaborate on '201 γδ-TCR target discovery, and we will have the option to develop ImmTAC therapies derived from the '201 TCR as part of the research collaboration. We have an option for an exclusive license to further research, develop and commercialize an ImmTAC candidate from the collaboration. If we exercised this option, Gadeta could be eligible to receive further payments.

Assignment and Exclusive License Agreement with Adaptimmune Limited

In May 2013, we entered into an assignment and exclusive license agreement with Adaptimmune Limited, or Adaptimmune, which relates to the joint ownership and licensing of certain patents, patent applications, rights in know-how and other intellectual property rights, or the Adaptimmune License. Pursuant to the Adaptimmune License, we and Adaptimmune jointly own certain identified patents, patent applications, rights in know-how and other intellectual property rights in equal shares. We each grant the other party an exclusive, royalty-free, irrevocable license, with the right to sub-license, under those jointly owned intellectual property rights in separate fields. Adaptimmune's exclusive field relates to treatment of patients with engineered TCR therapeutic candidates and our exclusive field relates to the treatment of patients with soluble TCRs. There is no royalty payable under the Adaptimmune License but we share equally in the costs associated with the filing, maintenance and prosecution of the jointly owned patents and patent applications covered by the Adaptimmune License.

The Adaptimmune License is effective until the later of the expiration of the last to expire jointly owned patent under the Adaptimmune License or the jointly owned know-how ceasing to be confidential. The Adaptimmune License cannot be terminated by either party. Upon the insolvency of either party, the other party has the right to take over patent prosecution of the licensed patents and to request assignment of the insolvent party's interest in all the licensed patents, know-how and results on commercially reasonable terms.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Data Privacy and Security Laws

We also are or may become subject to privacy laws in the jurisdictions in which we operate, have partners, or sell or market our products or run clinical trials. For example, we are or may become subject to privacy and data protection laws, such as the EU's General Data Protection Regulation ("EU GDPR"), the United Kingdom's equivalent law ("UK GDPR"), and the Health Insurance Portability and Accountability Act as amended, or, HIPAA, in the United States, among many others. Our regulatory obligations in foreign jurisdictions could harm the use or cost of our solution in international locations as data protection and privacy laws and regulations around the world continue to evolve.

Certain aspects of our business, including those for which we rely upon collaborators, service providers, contractors or others, are or may become subject to HIPAA and its implementing regulations, which establish standards for covered entities (certain healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information, including, among other requirements, mandatory contractual terms and technical safeguards designed to protect the privacy, security and transmission of protected health information and notification to affected individuals and regulatory authorities in the event of certain breaches of security of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the HITECH makes HIPAA's privacy and security standards directly applicable to business associates, or independent contractors or agents of covered entities, that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions.

Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce and be construed as a violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

As a company established in the United Kingdom, our processing of personal data is subject to the United Kingdom's implementation of the European Union's General Data Protection Regulation ("UK GDPR"); it is also, or may also become, in certain circumstances subject to the European Union's own General Data Protection Regulation ("EU GDPR"). Each of these regulations requires stringent standards of data privacy and security concerning personal data and potentially significant sanctions.

The United Kingdom and EU Member States each may introduce further restrictions on personal data processing, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase. In particular, the UK GDPR and EU GDPR significantly restrict the transfer of personal data to the United States and other countries whose privacy laws are considered 'inadequate' for the purposes of either or both of those regulations, as they may apply. If there is no lawful manner for us to effect cross-border transfers of personal data in compliance with the UK GDPR and/or EU GDPR, as applicable, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate certain parts of our operations, increased exposure to regulatory actions, substantial fines and penalties, the inability to work with certain collaborators, partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business.

Sanctions for breaches of the UK GDPR and/or EU GDPR are significant:companies may face temporary or definitive bans on processing of personal data and other corrective actions; fines of up to 17.5 million pounds sterling under the UK GDPR / 20 million Euros under the EU GDPR, or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the United States, state laws may be more stringent, broader in scope and offer greater individual rights with respect to health information than HIPAA, and state laws may differ from each other, which may complicate compliance efforts. By way of example, the California Consumer Privacy Act, or CCPA, creates individual privacy rights for California residents and places increased privacy and security obligations on entities that are subject to the law and which handle certain personal data of such residents. The CCPA requires covered companies to provide new disclosures to California residents about such covered businesses' data collection, use and sharing practices and provide such residents new ways to opt out of certain disclosures of personal information and provides such residents with additional causes of action. The CCPA became effective on January 1, 2020, and (a) allows enforcement by the California Attorney General, with fines set at $2,500 per non-intentional violation or $7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. Additionally, a new privacy law, the California Privacy Rights Act, or CPRA, was recently approved by California voters in November 2020. The CPRA significantly modifies the CCPA, resulting in further uncertainty and requiring us to incur additional costs and expenses to comply.

Patent Term Restoration and Extension

Depending upon the timing, duration and specifics of FDA approval of product candidates, some of a sponsor's 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 14 years from the product's approval date. The patent term restoration period generally is one-half the time between the effective date of an IND and the submission date of a BLA less any time the sponsor did not act with due diligence during the period, plus the time between the submission date of a BLA and the approval of that application less any time the sponsor did not act with due diligence during the period. Only one patent applicable to an approved biologic product is eligible for the extension, only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. Moreover, a given patent may only be extended once based on a single product. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see "Item 3.D — Risk Factors—Risks Related to Intellectual Property."

Licensure and Regulation of Biologics in the United States

In the United States, biological products are subject to regulation under the Federal Food, Drug and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Product candidates must be approved by the FDA before they may be legally marketed in the United States.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- nonclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a BLA for a biological product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;
- one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA approval of the BLA and licensure of the new biological product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies required by the FDA.

Nonclinical Studies and Investigational New Drug Application

Before testing any biological product candidate in humans, the product candidate must undergo nonclinical testing. Nonclinical tests include laboratory evaluations of product formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The results of the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical study or cause suspension of an ongoing study, or in the case of a partial clinical hold place limitations on the conduct of the study such as duration of treatment, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed and then only under terms authorized by the FDA. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner. The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study. Information about certain clinical studies must be submitted within specific timeframes to the National Institutes of Health for public dissemination.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials.

Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

Compliance with cGMP Requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics 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.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a BLA

The results of product candidate development, nonclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting a license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the BLA is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of an application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA or withdraw the application or request a hearing. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides 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.

If the FDA approves a new product, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of 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 ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A biological product may also be subject to official lot release, meaning that 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 lot release, the manufacturer must submit samples of each lot, 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, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. FDA also has authority to require post-market studies, in certain circumstances, on reduced effectiveness of a product and may require labeling changes related to new reduced effectiveness information. Other potential consequences for a failure to maintain regulatory compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications 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, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan Drug Designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan Drug Designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives Orphan Drug Designation from the Office of Orphan Products Development, or OOPD, at the FDA based on an acceptable confidential request made under the regulatory provisions. The product must then go through the review and approval process like any other product in order to be marketed.

A sponsor may request Orphan Drug Designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain Orphan Drug Designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive Orphan Drug Designation for the same product for the same rare disease or condition, but each sponsor seeking Orphan Drug Designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, as amended, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Generally, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act, or BPCIA, established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, while biosimilar products have been approved by the FDA for use in the United States, no interchangeable biosimilars have been approved.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that 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.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. However, to rely on such exclusivities for establishing or protecting a manufacturer's market position is not without risk, as such laws are subject to changes by the legislature. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in European Union Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The CTA, must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which came into application on January 31, 2022, replacing the Clinical Trials Directive 2001/20/EC, with a three-year transition period for trials authorised under the Directive and relevant legislation implementing the Directive into the national law of member states. The Clinical Trials Regulation provides that, a clinical trial application, or CTA, must be submitted to via the European Medicine Agency's, or EMA's, Clinical Trials Information System, which will cover all regulatory and ethics assessments from the member states concerned. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. Approval and monitoring of clinical trials in the European Union is the responsibility of individual member states, but compared to the position prior to the applicability of the Clinical Trials Regulation there is likely to be more collaboration, information-sharing, and decision-making between member states.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug has to be of significant benefit compared to products available for the condition.

An Orphan Drug Designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." 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. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for Orphan Drug Designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either to EMA using the centralized procedure or to competent authorities in European Union Member States using the other procedures (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No. 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which the centralized procedure is in the interest of public health, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation 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 viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

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 compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Regulation in the United Kingdom

Brexit may influence the attractiveness of the United Kingdom as a place to conduct clinical trials. Clinical trials that take place in the United Kingdom are seen as trials that have taken place in a "third country" and will only be considered during the course of a marketing authorization application if they are carried out on a basis that is in line with the regulations governing clinical trials in the EU. Clinical trials in the EU must be conducted in accordance with the requirements of the EU Clinical Trials Regulation (although some ongoing trials are still governed by the requirements of the EU Clinical Trials Directive, as implemented in national law by individual member states), and applicable good clinical practice standards. Clinical trials in the United Kingdom must be conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, which implement the provisions of the EU Clinical Trials Directive into United Kingdom law. There has, therefore, been divergence between the rules governing clinical trials in the EU and those that govern trials that take place in the United Kingdom law.

In the short term, there will be few changes to clinical trials that only have sites in the United Kingdom. The MHRA have confirmed that the sponsor of a clinical trial can be based in the EEA for an initial period following Brexit. Further investigational medicinal products can be supplied directly from the EU/EEA to either a trial site or a distribution hub in Great Britain. Such products will require oversight by the holder of a UK Manufacturing and Import Authorisation but do currently require recertification.

As the United Kingdom is now a "third country" for the purpose of clinical trials that have sites in the EEA, the sponsor/legal representative for such trials can no longer be based in the United Kingdom.

Other Healthcare Laws and Regulations

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and use of pharmaceutical products that are granted marketing approval. Arrangements with third-party payors, existing or potential customers and referral sources, including healthcare providers, are subject to broadly applicable fraud and abuse, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers conduct research, market, sell and distribute the products for which they obtain marketing approval. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers, formulary managers and other individuals and entities on the other. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to commit a violation;

- the federal civil and criminal false claims, including the civil False Claims Act, or the FCA, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. Certain marketing practices, including off-label promotion, also may implicate the FCA. In addition, the ACA codified case law 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 FCA.

- HIPAA imposes criminal and civil liability, among other things, for executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the transmission, security and privacy of individually identifiable health information on covered entities, such as health plans, health care clearinghouses and certain healthcare providers, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing and/or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, and may not have the same effect, thus complicating compliance efforts.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including administrative, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a person becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of KIMMTRAK or any other products for which we may obtain regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. New metrics frequently are used as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. In order to obtain coverage and reimbursement for any product that might be approved for sale, it may be necessary to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the products, in addition to the costs required to obtain regulatory approvals. 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. Additionally, any companion diagnostic test that we develop will be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. If any companion diagnostic is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Health Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the ACA was signed into law, which, among other things, was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the healthcare industry and impose additional health policy reforms.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach its target goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There also has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, for example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the IRA, among other things: (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. Additionally, the 2021 Infrastructure Investment and Jobs Act requires certain manufacturers to refund the government for discarded amounts of certain drugs from single use containers under Medicare Part B. At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these initiatives, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. It is also possible that additional governmental action is taken to address the COVID-19 pandemic. Further, any reduction in reimbursement from Medicare or other government-funded 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 product candidates.

Further, additional healthcare reform initiatives may arise from future legislation or administrative action, particularly as a result of the most recent U.S. presidential election.

Additional Regulation

In addition to the foregoing, provincial, state and federal U.S. and European Union laws regarding environmental protection and hazardous substances 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.

Anti-Corruption Laws

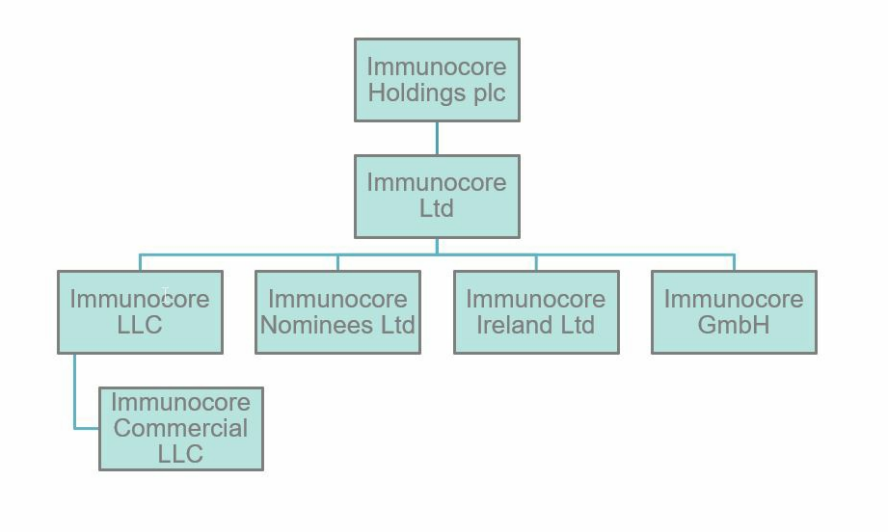
We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the UK Bribery Act 2010 and the UK Proceeds of Crime Act 2002 and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities, collectively, Anti-Corruption Laws. Among other matters, such Anti-Corruption Laws prohibit corporations and individuals from directly or indirectly paying, offering to pay or authorizing the payment of money or anything of value to any foreign government official, government staff member, political party or political candidate, or certain other persons, in order to obtain, retain or direct business, regulatory approvals or some other advantage in an improper manner. We can also be held liable for the acts of our third-party agents under the FCPA, the UK Bribery Act 2010 and possibly other Anti-Corruption Laws. In the healthcare sector, anti-corruption risk can also arise in the context of improper interactions with doctors, key opinion leaders and other healthcare professionals who work for state-affiliated hospitals, research institutions or other organizations.

Government Regulation Outside of the United States and the European Union

In addition to regulations in the United States and European Union, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of their products. Whether or not we obtain FDA or EU approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the United States and the European Union have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. The requirements and process governing the conduct of clinical studies, product licensing, coverage, pricing and reimbursement vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

C. Organizational structure.

The following diagram illustrates our corporate structure with 100% ownership parent-subsidiary relationships:



The country of incorporation for the Group's companies is as follows:

Company	Country of incorporation
Immunocore Holdings Plc	United Kingdom
Immunocore Limited	United Kingdom
Immunocore LLC	United States
Immunocore Commercial LLC	United States
Immunocore Ireland Limited	Ireland
Immunocore GmbH	Switzerland
Immunocore Nominees Limited	United Kingdom

D. Property, plant and equipment.

Our corporate headquarters are located in Oxfordshire, United Kingdom, where we currently lease facilities containing our research and development, laboratory and office space, which consists of approximately 114,000 square feet. Our leases expire between 2037 and 2042, although there are points at which we may terminate the leases prior to the termination date under certain conditions. In addition, we lease approximately 15,000 and 5,000 square feet of office space serving as our U.S. headquarters, in Conshocken, Pennsylvania, and Rockville, Maryland, respectively.

We also lease approximately 240 square feet of office space in Ireland and approximately120 square feet in Switzerland.

We anticipate leasing additional office and manufacturing space as we add employees and continue to grow as a commercial-stage organization. We believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 4A. Unresolved Staff Comments.

Not applicable.

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 the related notes thereto appearing elsewhere in this Annual Report. The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis, as well as the section titled "Special Note Regarding Forward-Looking Statements."

We maintain our books and records in pounds sterling. For the convenience of the reader, we have translated pound sterling amounts as of and for the period ended December 31, 2022 into U.S. dollars on December 31, 2022, which was £1.00 to $1.207. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

We have historically conducted our business through Immunocore Limited, and therefore our historical consolidated financial statements presented the consolidated results of operations of Immunocore Limited. Following the completion of our initial public offering in February 2021, our consolidated financial statements present the consolidated results of operations of Immunocore Holdings plc.

Discussion related to our financial condition, changes in financial condition, and results of operations for 2020 and a comparison of results of operations for 2021 compared to 2020, can be found in Part I, Item 5 'Operating and Financial Review and Prospects', in our Annual Report on Form 20-F for the financial year ended December 31, 2021, which was filed with the SEC on March 3, 2022, and are incorporated by reference herein.

A. Operating Results

Overview

We are a commercial stage biotechnology company pioneering the development of a novel class of TCR bispecific immunotherapies called ImmTAX – Immune mobilizing monoclonal TCRs Against X disease – designed to treat a broad range of diseases, including cancer, infectious and autoimmune diseases. Leveraging our proprietary, flexible, off-the-shelf ImmTAX platform, we are developing a deep pipeline in multiple therapeutic areas, including four clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune disease and multiple earlier pre-clinical programs.

In January and April 2022, we received approval from the U.S. Food and Drug Administration, or FDA, and European Commission, or EC, respectively, for our lead product candidate, KIMMTRAK, for the treatment of unresectable or metastatic uveal melanoma, or mUM. In June 2022, we received approval from the UK's Medicines and Healthcare products Regulatory Agency, or MHRA, the Australian Therapeutic Goods Administration, or TGA, and Health Canada. KIMMTRAK is now approved in over 30 countries and we have commercially launched in the United States, Germany and France, among other territories, with further commercial launches underway in additional territories where we have received approval.

KIMMTRAK is the lead product from our ImmTAX platform and is the first approved new therapy in uveal melanoma in four decades. To date, we have dosed over 1,000 cancer patients with KIMMTRAK, tebentafusp, and our other ImmTAX product candidates, which we believe is the largest clinical data set of any bispecific in a solid tumor and any TCR therapeutic. Our other clinical programs are being conducted with patients with a broad range of cancers including lung, bladder, gastric, and ovarian, among others. We believe that these other ImmTAX product candidates have the potential to address other tumor types with larger addressable patient populations and significant unmet need.

Since our inception, we have focused on organizing and staffing our company, raising capital and performing research and development activities to advance our research, development and technology, and commercializing KIMMTRAK. 2022 represents the first year during which we have generated revenue from a marketed product, and our ability to generate higher levels of product revenue from other marketed products, which may never be fully developed or commercialized, depends on the successful development and regulatory approval of one or more of our product candidates and our ability to finance operations. Since inception, we have raised an aggregate of $1,275 million through private placements of our ordinary and preferred shares, debt financing, payments from our collaboration partners, the sale of our Series C preferred shares, and the completion of our initial public offering where we listed our ADSs on the Nasdaq Global Select Market in February 2021. These funds have been and are being used to fund operations and invest in activities for technology creation, drug discovery and clinical development programs, infrastructure, creation of portfolio of intellectual property and administrative support. We have assembled a team of over 400 employees. We have also established relationships with pharmaceutical collaborators including Genentech, Inc., or Genentech, and Sanofi S.A, or Sanofi.

We have incurred significant operating losses and expect to continue to incur significant expenses and operating losses for the near future. These losses were £41.2 million, £131.5 million and £74.1 million, for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, our accumulated deficit was £261.3 million. We expect to continue to incur significant and increasing expenses and to incur operating losses for the foreseeable future, as we advance our product candidates through preclinical and clinical development and seek regulatory approvals, manufacture drug product and drug supply, maintain and expand our intellectual property portfolio, as well as hire additional personnel, pay for further accounting, audit, legal, regulatory and consulting services, and pay costs associated with maintaining compliance with Nasdaq listing rules and the requirements of the U.S. Securities and Exchange Commission, or SEC, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company.

While we have received regulatory approval for KIMMTRAK in the United States, the European Union and other territories, 2022 is the first year in which we have recorded sales of KIMMTRAK. Further, we do not expect to generate revenue from the sale of our other product candidates unless and until we successfully complete clinical development of and obtain regulatory approval for such product candidates. As a result, we will need substantial additional funding to support our continued operations and pursue our clinical development and growth strategy. Until we can generate sufficient revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, government funding arrangements, collaborations and marketing, distribution and licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements on favorable terms, or at all, particularly in light of recently worsening macroeconomic conditions, such as rising interest rates and volatility in the capital markets. If we fail to raise capital or enter into such arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Recent Developments

The Company has screened the first patient in a randomized Phase 2/3 trial in previously treated advanced melanoma. The trial will enroll patients with advanced melanoma, excluding uveal melanoma, who have progressed on an anti-PD1, received prior ipilimumab and, if applicable, received a tyrosine kinase inhibitor (TKI). Patients will be randomized to one of three arms including tebentafusp, as monotherapy or in combination with an anti-PD1, and a control arm. The Phase 2 portion of the trial will include 40 patients per arm and has a dual primary endpoint of OS and circulating tumor DNA (ctDNA) reduction.

In February 2023, the company presented initial safety and pharmacodynamic activity data with first soluble TCR therapy for people living with HIV at the Conference on Retroviruses and Opportunistic Infections (CROI). IMC-M113V is an immunotherapeutic approach designed to specifically eliminate CD4+ cells that are persistently infected with HIV (‘reservoirs’). All (1.6 mcg, 5 mcg, and 15 mcg) doses of IMC-M113V were well tolerated and were not associated with cytokine release syndrome or neurotoxicity of any grade. There were no serious adverse events, nor significant changes in hematology or chemistry. Plasma viral load remained suppressed throughout dosing and follow-up. In addition, transient, dose-dependent increases in serum IL6 occurred 8-24 hours post-infusion. Five out of the ten participants who received the 15-mcg dose showed a >4-fold rise in IL6, which had been prespecified as indicative of pharmacodynamic activity based on prior experience from clinical trials with KIMMTRAK. The Company has started enrolling people living with HIV in the multiple ascending dose (MAD) part of the trial, to identify a safe and tolerable dosing schedule that could lead to reduction in the viral reservoir and control of HIV after stopping antiretroviral therapies (ART), or functional cure. The MAD trial will enroll up to 28 participants.

In January 2023, we announced our strategic priorities including pipeline expansion for 2023-2024 ahead of the J.P. Morgan Healthcare Conference. The Company disclosed three new ImmTAC product candidates (targeting PRAME-A24, PRAME-A02 half-life extended [HLE], and PIWIL1) in its pipeline. Building on enthusiasm for IMC-F106C targeting PRAME HLA-A02, the Company has expanded its franchise targeting PRAME with ImmTACs targeting PRAME-A24 and PRAME-A02 half-life extended. In order to expand the potential of TCR therapy targeting PRAME, the Company is developing IMC-T119C, a first-in-class ImmTAC product candidate targeting a PRAME peptide presented by HLA-A24. HLA-24 is an HLA-type that is estimated to be present in 60% of people in Japan and 15-20% in Western populations. The second newly announced product candidate, IMC-P115C, is a half-life extended (HLE) ImmTAC product candidate targeting PRAME-A02, with the aim of improving patient convenience. IMC-P115C targets the same PRAME-A02 peptide and uses the same CD3 end and TCR specificity as IMC-F106C.

In addition, the Company is advancing a first-in-class ImmTAC candidate, IMC-R117C, for colorectal and gastrointestinal cancers. The Company has leveraged its proprietary peptidomic database to validate a novel target, PIWIL1. PIWIL1 is believed to play a role in tumor progression and is expressed across a range of tumors including colorectal, which is historically insensitive to immune checkpoints, as well as gastro-esophageal, and pancreatic cancer. PIWIL1 is also reported to be a negative prognostic marker. The Company believes IMC-R117C is the first PIWIL1 targeted immunotherapy and plans to submit an IND in the fourth quarter of 2023.

Our Key Collaboration Agreements

Genentech Collaboration

In June 2013, we entered into a research collaboration and license agreement, or the 2013 Genentech Agreement, with Genentech, and F. Hoffmann-La Roche Ltd, or Roche, pursuant to which we along with Genentech and Roche agreed to collaborate in the development, manufacture and ultimately, commercialization of soluble TCR bispecific therapeutic candidate compounds. Under the 2013 Genentech Agreement, Genentech paid us an initial upfront payment of $20 million in exchange for exclusive licenses to two of our targets, MAGE-A4 and as well as an undisclosed target.

The first pre-clinical program nominated under the 2013 Genentech Agreement was target MAGE-A4, which we refer to as our IMC-C103C program.

In November 2018, Genentech exercised its right of first negotiation with respect to our IMC-C103C program. We received an aggregate of $100 million from Genentech, consisting of an initial upfront payment of $50 million and $50 million paid upon an IND filing for the first clinical trial of the product candidate compound, in exchange for granting Genentech rights to co-develop/co-promote our IMC-C103C program. In November 2018, in response to Genentech's exercise of its right of first negotiation in regards to our IMC-C103C program, we entered into a new license and collaboration agreement, or the 2018 Genentech Agreement, pursuant to which we and Genentech agreed to collaborate in the development and commercialization of certain compounds targeting MAGE-A4, specifically pHLA-A2. Under the 2018 Genentech Agreement, we granted Genentech a co-exclusive worldwide license to our intellectual property rights in MAGE-A4 soluble TCR bispecific therapeutic candidate compounds to advance the development and commercialization of such compounds as contemplated under the 2018 Genentech Agreement. We were responsible for development of the IMC-C103C program through the completion of the Phase 1 clinical trial, with costs being shared equally between us and Genentech, and we were required to use diligent efforts with respect to our development and commercialization obligations. However, in February 2023, Genentech accepted our proposal to cease co-funding the development of MAGE-A4 HLA-A02 targeted programs under our co-development and co-promotion agreement. For more information, please see "Item 4B. Business overview —Our Collaborations and License Agreements—Genentech Collaboration."

GSK Collaboration

In 2022, our collaboration and license agreement, or the GSK Agreement, with GlaxoSmithKline Intellectual Property Development Ltd, or GSK, was terminated, and no further revenue is expected from GSK. GSK has no further rights to targets under the GSK Agreement.

We originally entered into the GSK Agreement pursuant to which we and GSK agreed to collaborate in the development of soluble TCR bispecific therapeutic compounds, for up to four targets, in June 2013, and we received payments totaling £22.9 million in upfront payments and early development milestones under the agreement.

Lilly Collaboration

In 2022, our development and license agreement, referred to, as subsequently amended, as the Lilly Collaboration, with Eli Lilly and Company, or Lilly, was terminated and no further revenue is expected from Lilly. Lilly has no further rights to targets under the Lilly Collaboration.

We originally entered into the Lilly Collaboration in July 2014, pursuant to which we and Lilly agreed to collaborate in the development, manufacture and commercialization of soluble TCR bispecific therapeutic compounds for up to three targets. We received an upfront fee payment of $45 million under the agreement.

Gadeta Collaboration

In December 2022, we entered into a Collaboration, Option and License Agreement (the "Gadeta Collaboration") with Gadeta B.V. ("Gadeta"). Under the agreement, we and Gadeta will collaborate on '201 γδ-TCR target discovery, and we will have the option to develop ImmTAC therapies derived from the '201 TCR as part of the research collaboration. We have an option for an exclusive license to further research, develop and commercialize an ImmTAC candidate from the collaboration. If we exercised this option, Gadeta could be eligible to receive further payments.

Components of Results of Operations

Revenue

Product revenue, Net

Product revenue, net, relates to the sale of KIMMTRAK following marketing approval. We recognize product revenue at the point in time that control transfers to a customer, which is typically on delivery to our distributors. We also operate under consignment arrangements where control passes when our distributor takes KIMMTRAK out of consignment inventory. The amount of revenue recognized reflects the consideration to which we expect to be entitled, net of estimated deductions for rebates, chargebacks, other customer fees and product returns. These estimates consider contractual and statutory requirements, the expected payer and patient mix, sell-through data, our customers' inventory levels, anticipated demand and the volume of customer purchase orders, internal data, and other information provided by our customers and third-party logistics providers.

Pre-Product Revenue, Net

Pre-product revenue, net, relates to the sale of tebentafusp under a compassionate use and an early access program up to September 2022. These programs provided patients with access to tebentafusp prior to KIMMTRAK becoming available as a marketed product in France. Pre-product revenue is recognized on delivery of tebentafusp to healthcare providers, which is the point in time when control is transferred. Such revenue is recognized net and represents the prices set by the Company that are expected to be retained after estimated deductions for product returns and government rebates, which are dependent on the outcome of French legislative processes and price negotiations. In September 2022, we began selling KIMMTRAK as a commercial product in France, and these sales are reflected in Product revenue, net.

Collaboration Revenue

Collaboration revenue arises under our collaboration agreements with Genentech, GSK and Lilly. This revenue consists of non-refundable upfront payments, development milestones as well as reimbursement of research and development expenses. To the extent that existing or potential future collaborations generate revenue, such revenue may vary due to many uncertainties in the development of our product candidates and other factors.

As of December 31, 2022, we have received a total of $216.8 million of upfront and milestone payments, intended to fund the research and development activities under each contract. As part of the agreements, we contribute our ImmTAC technology and commit to participate in joint research activities. In addition, we agree to license or option certain target rights and the possible product candidates developed under the collaboration. The agreements provide for future payments if development, regulatory or sales milestones are achieved. In addition, we are entitled to future royalties. The uncertainty of achieving these certain milestones significantly impacts our ability to project collaboration revenue.

Upfront payments and development milestones are initially recorded on our statement of financial position as deferred revenue and are subsequently recognized as revenue as the underlying programs progress through research and development using an estimate of the percentage completion of each program in accordance with our revenue recognition policy as described further in the notes to the consolidated financial statements.

Following the termination of our collaboration agreements with GSK and Lilly in 2022, our only revenue collaboration at December 31, 2022, was with Genentech. For more information, including regarding subsequent developments with respect to our Genentech collaboration, please see "Item 4B. Business overview—Our Collaborations and License Agreements—Genentech Collaboration."

Operating Expenses

Costs of Product Revenue

Cost of product revenue represents production costs including raw materials, external manufacturing costs, and other costs incurred in bringing inventories to their location and condition prior to sale. Overheads and internal costs of product revenue are minimal under our manufacturing arrangements. Approximately £410,000 of manufacturing costs associated with KIMMTRAK sold in the year ended December 31, 2022, were previously recognised in Research and development expenses as the vials were not originally manufactured for sale in the ordinary course of business. There are approximately £690,000 of such manufacturing costs previously recognized in Research and development expenses associated with our inventory on hand at December 31, 2022, and we expect to sell the majority of these vials in 2023. Due to the low costs involved in manufacturing KIMMTRAK, cost of product revenue is currently not material, and while these costs are expected to increase in future periods as the full costs of manufacturing are recognized through Cost of product revenue, we do not expect such costs to be material for the foreseeable future.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for current or planned investigations undertaken with the prospect of gaining new scientific or technical knowledge and understanding and consist primarily of personnel-related costs, including salaries and share-based compensation expense, for the various research and development departments, costs associated with clinical trial activities undertaken by contract research organizations, or CROs, and external manufacturing costs associated with research and development undertaken by contract manufacturing organizations, or CMOs, research and development laboratory consumables, internal clinical trial expenses, costs associated with maintaining laboratory equipment, and pre-launch inventory provision costs. All research and development expenses are expensed as incurred due to scientific uncertainty. Those research and development expenses incurred with external organizations to undertake research and development activities on our behalf typically relate to clinical programs and are assigned to the individual programs, however for pre-clinical programs and other research spend incurred externally, such spend is typically not assigned to individual programs. Internal research and development expenses primarily relate to personnel-related costs and research and development laboratory consumables and due to the cross functional expertise of our people it is not possible to provide a breakdown of internal costs by program.

We expect our research and development expenses to increase in the future as we advance existing and future product candidates into and through clinical studies and pursue further regulatory approval. The process of conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming. We maintain our headcount at a level required to support our continued research activities and development of our product candidates. Clinical trials generally become larger and more costly to conduct as they advance into later stages. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any product candidates that we develop from our programs. 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. Several of our research and development programs are at an early stage. We must demonstrate the safety and efficacy of our product candidates in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of our products, including but not limited to the following:

- we may face disruptions affecting the site initiation, patient enrollment, clinical trial site monitoring, development and operation of our clinical trials, including public health emergencies such as the ongoing COVID-19 pandemic;
- after reviewing trial results, our collaboration partners may abandon projects that might previously have been believed to be promising;
- we, our collaboration partners, or regulators may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks;
- our potential products may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved;
- manufacturers may not meet the necessary standards for the production of the product candidates or may not be able to supply the product candidates in a sufficient quantity, including as a result of supply chain disruptions caused by the COVID-19 pandemic and war in Ukraine and global geopolitical tensions;
- we may be unable to obtain additional funding necessary to continue our operations, including as a result of rising interest rates, credit and capital market instability and other impacts on global financial markets of the ongoing COVID-19 pandemic, war in Ukraine, and global geopolitical tensions;
- we may face increased costs as a result of rising global inflation including significant increases in commodity prices, energy and fuel prices, and employee costs;

- regulatory authorities may find that our clinical trial design or conduct does not meet the applicable approval requirements; and
- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on other product candidates. For example, if the FDA, EMA or another.

Selling & Administrative Expenses

Selling and administrative expenses consist primarily of personnel-related costs, including salaries and share-based compensation expense, for selling, corporate and other administrative and operational functions including finance, legal, human resources, commercial related expenses, information technology, as well as facility-related costs and foreign currency movements.

Following our commercialization of KIMMTRAK and our substantial increase in planned research and development expenses, as explained above, we also expect that our selling and administrative expenses will increase. We expect that we will incur increased selling, distribution, commercial, accounting, audit, legal, regulatory, compliance, director, and officer insurance costs as well as investor and further public relations expenses associated with being a public company operating in multiple territories. We anticipate that the additional costs for these services will substantially increase our selling and administrative expenses. Additionally, if and as we receive further regulatory approvals of product candidates, we anticipate an increase in payroll and expenses in connection with our commercial operations. We have experienced, and may continue to experience, increased personnel costs attributable to offering and maintaining competitive salaries due to rising global inflation. We may continue to experience these and other increased costs attributable to inflation, and may also experience increased selling and administrative costs as a result of further volatility in the impact of foreign exchange differences.

Net Other Operating Income / (Loss)

Net other operating income / (loss) consists primarily of the profit or loss on derecognition of leases, loss on disposal of property, plant and equipment, and sublease income.

Finance Income

Finance income arises primarily from interest income on cash and cash equivalents, short-term deposits and gains on entering into sub-lease arrangements on leasehold properties.

Finance Costs

Finance costs consist of interest expenses related to financial liabilities and lease liabilities, losses on derecognition of financial assets measured at amortized cost, and the movement in fair value of an embedded derivative asset.

Income Tax Credit

Our income tax balance largely comprises research and development tax credits. Research and development credits are obtained at a maximum rate of 33.35% of our qualifying research and development expenses.

We are subject to corporate taxation in the United Kingdom and Ireland. Our wholly owned U.S. subsidiaries, Immunocore LLC and Immunocore Commercial LLC, are subject to corporate taxation in the United States. Our wholly owned Irish subsidiary is subject to corporate taxation in Ireland. Due to the nature of our business, we have generated losses since inception. Our income tax credit recognized represents the sum of the research and development tax credits recoverable in the United Kingdom and income tax payable in the United States and Ireland.

As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax regime. As a Small and Medium-sized Enterprise, or SME, we are able to surrender some of our losses for a cash rebate of up to 33.35% of expenditures related to eligible research and development projects. Qualifying expenditures largely comprise clinical trial and manufacturing costs, employment costs for relevant staff and consumables incurred as part of research and development projects. Certain subcontracted qualifying research and development expenditures are eligible for a cash rebate of up to 21.68%. A large portion of costs relating to our research and development, clinical trials and manufacturing activities are eligible for inclusion within these tax credit cash rebate claims.

We may not be able to continue to claim research and development tax credits, under the SME Program in the future, if we cease to qualify as an SME, based on size criteria concerning employee headcount, turnover and gross assets. When we cease to qualify as an SME and whilst we continue to generate losses and do not pay any U.K. corporation tax, we may be able to generate a cash rebate under the large company scheme, or RDEC Program. The cash rebate under the RDEC Program is up to 10.53% of such qualifying research and development expenditures.

Amendments to the U.K. R&D tax credit regime have recently been enacted, or proposed. These amendments (amongst other things) (i) will reduce the cash rebate that may be claimed under the SME Program to 18.6% of qualifying expenditure, and (ii) may (unless limited exceptions apply) introduce restrictions on the tax relief that can be claimed for expenditure incurred on sub-contracted R&D activities or externally provided workers, where such sub-contracted activities are not carried out in the U.K. or such workers are not subject to U.K. payroll taxes. These amendments are expected to take effect from April 2023. In addition, the U.K. Government has recently launched a consultation on its proposal to merge the SME Program and the RDEC Program into a single scheme with effect from April 2024; if such proposal is implemented, it may be the case that we are no longer able to make claims in respect of sub-contracted R&D activities, and that different (and potentially lower) caps are imposed on the amount of tax relief that we can claim. These and other potential future changes to the U.K. R&D tax relief programs may mean we no longer qualify. or have a material impact on the extent to which we can make claims.

Un-surrendered tax losses are carried forward to be offset against future taxable profits. After accounting for tax credits receivable, there were accumulated tax losses for carry forward in the United Kingdom of £241 million as of December 31, 2022. No deferred tax asset is recognized in respect of accumulated tax losses in the United Kingdom because future profits are not sufficiently certain. A deferred tax asset is recognized in respect of the unused tax credits for the subsidiary in the United States.

As we begin to generate significant net product revenue, we may benefit from the U.K.'s "patent box", which allows profits attributable to revenues from patents or patented products to be taxed at a lower rate than other revenue. The rate of tax for relevant streams of revenue for companies receiving this relief will be 10%.

Comparison of the Years ended December 31, 2022 and 2021

The following table summarizes our consolidated statement of loss for each period presented:

	Year ended December 31,		
	2022		2021
	$ '000	£ '000	£ '000
Product revenue	130,610	108,148	—
Pre-product revenue	10,460	8,661	3,010
Total revenue from sale of therapies	141,070	116,809	3,010
Collaboration revenue	32,521	26,928	23,510
Total revenue	173,591	143,737	26,520
Cost of product revenue	(548)	(454)	—
Net other operating income / (loss)	4	3	(57)
Research and development costs	(107,691)	(89,170)	(73,226)
Selling and administrative expenses	(113,189)	(93,723)	(88,399)
Operating loss	**(47,833)**	**(39,607)**	**(135,162)**
Finance income	3,809	3,154	47
Finance costs	(9,290)	(7,692)	(5,813)
Non-operating expense	**(5,481)**	**(4,538)**	**(5,766)**
Loss before taxes	**(53,314)**	**(44,145)**	**(140,928)**
Income tax credit	3,528	2,921	9,405
Loss for the period	**(49,786)**	**(41,224)**	**(131,523)**

Revenue

	Year ended December 31,		
	2022		2021
	$ '000	£ '000	£ '000
Product revenue	130,610	108,148	—
Pre-product revenue	10,460	8,661	3,010
Total revenue from sale of therapies	141,070	116,809	3,010
Collaboration revenue			
GSK	—	—	6,083
Eli Lilly	8,890	7,361	—
Genentech	23,631	19,567	17,427
Total collaboration revenue	32,521	26,928	23,510
Total revenue	**173,591**	**143,737**	**26,520**

Revenue from the sale of therapies

Net product revenue from the sale of KIMMTRAK, and net pre-product revenue from the sale of tebentafusp as part of an early access program are presented by region based on the location of the customer below.

	Year ended December 31,		
	2022		2021
	$ '000	£ '000	£ '000
United States	97,157	80,448	—
Europe	42,861	35,490	3,010
Rest of World	1,052	871	—
Total revenue from the sale of therapies	141,070	116,809	3,010

For the year ended December 31, 2022, we generated total revenue from the sale of therapies of £116.8 million ($141.1 million) due to the sale of KIMMTRAK and tebentafusp, of which £80.4 million ($97.2 million) was in the United States, £35.5 million ($42.9 million) in Europe and £0.9 million ($1.1 million) in the rest of the world. We received marketing approval for KIMMTRAK in the United States, Europe and other territories in the year ended December 31, 2022, and did not have marketing approval for, and thus no product revenue from, KIMMTRAK in the year ended December 31, 2021.

We recorded £3.0 million of net pre-product revenue from the sale of tebentafusp under a compassionate use program in the year ended December 31, 2021.

Collaboration revenue

Revenue from collaboration agreements increased by £3.4 million to £26.9 million in the year ended December 31, 2022, compared to £23.5 million for the year ended December 31, 2021. This increase was due to an increase in Genentech revenue and the release of the remaining deferred revenue under the Lilly Collaboration after the parties agreed to terminate the agreement in 2022, partly offset by a decrease in revenue under the GSK Collaboration, under which no revenue has been recognised in 2022 following our joint election with GSK not to progress with the final collaboration program in 2021 and the subsequent termination of the GSK Collaboration.

The majority of collaboration revenue arose in both years under our agreement with Genentech, our only remaining revenue collaboration. We expect to recognize the remaining £6.4 million of revenue under the Genentech Collaboration in the year ended December 31, 2023.

Research and Development Expenses

	Year ended December 31,		
	2022		2021
	$ '000	£ '000	£ '000
External research and development expenses:			
Tebentafusp	17,326	14,346	24,981
IMC-F106C (PRAME)	17,997	14,902	5,074
IMC-C103C (MAGE-A4)	8,239	6,822	4,723
IMC-I109V (HBV)	1,953	1,617	1,653
HIV	3,764	3,117	2,342
Other expenses	8,712	7,214	5,305
Research expenses	1,194	989	471
Total external research and development expenses	**59,185**	**49,007**	**44,549**
Internal research and development expenses:			
Headcount related expenses	33,516	27,752	22,674
Laboratory consumables	9,238	7,649	4,129
Laboratory equipment expenses	5,090	4,215	1,782
Other	661	547	92
Total internal research and development expenses	**48,505**	**40,163**	**28,677**
Total research and development expenses	**107,690**	**89,170**	**73,226**

For the year ended December 31, 2022, our research and development expenses were £89.2 million, as compared to £73.2 million for the year ended December 31, 2021. This increase of £16.0 million was attributable to an increase in external research and development expenses of £4.5 million and an increase in internal research and development expenses of £11.5 million.

For the year ended December 31, 2022, our external research and development expenses increased by £4.5 million. This was driven by an increase of £9.8 million in expenses incurred for our IMC-F106C program due to a higher level of clinical trial activity, and £2.9 million in expenses incurred in connection with our IMC-C103C and HIV programs. These increases were partially offset by a reduction in spend of £10.6 million incurred for our tebentafusp programs due to a reduction in development costs following approval of KIMMTRAK in the United States and Europe in the first half of 2022. We expect our tebentafusp costs to continue in future periods as we seek to progress our advanced melanoma trials.

For the year ended December 31, 2022, our internal research and development expenses increased by £11.5 million. This was primarily due to an increase of £5.1 million in headcount related expenses as our number of employees and associated staff costs increased. Our laboratory expenses also increased by £6.0 million as the number of employees engaged in research utilizing equipment and materials increased.

In recent months, inflation has begun to impact our costs more identifiably, and we anticipate this could increase our research and development expenses in 2023 and future years. We also expect our research and development expenses to increase in future periods as we advance our trials and further develop our clinical and preclinical pipeline.

Selling and Administrative Expenses

For the year ended December 31, 2022, our selling and administrative expenses were £93.7 million, compared to £88.4 million for the year ended December 31, 2021, an increase of £5.3 million. The administrative expenses for years ended December 31, 2022, and 2021, comprised the following:

	Year ended December 31,		
	2022		2021
Selling and administrative expenses:	$ '000	£ '000	£ '000
Share-based payment charge	27,386	22,676	31,941
Other employee related expenses	26,950	22,315	14,119
Pre-commercial costs	—	—	19,134
Selling and commercial costs	44,522	36,865	—
Legal and professional fees	13,073	10,825	7,402
Depreciation	4,914	4,069	7,012
Other expenses	10,988	9,098	9,248
Foreign exchange gains	(14,643)	(12,125)	(457)
Total selling and administrative expenses	**113,190**	**93,723**	**88,399**

Selling and administrative expenses increased by £5.3 million in the year ended December 31, 2022. Commercial related costs have increased by £17.7 million with selling and commercial costs incurred in the year ended December 31, 2022 of £36.9 million reflecting costs of commercializing and distributing KIMMTRAK following U.S. and E.C. approval. Prior to regulatory approval of KIMMTRAK during the year ended December 31, 2021, £19.1 million of costs were incurred in pre-commercialisation activities performed before commercial launch. In addition, other employee related expenses increased by £8.2 million during the year ended December 31, 2022, due to an increase in employees engaged in commercial and administrative activities, and our legal and professional fees increased by £3.4 million in the year ended December 31, 2022, due to ongoing costs associated compared to with expansion as a growing publicly listed company.

These increases were partially offset by a decrease in the share-based payment charge of £9.2 million to £22.7 million compared to £31.9 million in the year ended December 31, 2021. This decrease was a result of a significantly higher number options being granted in 2021 in connection with our IPO and the associated accelerated recognition of expense on these grants due to the graded vesting that is applicable to the majority of our options. There was a further offset to the increase in Selling and administrative expenses as a result of an increase in favourable foreign exchange gains in the year ended December 31, 2022, of £11.7 million arising primarily on the translation of cash balances held by our main U.K. operating subsidiary following significant fluctuations in the pounds sterling and U.S. dollar exchange rates in the year ended December 31, 2022. Our depreciation charge also decreased by £2.9 million as we continued to operate under our existing facilities and fixed assets without major capital expenditure.

In recent months, inflation has begun to impact our costs more identifiably, and we anticipate this could increase our selling and administrative expenses in 2023 and future years. We also expect our selling and administrative expenses to increase in future periods as we further expand our commercial and corporate operations.

Finance Income

For the year ended December 31, 2022, finance income was £3.2 million compared to £47,000 for the year ended December 31, 2021. This increase of £3.1 million reflects higher levels of cash and cash equivalents held in 2022 relative to 2021 and increases in interest rates.

Finance Costs

For the year ended December 31, 2022, finance costs amounted to £7.7 million, compared to £5.8 million for the year ended December 31, 2021. This increase of £1.9 million is primarily due to the £1.4 million loss arising on the early repayment of the loan to Oxford Finance, prior to entering into our loan agreement with Pharmakon, and the amortized cost carrying value at the time of repayment. In addition we incurred higher interest expenses in 2022 relative to 2021 under the floating element of our loan with Oxford Finance prior to settlement in the year ended December 31, 2022.

Income Tax Credit

For the year ended December 31, 2022, the income tax credit amounted to £2.9 million compared to £9.4 million for the year ended December 31, 2021. This decrease of £6.5 million relates to a reduction in the level of tax losses available for surrender under the U.K. SME R&D tax credit regime following commercialisation and the generation revenue from the sale of therapies.

Off-balance sheet arrangements

We have no off-balance sheet arrangements besides a contingent liability of £1.1 million at December 31, 2022, which relates to one further leasehold property, under which we are obligated to take on the lease, should the property become vacant at a specified date in the future. We previously held a similar contingent liability in relation to another leasehold property. We entered into a lease for this property in 2022 and have recognized a right-of-use asset and associated lease liability in the consolidated statement of financial position. Further details of our lease commitments and liabilities can be found in Notes 12 and 22 to the Consolidated financial statements.

B. Liquidity and Capital Resources

Sources of Liquidity

Although we have recorded product and pre-product revenue for sales of KIMMTRAK and tebentafusp in the year ended December 31, 2022, we have continued to incur operating losses and negative cash flows from our operations since our inception.

We expect to incur significant expenses and operating losses for the foreseeable future in connection with our ongoing activities, particularly as we continue to commercialize KIMMTRAK, continue research and development and the advancement of our product candidates through preclinical and clinical development, and seek regulatory approval and pursue commercialization of any approved product candidates. We expect that our research and development and general and administrative costs will increase in connection with our planned clinical and commercial activities. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development programs, the status of, and results from, clinical trials, the potential need to conduct additional clinical trials to obtain approval of our product candidates for all intended indications, the timing and outcome of regulatory filings and actions, commercialization of approved products, as well as any technology acquisitions or additional collaborations into which we may enter with third parties for our product candidates increased costs attributable to macroeconomic factors such as rising inflation and interest rates and supply chain disruptions, and any unforeseen cash needs. As a result, we will need additional capital to fund our operations until such time as we can generate sufficient revenue from product sales.

We have funded our operations to date primarily with proceeds from sales of equity securities, debt financing and collaboration agreements. Through December 31, 2022, we have raised an aggregate of $1,275 million from sales of equity securities, debt financing and collaboration agreements. At our IPO in February 2021, we listed our ordinary shares in the form of ADSs on the Nasdaq Global Select Market and raised gross proceeds of approximately $297 million. In addition to the ADSs sold in the IPO, we completed the concurrent sale of an additional 576,923 ADSs at the IPO price of $26.00 per ADS, for gross proceeds of approximately $15 million, in a private placement to the Gates Foundation, and in July 2022, we raised gross proceeds of approximately $140 million through the sale of our ordinary shares in the form of ADSs and non-voting ordinary shares in a private placement.

On September 9, 2022, we entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or Jefferies, pursuant to which we may issue and sell ADSs, each representing one ordinary share, having an aggregate offering price of up to $250,000,000, from time to time, in one or more at-the-market offerings, for which Jefferies will act as sales agent and/or principal. The at-the-market facility has been registered under the Securities Act pursuant to our Registration Statement on Form F-3ASR (File No. 333-264105). As of December 31, 2022, no issuances or sales had been made pursuant to the Sales Agreement.

As of December 31, 2022, and 2021, we had cash and cash equivalents of £332.5 million and £237.9 million, respectively.

Other than our loan facility with Pharmakon, we currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity, other than our lease obligations and supplier purchase commitments described below.

Cash Flows

The following table summarizes the primary sources and uses of cash for each period presented:

	Year ended December 31,		
	2022		2021
	$ '000	£ '000	£ '000
Cash and cash equivalents at beginning of the year	287,295	237,886	129,716
Net cash flows used in operating activities	(31,269)	(25,891)	(96,110)
Net cash flows from / (used in) investing activities	233	193	(367)
Net cash flows from financing activities	138,226	114,454	204,631
Net foreign exchange difference on cash held	7,122	5,897	16
Cash and cash equivalents at end of the year	401,607	332,539	237,886

Operating Activities

Net cash used in operating activities was £25.9 million for the year ended December 31, 2022, compared to cash used in operating activities of £96.1 million for the year ended December 31, 2021. This decrease of £70.2 million in the year ended December 31, 2022 is primarily due to net pre-product and product revenue receipts in the year ended December 31, 2022, following regulatory approval of KIMMTRAK, partly offset by increased payments in connection with our Research and development and Selling and administrative expenses in the year ended December 31, 2022.

Our cash used in operating activities for the year ended December 31, 2022 of £25.9 million comprised a loss for the year of £41.2 million, working capital movements of £12.9 million and tax paid of £0.6 million. These items increasing cash used in operating activities were offset by other adjusting items of £28.9 million (primarily relating to the share-based charge of £27.1 million).

Our cash used in operating activities for the year ended December 31, 2021 of £96.1 million comprised a loss for the year of £131.5 million and working capital movements of £17.0 million. These items increasing cash used in operating activities were offset by other adjusting items of £40.0 million (primarily relating to the share-based charge of £35.9 million) and tax credits received of £12.4 million.

Financing Activities

Net cash from financing activities during the year ended December 31, 2022 was £114.5 million, mainly representing net financing proceeds from the PIPE in July 2022 of £116.4 million. Net cash generated from financing activities of £204.6 million in the year ended December 31, 2021 largely reflected the net proceeds we received of £211.0 million in connection with our IPO and concurrent private placement. Other financing activities included proceeds from the exercise of share options of £8.1 million and £1.0 million in the years ended December 31, 2022 and 2021, respectively, and payments made by the Company in relation to its loan and lease agreements totalling £10.1 million and £7.3 million in the years ended December 31, 2022 and 2021, respectively.

Liquidity and Capital Resources

Since our inception, we have incurred significant losses due to our substantial research and development expenses. We have an accumulated deficit of £261.3 million as of December 31, 2022. We expect to continue to incur significant losses in the foreseeable future and expect our expenses to increase in connection with our ongoing activities, particularly as we continue to commercialize KIMMTRAK in additional territories and continue research and development and clinical activities for our product candidates. In addition, since our initial public offering in February 2021, we have incurred additional costs associated with operating as a public company, which could increase further in future periods.

Our expenses will also increase if, and as, we:

- pursue further approval and commercialization of KIMMTRAK in additional territories;
- continue to advance the development of our clinical trials and pre-clinical programs;
- continue to invest in our soluble TCR platforms to conduct research to identify novel technologies;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as we progress product candidates toward commercialization;
- seek to attract and retain skilled personnel;
- create additional infrastructure to further support our operations as a public company listed in the United States and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our other product candidates;
- further develop a sales, marketing and distribution infrastructure to further commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays, interruptions or encounter issues with any of the above, including any delays or other impacts as a result of the war in Ukraine, global geopolitical tension, supply chain disruptions, worsening macroeconomic conditions, including rising interest rates and inflation, and health epidemics or pandemics such as the COVID-19 pandemic.

Lease and manufacturing obligations

As part of our ongoing operations, we have material contractual lease obligations over expected lease terms of several years and expiry dates extending to 2042 under our most significant facilities in the United Kingdom. These obligations and potential obligations could result in payments of up to £63.4 million. The majority of such payments represent longer-term commitments as outlined in Note 12 to our consolidated financial statements. The lease agreements are cancellable assuming certain conditions are met prior to expiry. We expect to continue to incur expenses for such leases for the foreseeable future. As we continue to grow, launch further products or expand our operations in other countries, we may determine that it is necessary to enter into further lease agreements, which would further increase our cash outflows.

We have a number of existing manufacturing obligations, some of which relate to the manufacture of KIMMTRAK. We have similar obligations related to our earlier stage programs. Our obligations and commitments in relation to these programs have increased, and are expected to further increase as we commit to advancing the development of our IMC-F106C program in 2023 and beyond. While we have already incurred costs in for commercial launches in the United States, Europe and other territories, additional manufacturing obligations may arise in future in relation to product sales in these territories. We have also entered into third-party agreements relating to marketing and distribution. The majority of such obligations have standard payment terms, and our level of non-cancellable commitments with such parties is not considered material. To meet demand, we may amend or enter into further agreements with CMOs or other parties which could cause our cash requirements to increase. While receipts from the sale of KIMMTRAK or other future products may fund our ongoing manufacturing and sales efforts, there can be no assurance that we will earn such revenues. In the longer term, if we received regulatory approval for our other product candidates, we would expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates.

Financing obligations and capital requirements

From a financing perspective, we are required to make interest payments, and, from 2026 onward, repayments of principal borrowings under our loan agreement with Pharmakon, until at least 2028. The loan liability at December 31, 2022 was £39.5 million, and further details regarding this loan facility are provided in Note 17 to our consolidated financial statements. We have the option to draw down a further $50 million under our agreement with Pharmakon.

Since inception, we have raised an aggregate of approximately $1.28 billion from sales of equity securities, debt financing and collaboration agreements. In order to maintain such levels of expenditure and our anticipated expenditure, we expect to raise further funds by exploring debt or equity financing, or potentially further collaborations, in the future. The amount we are able to raise from these options can vary with market conditions, including the impacts of recently worsening macroeconomic conditions such as rising interest rates and volatility in the capital markets, and our longer term strategy as a company is dependent on our ability to successfully raise such funding. Moreover, we have based our estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Under the terms of our agreement with the Gates Foundation, we are required to develop, manufacture and commercialize soluble TCR bispecific therapeutic candidates targeted to mutually agreed neglected diseases, currently HIV, with the potential to treat people at an affordable price in developing countries. In the event of certain defaults by us under the agreement, the Gates Foundation has the right to sell, or require us to buy-back, any of the shareholdings of us held by the Gates Foundation. In such an event, if within 12 months after such redemption or sale, we experience a change in control at a valuation of more than 150% of the valuation used for the redemption or the sale of the shares, we have agreed to pay the Gates Foundation compensation equal to the excess of what it would have received in such transaction if it still held its shares at the time of such change of control over what it received in the sale or redemption of its shares.

Further obligations and commitments

Further obligations or commitments in the near term relate to our capital expenditure requirements for the purpose of improving our leased facilities. If we continue to grow, such commitments may become significant in value.

In addition to the above obligations, commitments and potential future cash outflows, we enter into a variety of agreements and financial commitments in the normal course of business. The terms generally provide us the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. However, it is not possible to predict the amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each particular agreement.

Our cash and working capital expectations

We held cash and cash equivalents of £332.5 million as at December 31, 2022. We expect that our existing cash, along with anticipated revenue from KIMMTRAK, will be sufficient to fund our planned operating expenses, financial commitments and other cash requirements into 2026. Therefore, based on our current operating plans, we expect that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of filing of this Annual Report on Form 20-F. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Given our need for additional financing to support the long-term clinical development of our programs, we intend to consider additional financing opportunities when market terms are favorable to us.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely initiate clinical sites, enroll subjects and manufacture soluble bispecific TCR product candidates for our ongoing, planned and potential future clinical trials;
- the time and costs required to perform research and development to identify and characterize new product candidates from our research programs;
- the time and cost necessary to obtain regulatory authorizations and approvals that may be required by regulatory authorities to execute clinical trials or commercialize our products;
- the amount of sales and other revenues from KIMMTRAK in the U.S., Europe, and other regions, if approved;
- our ability to successfully commercialize our other product candidates;
- our ability to have clinical and commercial products successfully manufactured consistent with FDA, EMA and other authorities' regulations;
- the amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;
- the sales and marketing costs associated with commercializing our products, if approved, including the cost and timing of building our marketing and sales capabilities;
- the cost of building, staffing and validating our manufacturing processes, which may include capital expenditure;
- the terms and timing of any revenue from our existing collaborations;
- the costs of operating as a public company;
- the time and cost necessary to respond to technological, regulatory, political and market developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs, associated with, and terms and timing of, any future any potential acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish; and
- the inability of clinical sites to enroll patients as healthcare capacities are required to cope with natural disasters, epidemics or other health system emergencies, such as the COVID-19 pandemic.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development and commercialization of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements as well as grant funding. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our shareholders' ownership interest will be diluted. If we raise additional capital through debt financing, it would be subject to fixed payment obligations and may be subject to 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 obtain additional funding on favorable terms when needed, we may have to delay, reduce the scope of or terminate one or more of our research and development programs or clinical trials.

Our ability to raise additional capital may also be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. We are also mindful that conditions in the current macroeconomic environment could affect our ability to achieve our goals. We sell our products in countries that face economic volatility and weakness. Although we have historically collected receivables from customers in such countries, sustained weakness or further deterioration of the local economies and currencies and adverse effects of the impact of the ongoing COVID-19 pandemic may cause customers in those countries to be unable to pay for our products. We will continue to monitor these conditions and will attempt to adjust our business processes, as appropriate, to mitigate macroeconomic risks to our business.

Recently Issued and Adopted Accounting Pronouncements

For information on the standards applied for the first time as of January 1, 2022 and 2021, please refer to our consolidated financial statements as of December 31, 2022 elsewhere in this Annual Report.

C. Research and Development, Patents and Licenses, etc.

For a discussion of our research and development activities, see "Item 4.B — Business Overview" and "Item 5.A — Operating Results."

D. Trend Information

For a discussion of trends, see "Item 4.B — Business Overview," "Item 5.A — Operating Results" and "Item 5.B — Liquidity and Capital Resources."

E. Critical Accounting Estimates

Our consolidated financial statements for the years ended December 31, 2020, 2021, and 2022, respectively, have been prepared in accordance with IFRS as issued by the IASB. The preparation of the consolidated financial statements requires us to make judgements, estimates and assumptions that affect the value of assets and liabilities—as well as contingent assets and liabilities—as reported on the statement of financial position date, and revenues and expenses arising during the fiscal year.

The estimates and associated assumptions are based on information available when the consolidated financial statements are prepared, historical experience and various other factors which are believed to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the Group's control. Hence, estimates may vary from the actual values.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or the period of revision and future periods if this revision affects both current and future periods.

Expected rebate and chargeback percentage

We recognize revenue net of estimated deductions for rebates and chargebacks. Due to our short history of product sales, we have limited directly comparable information of actual rebate claims or chargebacks, and our early sales information may have limited predictive value. We use the expected value method to estimate expected rebate and chargeback percentages for revenue deductions, which considers the likelihood of a rebate or chargeback being applicable to sales. The proportion of sales subject to a rebate or chargeback, is inherently uncertain and the Group's estimates are based on internal assumptions, which may change as we develop more product experience, and third-party data, which we assess for reliability and relevance.

We are subject to state government Medicaid programs and other qualifying federal and state programs in the United States requiring rebates to be paid to participating state and local government entities, depending on the eligibility and circumstances of patients treated with KIMMTRAK after the Group has sold vials to specialty distributors. We are also subject to chargebacks from its specialty distributors under the 340B program in the United States, whereby qualifying hospitals are entitled to purchase KIMMTRAK at a lower price. For such sales, our specialty distributors charge back the difference between the wholesale acquisition cost and this lower price. Estimating expected rebate and chargeback percentages for revenue deductions is judgmental due to the time delay between the date of the sale to specialty distributors and the subsequent dates on which we are able to determine actual amounts of chargebacks and rebates. We form estimates of 340B chargeback deductions by analyzing sell-through data relating to the hospital mix of onward sales made by specialty distributors. For Medicaid and other rebates, we form estimates based on internal forecasts of the patient mix, information obtained from claims received and other industry data, and external health coverage statistics. Judgment is applied to consider the relevance and reliability of information used to make these estimates.

Judgment is also required in determining expected rebate percentages for the amount of our net pre-product revenue and product revenue in France. Rebates payable to the Economic Committee for Health Products ("CEPS") under compassionate use, early access and commercial programs are subject to a high degree of estimation uncertainty. Our estimate of these rebates represents the difference between the expected agreed price for the commercial sale of KIMMTRAK in France, which is subject to negotiation, and the initial price of tebentafusp and KIMMTRAK sold under early access and commercial programs until this price is agreed. Analysis of further legislative requirements, sales volumes and the expected benefit of KIMMTRAK to patients in France is also required in the assessment of rebates payable. We apply judgement to assess internal targets, pricing information of other therapies approved for sale in France, information obtained from price negotiations of KIMMTRAK in other countries, and information connected with KIMMTRAK's safety profile when forming its estimated rebate deduction from revenue.

We also apply judgment when recording net product revenue in Germany by considering internal targets, KIMMTRAK's benefit rating and the progress of negotiations to estimate the expected rebate percentages for the amount payable on conclusion of the pricing process following recent legislative changes in the country.

Our total accrued revenue deductions at December 31, 2022, including amounts of £22.5 million for the critical estimates subject to greater estimation uncertainty and judgments described above, were £25.5 million. These are included within Accruals in Trade and other payables and within Non-current accruals in the Consolidated statement of financial position at December 31, 2022.

A 20% increase or decrease in our estimates of expected rebate and chargeback percentages for amounts payable to governments or government agencies for the critical estimates described above would have resulted in a £4.5 million reduction or increase, respectively, in Total revenue from the sale of therapies reported in the Consolidated statement of loss for the year ended December 31, 2022. We believe our expected values of accruals reported in the Consolidated statement of financial position are materially appropriate; however, due to the uncertainties and judgements outlined above, it is possible eventual amounts could significantly differ to these estimates.

Item 6. Directors, Senior Management and Employees

A. Directors and senior management.

The following table sets forth information regarding members of our executive officers and our directors, including their ages as of December 31 2022.

Name	Age	Position(s)
Executive Officers:		
Bahija Jallal, Ph.D.	61	Chief Executive Officer and Director
Brian Di Donato	56	Chief Financial Officer and Head of Strategy
David Berman, M.D., Ph.D.	52	Head of Research and Development
Tina St Leger	54	Chief Human Resources Officer
Non-Executive Directors:		
Professor Sir John Bell	70	Chairman of the Board of Directors
Travis Coy	42	Director
Roy S. Herbst, M.D., Ph.D	59	Director
Robert Perez	58	Director
Kristine Peterson	63	Director
Professor Sir Peter Ratcliffe	68	Director
Siddharth Kaul	62	Director

Executive Officers

Bahija Jallal, Ph.D. has served as our Chief Executive Officer since January 2019. Previously, she served as President of MedImmune, LLC, at AstraZeneca plc's global biologics research and development unit, and Executive Vice President of AstraZeneca plc and a member of its senior executive team, where she worked from 2008 to 2019. Prior to joining MedImmune, Dr. Jallal was vice president, drug assessment and development, at Chiron Corporation. Dr. Jallal currently serves on the board of directors of Anthem, Inc. She is also a member of the Board of Trustees of the Johns Hopkins University and the board of directors of the University of Maryland Health Sciences Research Park Corporation. Dr. Jallal is also a Council Member of the Government-University-Industry Research Roundtable of the National Academies of Sciences, Engineering and Medicine, and the past president of the Association of Women in Science. Dr. Jallal received her Ph.D. in Physiology from Université de Paris VI, France and conducted her post-doctorate work in molecular biology and oncology at the Max Planck Institute for Biochemistry in Germany. We believe Dr. Jallal's extensive experience in the biotechnology industry, leading drug research and development efforts, her educational background and her knowledge of our company as our Chief Executive Officer, qualify her to serve on our board of directors.

Brian Di Donato has served as our Chief Financial Officer since April 2020. He joined us from Achillion Pharmaceuticals, Inc., where he was Chief Financial Officer from August 2018 to May 2020. Prior to joining Achillion, Mr. Di Donato was a private investor and a full-time student at Pennsylvania State University from May 2015 to May 2018. Previously, Mr. Di Donato held positions as Co-Portfolio Manager at Sorin Capital Management, where he worked from 2008 to 2014, and President and Chief Investment Officer at Capmark Investments, where he worked from 2002 to 2008. Mr. Di Donato also serves on the board of directors of iECURE. Mr. Di Donato holds an M.B.A. from New York University's Stern School of Business and B.S. degrees in biology from Penn State University and in mechanical engineering from Villanova University. Prior to business school, he was an aerospace engineering officer in the U.S. Navy.

David Berman, M.D., Ph.D. has served as our Head of Research and Development since January 2019, after initially joining us in September 2018. Previously, Dr. Berman served as Senior Vice President and Head of AstraZeneca plc's Immuno-oncology Franchise from 2017 to 2018. Prior to that, from 2015 to 2017, he was head of the early stage oncology program at MedImmune, LLC (now known as AstraZeneca plc). Dr. Berman has also held senior development roles at Bristol-Myers Squibb Company, where he worked from 2005 to 2015, including as Head of the Immuno-oncology exploratory development team. Dr. Berman received a B.S. from the Massachusetts Institute of Technology and a M.D. and Ph.D. from the University of Texas Southwestern Medical School. He trained in pathology at the National Cancer Institute followed by a fellowship at the Johns Hopkins Hospital.

Tina St. Leger has served as our Chief Human Resources Officer since February 3, 2022. Previously, she served as Chief Human Resources at GW Pharmaceuticals from July 2019 to December 2021. Prior to joining GW Pharmaceuticals, Ms. St. Leger served in various human resources positions at GlaxoSmithKline, where she worked from 2005 to 2019. Ms. St.Leger holds a B.Sc. from the University of St. Andrews.

Non-Executive Directors

Professor Sir John Bell has served on our board of directors since March 2015. Professor Sir John Bell has been the Regius Professor of Medicine at Oxford University since 2002. He is a distinguished scientist in the fields of genomic and genetic research and immunology, and has been a founding director at three biotechnology companies: Avidex Ltd (acquired by MediGene AG in 2006), Oxagen Ltd. and PowderJect Pharmaceuticals plc (acquired by Chiron Corporation in 2003). He also previously served on the boards of Roche Holding AG, Sensyne Health plc, and Genentech, Inc., and the scientific advisory board at AstraZeneca plc. Professor Sir John Bell was involved in the founding of the Wellcome Trust Centre for Human Genetics at Oxford University, now chairs the Global Health Scientific Advisory Board of the Bill and Melinda Gates Foundation, and is the Life Science Champion for the United Kingdom, advising the government on the life sciences industry. We believe his extensive scientific background and experience in the healthcare industry qualify him to serve on our board of directors.

Travis Coy has served on our board of directors since September 2019. Mr. Coy is currently Vice President, Head of Transactions and M&A, Corporate Business Development at Eli Lilly and Company, a position he has held since October 2019. Prior to this role, Mr. Coy had a variety of finance and business development experiences at Lilly, where he has worked since 2003, including positions as Vice President, Transactions - Oncology and Diagnostics; Vice President, Transactions - Cardiometabolic Diseases, Drug Delivery and Devices; Finance Director of the Oncology Business Unit; Director of Investor Relations; Director of Corporate Finance and Investment Banking; and other financial controllership roles. Before transitioning to finance and business development, he was a chemist in Lilly's research laboratories and a production manager for Milliken & Company. We believe that Mr. Coy's experience in finance and business development qualify him to serve on our board of directors.

Roy Herbst, M.D., Ph.D. has served on our board of directors since January 2021. He currently serves as Ensign Professor of Medicine, Deputy Director of Yale Cancer Center and Chief of Medical Oncology at Yale Cancer Center and Smilow Cancer Hospital. Previously, Dr. Herbst served as the Barnhart Distinguished Professor and Chief of the Section of Thoracic Medical Oncology in the Department of Thoracic/Head and Neck Medical Oncology, at the University of Texas M.D. Anderson Cancer Center from 1991 to 2011. He also served as Professor in the Department of Cancer Biology and Co-Director of the Phase I Clinical Trials Program from 2002 to 2011. In 2020, Dr. Herbst was awarded the Distinguished Public Service Award for Exceptional Leadership in Cancer Science Policy by the American Association for Cancer Research. He is also a member of the board of directors of the American Association for Cancer Research, the International Association for the Study of Lung Cancer, Shanghai Junshi Biosciences Co., Ltd. and the Thoracic Malignancy Steering Committee at the National Cancer Institute. We believe Dr. Herbst's extensive scientific background and expertise in cancer treatment and research qualifies him to serve on our board of directors.

Robert Perez has served on our board of directors since September 2019. Mr. Perez is an Operating Partner and part of General Atlantic's Operations Group, with a particular focus on the biopharma and life sciences sectors. Before joining General Atlantic in 2019, he served as Managing Director of Vineyard Sound Advisors, LLC, an advisory practice focused on growth companies in the biopharmaceutical industry, from March 2015 to January 2019. Prior to that, Mr. Perez was with Cubist Pharmaceuticals, Inc. from 2003 until its sale to Merck & Co. in 2015, where he held various positions of increasing responsibility, including most recently as its President and Chief Executive Officer. Mr. Perez currently serves on the board of directors of Vir Biotechnology, Inc. and Third Harmonic Bio, Inc., and he previously served on the board of directors of AMAG Pharmaceuticals, Zafgen, Inc., Spark Therapeutics, Inc., Unum Therapeutics and Cidara Therapeutics. We believe Mr. Perez's breadth of experience in investing and serving on boards of other companies in the biopharma and life sciences industries and his extensive management experience qualify him to serve on our board of directors.

Kristine Peterson has served on our board of directors since November 2017. Ms. Peterson most recently served as Chief Executive Officer for Valeritas, Inc. from 2009 to 2016. Prior to joining Valeritas, Ms. Peterson was Company Group Chair of the biotechnology group at Johnson & Johnson from 2006 until 2009, where she was responsible for Commercial, Research & Development, and biologics manufacturing for oncology, immunology and cell therapy, and was Executive Vice President of Pharmaceutical Group Strategic Marketing from 2004 to 2006. Previously, she served as President and Senior Vice President, Commercial Operations for Biovail Corporation. Earlier in her career, Kristine spent 20 years at Bristol-Myers Squibb Company in a variety of senior roles across multiple disease areas, including running their cardiovascular and metabolics business unit. Ms. Peterson currently serves on the board of directors of Amarin Corporation plc, Paratek Pharmaceuticals, Enanta Pharmaceuticals and ImmunoGen, Inc. She was previously on the board of directors for EyePoint Pharmaceuticals from 2017 to 2020, a senior advisor to the Healthcare Businesswomen's Association and a Member of the Biotechnology Industry Organization Board. Ms. Peterson has a B.S. and an M.B.A. from the University of Illinois at Urbana-Champaign. We believe Ms. Peterson's operational knowledge of, and executive-level experience in, the global pharmaceutical and biotech industry qualify her to serve on our board of directors.

Professor Sir Peter Ratcliffe has served on our board of directors since November 2020. Professor Sir Peter Ratcliffe currently serves as the Director of Clinical Research at The Francis Crick Institute in London and Director for the Target Discovery Institute and Distinguished Scholar of the Ludwig Institute for Cancer Research within the Nuffield Department of Medicine at the University of Oxford. Previously, Professor Sir Peter Ratcliffe served as Nuffield Professor and Head of the Nuffield Department of Clinical Medicine from 2004 to 2016. In 2019, Professor Sir Peter Ratcliffe was awarded the Nobel Prize for Physiology or Medicine alongside William G Kaelin, Jr. of Harvard University and Gregg L. Semenza of Johns Hopkins University. In 2002, Professor Sir Peter Ratcliffe was elected to the Fellowship of the Royal Society and to the Academy of Medical Sciences. He is also a member of European Molecular Biology Organization, a foreign honorary member of the American Academy of Arts and Sciences and a Fellow of the American Association for Cancer Research Academy. We believe Professor Ratcliffe's extensive scientific background qualifies him to serve on our board of directors.

Siddharth Kaul has served on our board of directors since June 2022. Mr. Kaul is a seasoned finance professional with deep expertise within the life sciences industry. He retired as Group Treasurer and Head of Business Planning and Analysis at Novartis in 2021 after a 17-year career at the company, where his previous roles included serving as Novartis' Chief Financial Officer, Pharma Europe and Chief Financial Officer, Pharma U.S. Mr. Kaul led the Novartis strategic review and spin-off of Alcon, Novartis' eye care business. Prior to joining Novartis, Mr. Kaul spent two decades at Procter & Gamble, where he worked in a number of finance leadership roles across financial planning and analysis, strategic planning, and accounting and auditing in the United States and Japan. Mr. Kaul holds a Bachelor of Science in Business Administration from West Virginia University and a Master of Business Administration from Indiana University Bloomington. We believe that Mr. Kaul's extensive experience in finance qualifies him to serve on our board of directors.

Diversity of the Board of Directors

The table below provides certain information regarding the diversity of our board of directors as of December 31, 2022.

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	8			
	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	2	6	-	-
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction		1		
LGBTQ+		-		
Did Not Disclose Demographic Background		1		

The information regarding the diversity of our board of directors as of December 31, 2021 is available in our Annual Report on Form 20-F for the year ended December 31, 2021.

Family Relationships

There are no family relationships among any of our executive officers or directors.

B. Compensation

Compensation of Executive Officers and Directors

For the year ended December 31, 2022, the aggregate compensation paid to the members of our board of directors and our executive officers for services in all capacities, including retirement and similar benefits, was £3.1 million ($3.8 million), (2021: £2.2 million). Dollar amounts have been converted using the average exchange rate of 1.2369 for the year ended December 31, 2022. In 2022, our highest paid director was Dr Bahija Jallal, our Chief Executive Officer, who received compensation of £1.1 million ($1.4 million) (2021: £0.9 million).

We maintain performance-based bonus arrangements with our executives pursuant to the terms of their services agreements (or otherwise pursuant to our discretionary annual bonus arrangements). The compensation amounts above include bonus amounts in respect of the year ended December 31, 2022 payable to members of our board of directors and our executive officers of £1.1 million ($1.4 million), of which £0.5 million ($0.6 million) is payable to Dr Jallal (being the only director eligible to receive such a bonus). We do not set aside or accrue any amounts to provide pension, retirement or similar benefits to members of our board of directors or executive officers, although we made defined contribution pension contributions to a 401(k) plan on behalf of our directors or executive officers in an aggregate amount of £41,979 ($50,698) during the year ended December 31, 2022, which amount is included in the foregoing aggregate compensation figure.

For the year ended December 31, 2022, the table below outlines the compensation payable to each of our directors and the rest of our executive officers (other than Dr Jallal) as a group. In the case of Dr Jallal, our chief executive officer, the table below sets forth the compensation paid to her for services as a member of our senior management. She does not receive any compensation for serving as an executive director. For executive compensation not paid in U.S. dollars, amounts in pounds sterling have been translated for convenience to U.S. dollars at a rate of 1.2077.

Name	Salary and Fees $	Benefits $	Pension (401(k)) $	Total Fixed Remuneration $	Annual Bonus $	Total Remuneration $	Share-Based Awards Number (1)
Executive Director							
Bahija Jallal, Ph.D.	700,000	46,106	15,250	761,356	656,250[2]	1,417,606	445,577
Non-Executive Directors							
Professor Sir John Bell	85,288	—	—	85,288	—	85,288	14,176
Travis Coy[3]	—	—	—	—	—	—	—
Roy Herbst, M.D., Ph.D.	56,199	—	—	56,199	—	56,199	14,176
Robert Perez[3]	—	—	—	—	—	—	—
Kristine Peterson	56,219	—	—	56,219	—	56,219	14,176
Professor Sir Peter Ratcliffe	57,158	—	—	57,158	—	57,158	14,176
Siddharth Kaul	32,610	—	—	32,610	—	32,610	10,268
Other Executive Officers	1,290,048	72,726	35,448	1,398,222	687,289	2,085,511	325,114
Total compensation	**2,227,522**	**118,832**	**50,698**	**2,447,052**	**1,343,539**	**3,790,591**	**837,663**

Notes to the compensation table:

1. The share-based awards included in the table above, reflect the number of share options awarded during the year ended December 31, 2022. The fair value of these share options ranged from $15.10 to $21.72, and were valued using the Black-Scholes option pricing model. The assumptions used in the valuations can be found in Note 19 to the Consolidated financial statements. Further information regarding these awards including date of grant, exercise price and expiration date is disclosed in the table below.

2. Represents a performance-based cash bonus awarded to Dr. Jallal in connection with the achievement of 2022 annual performance milestones (paid in 2023) pursuant to the terms of her amended and restated employment agreement. Dr. Jallal was assigned a target bonus expressed as a percentage of her base salary, and the target bonus amount for Dr. Jallal for 2022 was set 75%. For 2022, the Board determined to award Dr. Jallal an annual bonus of $656,250 (reflecting an achievement level of 100%), as reflected in the “Annual Bonus” column of the table above.

3. Robert Perez and Travis Coy were originally nominated to our board of directors by Eli Lilly S.A. and General Atlantic, respectively, pursuant to our Series C Shareholders’ Agreement, which granted a right to each of Eli Lilly S.A. and General Atlantic to appoint an individual to our board. Both directors elected to forgo remuneration in respect of their services as non-executive directors.

Outstanding Equity Awards, Grants and Option Exercises

The following table summarizes the options granted to our executive director and our non-executive directors and executive officers during the year ended December 31, 2022 and prior periods.

Name	Ordinary Shares Underlying Option Award	Exercise Price ($)	Grant Date[1]	Expiration Date
Executive Director				
Bahija Jallal, Ph.D.[2][3]	445,577	24.66	February 16, 2022	February 16, 2032
	2,076,080	26.00	February 4, 2021	February 4, 2031
	28,345	17.46	October 30, 2020	October 30, 2030
	2,079,470	17.46	January 7, 2019	January 7, 2029
Non-Executive Directors[4][5][6][7]				
Professor Sir John Bell	14,176	25.83	May 12, 2022	May 12, 2032
	33,985	26.00	February 4, 2021	February 4, 2031
	18,215	17.46	November 16, 2020	November 16, 2030
	1,335	40.93	December 13, 2016	December 12, 2026
	1,335	40.93	September 9, 2016	September 8, 2026
	6,915	11.83	June 12, 2015	June 11, 2025
Roy Herbst, M.D., Ph.D.	14,176	25.83	May 12, 2022	May 12, 2032
	10,620	26.00	February 4, 2021	February 4, 2031
Kristine Peterson	14,176	25.83	May 12, 2022	May 12, 2032
	13,778	26.00	February 4, 2021	February 4, 2031
	11,520	17.46	November 16, 2020	November 16, 2030
Siddharth Kaul	10,268	34.44	June 8, 2022	June 8, 2032
Professor Sir Peter Ratcliffe	14,176	25.83	May 12, 2022	May 12, 2032
Other Executive Officers	70,000	29.87	April 1, 2022	April 1, 2032
	255,114	24.66	February 16, 2022	February 16, 2032
	875,507	26.00	February 4, 2021	February 4, 2031
	831,790	17.46	July 16, 2020	July 16, 2030
	300,000	17.46	April 30, 2020	April 30, 2030

Notes to the options table:

1. Options granted during 2021 were granted at the time of our IPO. The exercise price of $26.00 is equal to the price per ADS sold in the IPO, and the awards have no performance conditions attached.
2. Options granted to Dr. Jallal on February 16, 2022, February 4, 2021, and October 30, 2020, vest over a four-year period from the date of grant. Twenty-five percent of the shares subject to the February 4, 2021 award vested on the first anniversary of the vesting commencement date, and the remaining shares vest in quarterly installments thereafter, subject to the officer's continued service through each vesting date. The options granted on October 30, 2020 have a vesting commencement date of April 1, 2020. Twenty-five percent of the shares subject to the October 30, 2020 award vest on the first anniversary of the vesting commencement date (April 1, 2021), and the remaining shares vest in quarterly installments thereafter, subject to the officer's continued service through each vesting date.
3. The options granted to Dr. Jallal on January 7, 2019 vesting over a five-year period were modified during 2020 and immediately prior to the IPO. The incremental fair values arising on these modifications for accounting purposes were $3.84 and $5.19, respectively.
4. Options granted to Siddharth Kaul on June 8, 2022 vest in monthly installments over three years from the date of grant.
5. Other options granted to our non-executive directors on May 12, 2022 vest after one year from the date of grant.

6. All option awards granted to our non-executive directors prior to 2022 vest over a four-year period from the date of grant, with 25% of the award vesting on the first anniversary of the grant date and the remaining shares vesting in quarterly installments thereafter, subject to the director's continued service through each vesting date.
7. Robert Perez and Travis Coy were originally nominated to our board of directors by Eli Lilly S.A. and General Atlantic, respectively, pursuant to our Series C Shareholders' Agreement, which granted a right to each of Eli Lilly S.A. and General Atlantic to appoint an individual to our board. Both directors elected to forgo remuneration in respect of their services as non-executive directors.

As of December 31, 2021, our officers and directors collectively held options to purchase an aggregate of 6,288,895 ordinary shares. No options were exercised by these persons during the year ended December 31, 2022.

Equity Incentives

Option arrangements are in place to involve directors and executive officers in the capital of the Company. The following policy is in place for Executive Directors and employees:

Element, purpose and link to strategy	The Company adopted the 2021 Equity Incentive Plan ("EIP") to enhance the Group's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Group by providing these individuals with equity ownership opportunities. The EIP facilitates share ownership to provide further alignment with shareholders. Executive Directors may also hold awards granted under the predecessor plans to the EIP and may also participate in any future discretionary equity incentive plan that may be adopted from time to time to replace the EIP.
How it operates	The EIP provides for the grant of market value options, share appreciation rights, restricted stock unit awards, dividend equivalents, performance awards (subject to performance conditions) and other share-based awards. Awards vest at such times and as specified in the Award Agreement. If the participant violates the non-competition, non-solicitation, confidentiality or other similar restrictive covenant provisions of any employment contract, the right of the participant to receive these shares on vesting shall terminate immediately. The Committee maintains discretion over the type and terms of equity awards granted. The EIP is administered by the Administrator. EIP awards are not subject to any holding period. All awards may be subject to malus and/or clawback under any malus and/or clawback policy that may be adopted in the future. Any share-based entitlements granted to an Executive Director under the Company's share plans will be treated in accordance with the relevant plan rules or any applicable agreement. Under the good leaver provisions unvested options lapse, but vested options can be exercised within a period as set out in the plan rules. The Committee retains the discretion to vest awards (and measure performance accordingly) on cessation and disapply time prorating; however, it is envisaged that this would only be applied in exceptional circumstances.
Maximum opportunity	There is no maximum opportunity under the EIP. However, the Company's Remuneration Committee will ensure that annual awards that are granted are guided by the market. The Committee will look at the position at similar sized comparators to help inform its decision.
Performance-related framework	The Committee has the discretion to choose the form of EIP awards for each year, as well as each individual grant. Currently, awards are granted subject to time-based vesting only, but the Committee may decide to introduce performance conditions for future awards and will be guided by the market in making any such decision.

The following policy is in place for Non-Executive Directors:

Element, purpose and link to strategy	To facilitate share ownership by Non-Executive Directors in the Company and provide alignment with shareholders.
How it operates	The EIP provides for the grant of market value options, share appreciation rights, restricted stock unit awards, dividend equivalents, performance awards (subject to performance conditions) and other share-based awards. Further, subject to the terms of the award agreement, awards can be granted in respect of ordinary shares, ADSs, cash or a combination thereof. However, performance awards (subject to performance conditions) are not intended to be issued to Non-Executive Directors. Awards vest in accordance with the vesting schedule set for the relevant award in its award agreement. The Committee maintains discretion over the type and terms of equity awards granted. Non-Executive Directors usually receive options on joining the Board and annually as part of their remuneration with phased vesting. Under normal circumstances, initial share awards vest monthly over three years and options awarded annually will usually vest upon the first anniversary of the date of grant. Non-Executive Directors may also hold awards granted under the predecessor plans to the EIP and may also participate in any future discretionary equity incentive plan that may be adopted from time to time to replace the EIP.
Maximum opportunity	There is no maximum number of equity incentive awards that may be awarded to individuals each year. However, when reviewing award levels, account is taken of market movements in equity incentive awards, Board committee responsibilities, ongoing time commitments and the general economic environment.
Performance-related framework	Non-Executive Directors do not participate in performance based equity incentives.

Insurance and Indemnification

To the extent permitted by the Companies Act 2006, we are permitted to indemnify our directors against any liability they incur by reason of their directorship. We maintain directors' and officers' insurance to insure such persons against certain liabilities and have entered into deeds of indemnity with each of our directors and executive officers.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to our directors, executive officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

C. Board Practices

Composition of Our Board of Directors

Our board of directors is currently composed of eight members. As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. Our board of directors has determined that Professor Sir John Bell, Mr. Coy, Dr. Herbst, Mr. Kaul, Mr. Perez, Ms. Peterson, and Professor Sir Peter Ratcliffe, representing seven of our eight 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, one-third of our directors will retire from office at each annual general meeting of shareholders. At each annual general meeting, the directors whose terms expire will retire and are eligible for re-appointment by ordinary resolution at such annual general meeting. At each annual general meeting, the successors to directors whose terms then expire or the directors who have been re-appointed will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- Class I consists of Travis Coy, Peter Ratcliffe and Roy S. Herbst, who were each re-appointed at our annual general meeting which was be held in May 2022, and whose terms will expire at our annual general meeting to be held in 2025;
- Class II consists of Robert Perez, Kristine Peterson and Siddharth Kaul, whose terms will expire at our annual general meeting to be held later this year; and
- Class III consists of John Bell and Bahija Jallal, whose terms will expire at our annual general meeting to be held in 2024.

	Current position(s)	Year of initial appointment	Term expiration year
Bahija Jallal	Chief Executive Officer and Director	2019	2024
Professor Sir John Bell	Chairman of the Board of Directors	2015	2024
Travis Coy	Director	2019	2025
Roy S. Herbst, M.D., Ph.D.	Director	2021	2025
Robert Perez	Director	2019	2023
Kristine Peterson	Director	2017	2023
Professor Sir Peter Ratcliffe	Director	2020	2025
Siddharth Kaul	Director	2022	2023

Each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. None of our directors' service contracts provide for benefits upon termination of employment.

Non-Executive Director Appointment Letters

Non-executive directors are engaged on letters of appointment that set out their duties and responsibilities. The non-executive directors do not receive benefits upon termination or resignation from their respective positions as directors. Under the non-executive director appointment letters, our non-executive directors are entitled to receive annual fees in accordance with our non-executive director remuneration policy, and in each case inclusive of fees payable for all duties.

Non-Executive Director Remuneration Policy

In January 2021, our board adopted our non-executive director remuneration policy, which was most recently amended in February 2023. Robert Perez and Travis Coy have each elected to forgo remuneration in respect of their services as non-executive directors.

Cash Compensation

Under this policy, we pay each of our non-executive directors annual fees for service on our board of directors and committees of our board of directors, which amounts may be amended from time to time by the board of directors. We also reimburse non-executive directors for all reasonable and properly documented expenses related to attendance at board and committee meetings. Non-executive directors may also be provided with tax-equalisation benefits. Non-executive directors do not receive any pension benefits or cash in lieu thereof.

Non-executive directors are eligible to receive cash compensation as follows:

	Annual Fee Retainer ($)
Annual fee for board of director chairman (in addition to annual member service retainer)	30,000
Annual fee for board of director member	40,000
Additional fee for audit committee chair	7,500
Additional fee for audit committee member	7,500
Additional fee for nominating and corporate governance committee chair	5,000
Additional fee for nominating and corporate governance committee member	4,000
Additional fee for remuneration committee chair	4,000
Additional fee for remuneration committee member	5,000

Equity Compensation

In addition to cash compensation, each non-executive director is eligible to participate in the Non-Employee Sub-Plan to our Equity Incentive Plan as described in additional detail under "Equity Incentives." All share options granted under our non-executive director remuneration policywill be nonstatutory stock options, with an exercise price per share equal to 100% of the fair market value (as such term is defined in our 2021 EIP) of the underlying Shares on the date of grant, and a term of ten years from the date of grant, subject to earlier termination in connection with a termination of service (as such term is defined in our 2021 EIP).

Initial Grant

Each eligible director who is first elected or appointed to our board of directors automatically, and without further action by our board of directors or the Remuneration Committee of our board of directors, upon the date of his or her initial election or appointment to be an eligible director (or, if such date is not a market trading day, the first market trading day thereafter), be granted a share option to purchase an estimated $185,000 of ordinary shares, or the Initial Grant. The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant; provided, that the eligible director continues to be a service provider (as such term is defined in our 2021 EIP) through each such vesting date.

Annual Grant

At the close of business on the date of each of our annual general meetings, each eligible director who continues to serve as a non-employee member of our board of directors following such meeting will be automatically, and without further action by our board of directors or the Remuneration Committee of our board of directors, be granted a share option to purchase an estimated $185,000 of ordinary shares, or the Annual Grant. The shares subject to the Annual Grant will vest at the earlier of (i) the one-year anniversary of the date of grant and (ii) the day immediately prior to the date of our next annual general meeting; provided, that the eligible director continues to be a service provider (as defined in the 2021 EIP) through such vesting date.

Vesting; Change of Control

All vesting is subject to the eligible director continuing to be a service provider (as such term is defined in our 2021 EIP) on each applicable vesting date. Notwithstanding the foregoing vesting schedules, for each eligible director who remains continuously a service provider until immediately prior to the closing of a change in control (as such term is defined in our 2021 EIP), the shares subject to his or her then-outstanding equity awards will become fully vested immediately prior to the closing of such change in control.

Committees of our Board of Directors

Our board of directors has three standing committees: an audit committee, a remuneration committee and a nominating and corporate governance committee. The board has adopted a written charter for each of the committees below that is available to shareholders on our website at https://ir.immunocore.com/corporate-governance/document-charters.

Audit Committee

Our audit committee is composed of Mr. Coy, Dr. Herbst, Mr. Kaul, Mr. Perez, and Professor Sir Peter Ratcliffe, and assists the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Mr. Coy serves as chairman of the audit committee. The audit committee consists exclusively of members of our board who are financially literate, and Mr. Coy is considered 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 audit committee is composed solely of independent directors under the requirements of the Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act, subject to the phase-in periods available to newly-listed companies.

The audit committee's responsibilities include:

- determining whether to appoint, reappoint or remove any auditors, and making recommendations to the board of directors to be put to the shareholders for approval at the annual general meeting;

- reviewing audit plans, the adequacy of staffing and fees, whilst overseeing the negotiation and execution of any engagement letters on our behalf;
- at least annually, assessing the qualifications, performance, and independence of the auditors, or in the case of prospective auditors, before they are engaged;
- overseeing the policies and procedures governing how we may employ individuals who are or once were employed by the auditors;
- reviewing results of the annual audit, audited financial statements, periodic and annual reports, earnings announcements, proxy report, accounting principles and policies;
- evaluating management's cooperation with the auditors during their audit examination;
- reviewing and reporting on policies on financial risk management and assessment;
- reviewing the audit plan of any internal audit team;
- reviewing the scope, design, adequacy and effectiveness of internal controls;
- reviewing correspondence with regulators or governmental agencies that raise material issues regarding our financial statements or accounting policies;
- overseeing procedures for receiving, retaining and investigating complaints;
- monitoring compliance with our Code of Business Conduct and Ethics and related party transactions rules; and
- reviewing with management legal and regulatory compliance and any actual, pending, or threatened legal or financial matters that could significantly affect our business or financial statements or as otherwise deemed appropriate by the audit committee.

Remuneration Committee

Our remuneration committee is composed of Mr. Coy, Ms. Peterson, Professor Sir John Bell, Mr. Perez, and Mr. Kaul and assists the board of directors in determining executive officer compensation. Ms. Peterson and Professor Sir John Bell serve as co-chairs of the remuneration committee.

The remuneration committee's responsibilities include:

- reviewing, modifying and overseeing the company's overall compensation strategy and policies;
- reviewing and approving the compensation and other terms of employment of our Chief Executive Officer;
- reviewing and approving all elements of the compensation and other terms of employment of the executive officers and other senior management reporting directly to the Chief Executive Officer;
- reviewing and recommending to the board of directors for its approval the type and amount of compensation to be paid or awarded to members of the board of directors;
- undertaking sole responsibility for the appointment, authority to select, retain, and terminate any compensation and oversight of the work of compensation consultants, legal counsel, or any other advisors engaged for the purpose of advising the remuneration committee;
- exercising full power and authority to adopt, amend, terminate, and administer our equity award, pension, and profit sharing plans, incentive plans, bonus plans, executive benefit plans, stock purchase plans, deferred compensation plans and other similar programs;
- when required, reviewing and discussing with management our Compensation Discussion and Analysis section of our annual reports, registration statements, proxy statements, or information statements filed with the SEC;

- reviewing and discussing with management any conflicts of interest raised; and
- overseeing the preparation of any report required by applicable U.S. and U.K. rules and regulations to be included in our public filings relating to compensation policy and practices, including but not limited to the directors' remuneration report required under the Companies Act.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is composed of Professor Sir John Bell, Mr. Perez, Ms. Peterson , and Professor Sir Peter Ratcliffe, and assists our board of directors in identifying individuals qualified to become members of our board and executive officers consistent with criteria established by our board and in developing our corporate governance principles. Mr. Perez serves as chairman of the nominating and corporate governance committee.

The nominating and corporate governance committee's responsibilities include:

- identifying and evaluating candidates, including nomination of incumbent directors for re-election and nominees recommended by shareholders to serve on the board of directors;
- making recommendations to the board of directors regarding nominees for directors at the next annual general meeting;
- periodically reviewing the performance of the board of directors, including committees of the board of directors and management;
- overseeing the board of directors' committee structure and operations, including authority to delegate to subcommittees and committee reporting to the board of directors;
- reviewing with the Chief Executive Officer the succession plans for our executive officers;
- instituting plans or programs for the continuing education of directors and orientation of new directors, as it deems appropriate; and
- periodically reviewing the processes and procedures to provide information to the board of directors and its committees.

D. Employees

As of December 31, 2022, we had 408 full-time employees, 128 (31%) of whom hold Ph.D. degrees. Of these employees, 286 are engaged in research and development activities and 122 are engaged in commercial, business development, finance, information systems, facilities, human resources or administrative support. None of our employees are subject to collective bargaining agreements. We consider our relationship with our employees to be good.

	At December 31,		
	2022	**2021**	**2020**
Function:			
Administrative	122	77	55
Research and development	286	247	236
Total	408	324	291
Geography:			
United Kingdom	318	264	242
European Union	4	2	2
United States	86	58	47
Total	408	324	291

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

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see "Item 6.B Compensation" and "Item 7.A Major Shareholders."

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 with respect to the beneficial ownership of our voting ordinary shares and non-voting ordinary shares as of February 1, 2023 for:

- each beneficial owner of 5% or more of our outstanding ordinary shares and non-voting ordinary shares;
- each of our directors and executive officers; and
- all of our directors and executive officers 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 issuable upon the exercise of options that are immediately exercisable or exercisable within 60 days of February 1, 2023. Percentage ownership calculations are based on 48,119,223 ordinary shares outstanding (including ordinary shares in the form of ADSs) as of February 1, 2023, of which 2,164,960 shares are non-voting ordinary shares.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

Except as otherwise indicated, the addresses of the persons listed in the table is c/o Immunocore Holdings plc, 92 Park Drive, Milton Park, Abingdon, Oxfordshire OX14 4RY, United Kingdom.

Name of Beneficial Owner	Number of Ordinary Shares Beneficially Owned (#)	Percent of Ordinary Shares Beneficially Owned (%)
5% or Greater Shareholders:		
Entities affiliated with RTW[1]	5,559,322	11.55 %
Entities affiliated with Baker Brothers [2]	4,685,690	9.74%
Entities affiliated with Rock Springs Capital [3]	3,321,066	6.90%
Entities affiliated with General Atlantic [4]	3,225,700	6.70%
Eli Lilly S.A. [5]	2,548,145	5.30%
Executive Officers and Directors:		
Bahija Jallal, Ph.D. [6]	2,728,523	5.37%
Brian Di Donato [7]	440,382	*
David Berman, M.D., Ph.D. [8]	1,095,579	2.23%
Tina St. Leger	0	—
Professor Sir John Bell [9]	58,244	*
Travis Coy	0	—
Roy Herbst[10]	5,310	*
Siddharth Kaul[11]	2,282	*
Robert Perez	0	—
Kristine Peterson [12]	18,409	*
Professor Sir Peter Ratcliffe[13]	333	*
All current directors and executive officers as a group (11 persons)[14]	4,349,062	8.29%

* Represents beneficial ownership of less than one percent.

(1) The information shown is based upon disclosures on a Schedule 13G filed with the SEC on February 14, 2023. Consists of 5,559,322 [ADSs] held by certain funds managed by RTW Investments, LP (collectively, the "RTW Funds"). RTW Investments, LP is the investment adviser to the RTW Funds. Roderick Wong, M.D. is the Managing Partner and Chief Investment Officer of RTW Investments, L.P. Each of the RTW Funds and Dr. Wong disclaims any beneficial ownership of the shares directly held by the RTW Funds, except to the extent of its or his pecuniary interest therein. The address for each of these entities and individuals is 40 10th Avenue, Floor 7, New York, New York 10014.

(2) The number reported includes (i) 186,127 ordinary shares held in the form of ADSs and 173,907 non-voting ordinary shares held directly by 667, L.P. ("667") and (ii) 2,334,603 ordinary shares held in the form of ADSs and 1,991,053 non-voting ordinary shares held directly by Baker Brothers Life Sciences, L.P. ("Life Sciences", and together with 667, the "BBA Funds"). The non-voting ordinary shares may only be redesignated on a 1-for-1 basis into ordinary shares to the extent that after giving effect to such redesignation the holders 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 ("Beneficial Ownership Limitation"). By written notice to Immunocore, the BBA Funds may from time to time increase or decrease the Beneficial Ownership Limitation applicable to the BBA Funds 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 Immunocore. As a result of this restriction, the number of non-voting ordinary shares that may be redesignated into ordinary shares by the above holders may change depending upon changes in the outstanding ordinary shares. The Adviser is the investment adviser to the BBA Funds and has the sole voting and investment power with respect to the securities held by the BBA Funds and thus may be deemed to beneficially own such securities. Baker Bros. Advisors (GP) LLC (the "Adviser GP") is the sole general partner of the Baker Bros. Advisors LP (the "Adviser") and thus may be deemed to beneficially own the securities held by the BBA Funds. The managing members of the Adviser GP are Julian C. Baker and Felix J. Baker, who may be deemed to beneficially own the securities held by the BBA Funds. Julian C. Baker, Felix J. Baker, the Adviser and the Adviser GP disclaim beneficial ownership of all shares held by the BBA Funds, except to the extent of their indirect pecuniary interest therein. The business address of the Adviser, the Adviser GP, Julian C. Baker and Felix J. Baker is 860 Washington Street, 3rd Floor, New York, NY 10014.

(3) This information shown is based upon disclosures on a Schedule 13G filed with the SEC on February 14, 2023. Consists of (i)2,972,500 ADSs held by Rock Springs Capital Master Fund LP (the "Master Fund") and (ii) 348,566 ADSs owned by Four Pines Master Fund LP ("Four Pines"). Rock Springs Capital Management LP (the "Investment Advisor") is the investment advisor to the Master Fund and Four Pines. The Investment Advisor is ultimately owned and controlled by Kris Jenner, Mark Bussard and Graham McPhail. The general partner of the Master Fund is Rock Springs Capital LLC and the general partner of Four Pines is Four Pines General Partner LLC (the "General Partners"). The General Partners are each also ultimately owned and controlled by Kris Jenner, Mark Bussard and Graham McPhail. Kris Jenner, Mark Bussard and Graham McPhail disclaim beneficial ownership of these shares, except to the extent of their indirect pecuniary interest therein, if any. The address of the Investment Advisor is 650 South Exeter Street, Suite 1070, Baltimore, Maryland 21202.

(4) The information shown is based upon disclosures on a Schedule 13D/A filed with the SEC on January 17, 2023. Consists of 950,000 ADSs and 2,275,700 ordinary shares, held by GA IMC Holding, L.P. The limited partners that share beneficial ownership of the shares held by GA IMC Holding are the following General Atlantic investment funds: General Atlantic Partners (Bermuda) EU, L.P. ("GAP EU"), General Atlantic Partners (Bermuda) IV, L.P. ("GAP IV"), GAP Coinvestments III, LLC ("GAPCO III"), GAP Coinvestments IV, LLC ("GAPCO IV"), GAP Coinvestments V, LLC ("GAPCO V") and GAP Coinvestments CDA, LLC ("GAPCO CDA"). The general partner of GAP EU and GAP IV is General Atlantic GenPar (Bermuda), L.P. ("GenPar Bermuda"). GAP (Bermuda) Limited ("GAP (Bermuda) Limited") is the general partner of GenPar Bermuda. General Atlantic's address is c/o Conyers Client Services (Bermuda) Limited, Clarendon House, 2 Church Street, Hamilton MM II, Bermuda.

(5) The information shown is based upon disclosures on a Schedule 13G filed with the SEC on February 10, 2022 by Eli Lilly S.A and Eli Lilly and Company. Consists of 2,548,145 ordinary shares. Their business address is 16, Chemin des Coquelicots, 12 Geneva, Switzerland.

(6) Consists of 2,728,523 ordinary shares underlying options that are or will be exercisable within 60 days of February 1, 2023 held by Dr. Jallal.

(7) Consists of (a) 19,230 ordinary shares held by Mr. Di Donato and (b)421,152 ordinary shares underlying options that are or will be exercisable within 60 days of February 1, 2023 held by Mr Di Donato.

(8) Consists of 1,095,579 ordinary shares underlying options that are or will be exercisable within 60 days of February 1, 2023 held by Dr. Berman.

(9) Consists of (a) 13,452 ordinary shares and (b) 44,792 ordinary shares underlying options that are or will be immediately exercisable within 60 days of February 1, 2023 held by Professor Sir John Bell.

(10) Consists of 24,796 ordinary shares underlying options that are or will be exercisable within 60 days of February 1, 2023 held by Mr. Herbst.

(11) Consists of 2,282 ordinary shares underlying options that are or will be exercisable within 60 days of February 1, 2023 held by Mr. Kaul.

(12) Consists of 18,409 ordinary shares underlying options that are or will be exercisable within 60 days of February 1, 2023 held by Ms. Peterson.

(13) Consists of 333 ordinary shares held by Professor Sir Ratcliffe.

(14) Consists of (a) 33,015 ordinary shares and (b) 4,316,047 ordinary shares underlying options that are or will be exercisable within 60 days of February 1, 2023.

In February 2021, we completed our initial public offering and listed our ADSs on the Nasdaq Global Select Market. In the initial public offering, we issued and sold 11,426,280 ADSs, which included the full exercise by the underwriters of their option to purchase an additional 1,490,384 ADSs representing 11,426,280 ordinary shares. Upon the completion of our initial public offering and the concurrent private placement of 576,923 ADSs to the Bill and Melinda Gates Foundation, 43,786,088 ordinary shares were outstanding (including shares in the form of ADSs). While none of our existing shareholders sold ordinary shares in the initial public offering, the percentage ownership held by certain shareholders decreased as a result of the issuance of the ADSs sold by us in the initial public offering.

To our knowledge, other than as provided in the table above, our other filings with the SEC and this Annual Report, the significant changes in the percentage ownership held by our principal shareholders since January 1, 2019 are as a result of the transactions described in the final prospectus related to our initial public offering dated February 4, 2021, filed with the SEC on February 8, 2021 pursuant to Rule 424(b), under the heading “Related Party Transactions—Transactions with Our Principal Shareholders” and the dilution resulting from our initial public offering.

As of December 31, 2022, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States other than ADSs held by the entities set forth in the table above and certain other holders that we know to be non-residents of the United States, we estimate that approximately 48% of our outstanding ordinary shares (including ordinary shares underlying ADSs) were held in the United States by 139 holders of record. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

Policies and Procedures for Related Person Transactions

We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we or any of our subsidiaries and any related person are, were or will be participants in which the amount involved exceeds $120,000 or which is unusual in its nature or conditions. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our Audit Committee, or, if Audit Committee approval would be inappropriate, to another independent body of our board of directors for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third- party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

Transactions with Our Principal Shareholders, Directors and Executive Officers

The following is a description of related party transactions we and Immunocore Holdings Plc have entered into since January 1, 2021 with our directors, executive officers and holders of more than 5% of our outstanding voting securities and their affiliates, whom we refer to as our related persons, in which the amount involved exceeds $120,000 and that are material to us, other than the compensation arrangements we describe in "Item 6.B. Compensation—Compensation of Executive Officers and Directors." All of the historical share numbers in this section are as of dates prior to and do not reflect the conversion of each separate class of ordinary shares of Immunocore Holdings plc into a single class of ordinary shares, as described under Note 15 in our audited financial statements.

Agreements with Our Executive Officers and Directors

We have entered into service agreements with our executive officers and a direct services agreement with Dr. Bahija Jallal, our executive director. See "Item 6.B Compensation—Compensation of Executive Officers and Directors." These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by our executive officers. However, the enforceability of the non-competition provisions may be limited under applicable law.

Indemnification Agreements

We have entered into deeds of indemnity with each of our directors and executive officers. These agreements and our articles of association require us to indemnify our directors and executive officers to the fullest extent permitted by applicable law. See "Item 6.B Compensation—Insurance and Indemnification."

Securities Purchase Agreement and Registration Rights Agreement

On July 15, 2022, we entered into a securities purchase agreement, or Securities Purchase Agreement, with General Atlantic, Baker Brothers, Rock Springs Capital, and RTW (the "Investors"), pursuant to which we sold an aggregate of 3,733,333 ordinary shares, nominal value £0.002, consisting of 2,000,000 ADSs, and 1,733,333 non-voting ordinary shares, to the Investors through a private investment in public equity ("PIPE") at a purchase price of $37.50 per ADS/non-voting ordinary share, for gross proceeds of approximately $140 million.

Also on July 15, 2022, we entered into a registration rights agreement (the "Registration Rights Agreement") with the Investors, pursuant to which we agreed to register for resale the ADSs and the non-voting ordinary shares (the "Registrable Securities"). Under the Registration Rights Agreement, we agreed to use reasonable best efforts to file a registration statement covering the resale of the Registrable Securities by no later than September 30, 2022. We agreed to use reasonable best efforts to cause such registration statement to become effective as soon as practicable and to keep such registration statement effective until the date that (i) the Registrable Securities have been sold pursuant to an effective registration statement; (ii) the Registrable Securities have been sold by the Investors pursuant to Rule 144 (or another similar rule); (iii) the Registrable Securities have been sold or may be resold pursuant to Rule 144 without limitations or restrictions as to volume or manner of sale and without regard to compliance with any "current public information" requirement; or (iv) the date that is four (4) years from the Closing Date. The Company has agreed to be responsible for all fees and expenses incurred in connection with the registration of the Registrable Securities. In connection with the Registration Rights Agreement, we filed a prospectus supplement to the prospectus dated April 4, 2022 on September 30, 2022.

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 appended at the end of this Annual Report, starting at page F-1.

Dividend Distribution Policy

Since our incorporation, we have not declared or paid any dividends on our issued share capital. We intend to retain any earnings for use in our business and do not currently intend to pay dividends on our ordinary shares or ADSs. The declaration and payment of any future dividends will be at the discretion of our board of directors and will depend upon our results of operations, cash requirements, financial condition, contractual restrictions, any future debt agreements or applicable laws and other factors that our board of directors may deem relevant.

Under the laws of England and Wales, 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.

Legal Proceedings

We consider it in the ordinary course of our business that our patents and trademarks may become subject to adversarial proceedings. One of our patents, European Patent No. EP3116901, directed to a research tool relating to our ImmTAX platform, was opposed at the European Patent Office. Following the opposition hearing, the Opposition Decision issued a decision in favour of Immunocore, maintaining the patent as granted. The proceedings remain pending following the opposing party's appeal of the decision. We do not believe the ultimate resolution of this existing matter would have a material adverse effect on our business or financial condition and will also have no material adverse effect on the development of our product candidates. Trademark applications for our IMMTAX wordmark have been challenged by Immatics Biotechnologies GmbH (Immatics) in the UK, EU and US. A recent decision by the UK Intellectual Property Office (UKIPO) following the commencement of an invalidation action by Immatics found in favour of Immunocore. Immatics has subsequently filed an appeal of this decision. An ongoing invalidation action commenced by Immatics against our EU IMMTAX registration also remains pending. In addition, our U.S. trademark application for IMMTAX remains subject to an opposition by Immatics. In response, Immunocore has brought counterclaims against three of Immatics's U.S. registered trademarks for IMMATICS. If we are unsuccessful in defending one or more of these actions, we may be required to change our branding for our ImmTAX platform, which may cause us to incur substantial costs and impede our ability to build and sustain name recognition for ImmTAX.

There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage. However, we believe that no single patent, technology, trademark, intellectual property asset or license is material in relation to our business as a whole. For more information on risks associated with the European patent opposition proceedings and trademark opposition proceeding, see "Item 3.D Risk Factors—Risks Related to Intellectual Property."

In the summer and fall of 2020, we conducted an internal investigation as a result of receiving a whistleblower complaint alleging employee misconduct and other improper activities related to a kickback scheme involving an employee and two third-party vendors between 2018 and 2020. Our audit committee led the investigation utilizing outside counsel, during which the named employee resigned. The investigation led to the identification of a material weakness in our internal control over financial reporting. See "Item 3.D Risk Factors—We previously identified a material weakness in our internal control over financial reporting, which has since been remediated. We may identify or discover additional material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, which may impair our ability to produce timely and accurate financial statements or prevent fraud. If we are unable to establish and maintain effective internal controls, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs." After the investigation, we terminated the one remaining open contract with the third-party vendors and issued proceedings in October 2020 against the involved parties. We recovered our estimated losses of £1.8 million from the employee and third-party vendors in December 2020.

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

B. Significant Changes

Not applicable.

Item 9. The Offer and Listing.

A. Offer and Listing Details

Our ADS have been listed on the Nasdaq Global Select Market under the symbol "IMCR" since February 5, 2021. Prior to that date, there was no public trading market for ADSs or ordinary shares. Our ordinary shares are not listed on any exchange.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol "IMCR" since February 5, 2021. Prior to that date, there was no public trading market for ADSs or ordinary shares. Our ordinary shares are not listed on any exchange.

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 under the heading "Description of Share Capital and Articles of Association" is incorporated by reference from our final prospectus dated February 4, 2021 as part of our Registration Statement on Form F-1 (File No. 333-252166), declared effective by the SEC on February 4, 2021.

C. Material Contracts

In addition to the contracts described elsewhere in this Annual Report, the following are summaries of each material contract to which we are a party for the two years preceding the date of this Annual Report.

Underwriting Agreement

We entered into an underwriting agreement with Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC and Jefferies LLC as representatives of the underwriters, on February 4, 2021, with respect to the ADSs sold in our initial public offering. We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of such liabilities.

For additional information on our material contracts, please see "Item 4. Information on the Company," "Item 6. Directors, Senior Management and Employees," and "Item 7.B Related Party Transactions" of this Annual Report.

D. Exchange Controls

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or 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 U.K. and U.S. federal income tax consequences of the acquisition, ownership and disposition of our ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to beneficial owners of ADSs.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of 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 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, local and non-U.S. tax consequences, estate 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;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- 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;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- regulated investment companies or real estate investment trusts;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons holding shares or ADSs in connection with a trade or business outside the United States;
- persons that own or are deemed to own ten percent or more of our shares (by vote or value); 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 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 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 United Kingdom and the United States, the Treaty, all as of the date hereof, changes to any of which may affect the tax consequences described herein — possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs who is:

(1) an individual who is a citizen or resident of the United States;

(2) 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;

(3) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

(4) 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.

U.S. Holders are encouraged to consult their tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ordinary shares or ADSs in their particular circumstances.

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. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares.

Passive Foreign Investment Company rules

Under the Code, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the value of our assets (generally determined on the basis of a weighted quarterly average) consists of assets that produce, or are held for the production of, passive income (including cash). For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. Cash and cash-equivalents are passive assets for these purposes. 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 holds our shares, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements.

Based on our analysis of our activities and our income and assets, we believe that we were not a PFIC for our taxable year ending December 312022. However, 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, there can be no assurance that we will not be treated as a PFIC for the current or any future taxable year. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes (including goodwill) may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Accordingly, if our market capitalization declines while we hold a substantial amount of cash and cash-equivalents for any taxable year we may be a PFIC for that taxable year. Under the income test, our status as a PFIC depends on the composition of our income for the relevant taxable year which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how we spend the cash we raise in any offering. We currently do not generate product revenues and therefore we may be a PFIC for any taxable year in which we do not generate sufficient amounts of active income to offset our passive financing income. Therefore, we cannot express an expectation regarding our PFIC status for the current or any future taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for any prior, current or future taxable year.

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 we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules. If such a 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 are a PFIC and cease to be a PFIC and such election becomes available.

For each taxable year that we are treated as a PFIC with respect to U.S. Holders, U.S. Holders 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 a pledge) of ordinary shares or ADSs, unless (i) such U.S. Holder makes a "qualified electing fund" election, or QEF Election, with respect to all taxable years during such U.S. Holder's holding period in which we are a PFIC, or (ii) our ordinary shares or ADSs constitute "marketable stock" 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 a 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 disposition or distribution (as applicable), 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 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, 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 or any other entities in which we hold equity interests that also are PFICs ("lower-tier 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 lower-tier PFICs.

If a U.S. Holder makes an effective QEF election, the U.S. Holder will be required to include in gross income for each year in which we are a PFIC, whether or not we make distributions, as capital gains, such U.S. Holder's pro rata share of our net capital gains and, as ordinary income, such U.S. Holder's pro rata share of our earnings in excess of our net capital gains. An electing U.S. Holder's basis in our ordinary shares or ADSs will be increased to reflect the amount of any taxed but undistributed income. Distributions of income that had previously been taxed will result in a corresponding reduction of basis in the ordinary shares or ADSs and generally will not be taxed again as distributions to the U.S. Holder. In addition, a U.S. Holder that makes a QEF election will be taxed on the disposition of ordinary shares or ADSs as described in "Sale or other taxable disposition of ordinary shares and ADSs" below. In order to apply the QEF regime in lieu of the general PFIC rules described above, a U.S. Holder generally must make the QEF election for the first taxable year during a U.S. Holder's holding period in which we are treated as a PFIC.

A U.S. Holder can only make a QEF election with respect to ordinary shares or ADSs in a PFIC if the Company agrees to furnish such U.S. Holder with certain information annually. If we determine that the Company is a PFIC in any taxable year, we intend to make available to U.S. Holders, upon request and in accordance with applicable procedures and confidentiality requirements, a "PFIC Annual Information Statement" with respect to the Company for such taxable year. The "PFIC Annual Information Statement" may be used by U.S. Holders for purposes of complying with the reporting requirements applicable to a QEF election with respect to the Company.

A QEF election with respect to the Company will not apply to any of our lower-tier PFICs. If we determine that any of our current subsidiaries is a lower-tier PFIC for any taxable year in which the Company is a PFIC, we currently expect that we will provide the information necessary for U.S. Holders to make a QEF election with respect to such lower-tier PFIC, but there can be no assurance that we will be able to provide such information.

U.S. Holders should note that if they make a QEF election with respect to us, they may be required to pay U.S. federal income tax with respect to their ordinary shares or ADSs for any taxable year significantly in excess of any cash distributions (which are currently expected to be zero) received on the ordinary shares or ADSs for such taxable year. U.S. Holders should consult their tax advisors regarding PFIC investments and making QEF elections based on their particular circumstances.

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 stock." Ordinary shares or ADSs will be marketable stock if they are "regularly traded" on certain U.S. stock exchanges or on a non-U.S. 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. Our ADSs (but not ordinary shares) will be listed on the Nasdaq, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on the Nasdaq and are regularly traded, we expect the mark-to-market election would be available to U.S. Holders of our ADSs if we are a PFIC. Each U.S. Holder should consult its tax advisor as to the 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. 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 disposition of the ordinary shares or ADSs in any year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares 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 stock.

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 stock." 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 our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

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 may result in substantial penalties and extend the statute of limitations with respect to the U.S. Holder's federal income tax return. 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 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). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income." However, the qualified dividend income treatment will not apply if we are treated as a PFIC with respect to the U.S. Holder for our taxable year of the distribution 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 purposes, our dividends will generally be treated as passive category income.

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 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. 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. 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 taxpayer or an accrual basis taxpayer 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 taxpayer 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.

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.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals and certain closely-held 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 financial institutions, in which case the accounts themselves may have to be reported if maintained by non-U.S. financial institutions). 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.

U.K. Taxation

The following is intended as a general guide to current U.K. tax law and HM Revenue & Customs, or HMRC, practice 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 U.K. 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 U.K. taxation. It is written on the basis that the company does not (and will not) directly or indirectly derive 75% or more of its qualifying asset value from U.K. land, and that the company is and remains solely resident in the United Kingdom for tax purposes and will therefore be subject to the U.K. tax regime and not the U.S. tax regime save as set out above under "U.S. Federal Income Taxation."

Except to the extent that the position of non-U.K. 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 and to whom split year treatment does not apply) for tax purposes solely in the United Kingdom and do not have a permanent establishment, branch, agency (or equivalent) or fixed base in any other jurisdiction with which the holding of the ADSs is connected, or U.K. Holders, who are absolute beneficial owners of the ADSs (where the ADSs are not held through an Individual Savings Account or a Self-Invested Personal Pension) and who hold the ADSs as investments.

This guide may not relate to certain classes of U.K. Holders, such as (but not limited to):

- persons who are connected with the company;
- 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 officers or employees of the company or any of its affiliates; and
- individuals who are subject to U.K. taxation on a remittance basis

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 U.K. purposes as that person's own income) for U.K. direct tax purposes.

THESE PARAGRAPHS ARE A SUMMARY OF CERTAIN U.K. 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 SPECIFIC CIRCUMSTANCES FROM THEIR OWN TAX ADVISORS. IN PARTICULAR, NON-U.K. RESIDENT OR DOMICILED PERSONS ARE ADVISED TO CONSIDER THE POTENTIAL IMPACT OF ANY RELEVANT DOUBLE TAXATION AGREEMENTS.

Dividends

Withholding Tax

Dividends paid by the company will not be subject to any withholding or deduction for or on account of U.K. tax.

Income Tax

An individual U.K. Holder may, depending on his or her particular circumstances, be subject to U.K. tax on dividends received from the company. An individual holder of ADSs who is not resident for tax purposes in the United Kingdom should not be chargeable to U.K. income tax on dividends received from the company unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency to which the ADSs are attributable. There are certain exceptions for trading in the United Kingdom through independent agents, such as some brokers and investment managers.

All dividends received by an individual U.K. Holder from us or from other sources will form part of that U.K. Holder's total income for income tax purposes and will constitute the top slice of that income. A nil rate of income tax will apply to the first £2,000 of taxable dividend income received by the individual U.K. Holder in a tax year. Income within the nil rate band will be taken into account in determining whether income in excess of the £2,000 tax-free allowance falls within the basic rate, higher rate or additional rate tax bands. Dividend income in excess of the tax-free allowance will (subject to the availability of any income tax personal allowance) be taxed at 8.75% to the extent that the excess amount falls within the basic rate tax band, 33.75% to the extent that the excess amount falls within the higher rate tax band and 39.35% to the extent that the excess amount falls within the additional rate tax band. The annual tax-free dividend allowance will be reduced to £1,000 with effect from April 2023, and then to £500 with effect from April 2024.

Corporation Tax

A corporate holder of ADSs who is not resident for tax purposes in the United Kingdom should not be chargeable to U.K. corporation tax on dividends received from the company unless it carries on (whether solely or in partnership) a trade in the United Kingdom through a permanent establishment to which the ADSs are attributable.

Corporate U.K. Holders should not be subject to U.K. corporation tax on any dividend received from the company so long as the dividends qualify for exemption, which should be the case, although certain conditions must be met. If the conditions for the exemption are not satisfied, or such U.K. Holder elects for an otherwise exempt dividend to be taxable, U.K. corporation tax will be chargeable on the amount of any dividends (at the current rate of 19%, but with the main rate announced to increase to 25% with effect from April 1, 2023).

Chargeable Gains

A disposal or deemed disposal of ADSs by a U.K. Holder may, depending on the U.K. 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 U.K. capital gains tax and corporation tax on chargeable gains.

If an individual U.K. Holder who is subject to U.K. income tax at either the higher or the additional rate is liable to U.K. capital gains tax on the disposal of ADSs, the current applicable rate will be 20%. For an individual U.K. Holder who is subject to U.K. income tax at the basic rate and liable to U.K. capital gains tax on such disposal, the current applicable rate would be 10%, save to the extent that any capital gains when aggregated with the U.K. Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the rate currently applicable to the excess would be 20%.

If a corporate U.K. Holder becomes liable to U.K. corporation tax on the disposal (or deemed disposal) of ADSs, the main rate of U.K. corporation tax (currently 19%, but announced to increase to 25% with effect from April 1, 2023) would apply.

A holder of ADSs which is not resident for tax purposes in the United Kingdom should not normally be liable to U.K. 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 United Kingdom 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 United Kingdom for a period of less than five years and who disposes of ADSs during that period may be liable on his or her return to the United Kingdom to U.K. 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 Shares

No U.K. stamp duty or stamp duty reserve tax, or SDRT, is generally payable upon the issue of the underlying ordinary shares in the Company.

Transfers of Shares

An unconditional agreement to transfer ordinary shares in certificated form 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. The purchaser of the shares is liable for the SDRT. Transfers of ordinary shares in certificated form 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 next £5.00). Stamp duty is normally paid by the purchaser. The charge to SDRT will be canceled 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.

An unconditional agreement to transfer ordinary shares to, or to a nominee or agent for, a person whose business is or includes the issue of depositary receipts or the provision of clearance services will generally be subject to SDRT (or, where the transfer is effected by a written instrument, stamp duty) at a higher rate of 1.5% of the amount or value of the consideration given for the transfer unless the clearance service has made and maintained an election under section 97A of the U.K. 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 DTC. However, no SDRT is generally payable where the transfer of ordinary shares to a clearance service or depositary receipt system is an integral part of an issue of share capital.

Any stamp duty or SDRT payable on a transfer of ordinary shares to a depositary receipt system or clearance service will in practice generally be paid by the transferors or participants in the clearance service or depositary receipt system.

Issue of ADSs

No U.K. stamp duty or SDRT is payable on the issue of ADSs in the company.

Transfers of ADSs

No SDRT should be required to be paid on a paperless transfer of ADSs through the clearance service facilities of DTC, provided that no section 97A election has been made by DTC, and such ADSs are held through DTC at the time of any agreement for their transfer.

No U.K. stamp duty will in practice be payable on a written instrument transferring an ADS provided that the instrument of transfer is executed and remains at all times outside the United Kingdom. Where these conditions are not met, the transfer of, or agreement to transfer, an ADS could, depending on the circumstances, attract a charge to U.K. stamp duty at the rate of 0.5% of the amount or value of the consideration. If it is necessary to pay stamp duty, it may also be necessary to pay interest and penalties.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, 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. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at www.immunocore.com. We intend to post our Annual Report on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

With respect to references made in this Annual Report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this Annual Report for copies of the actual contract or document.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to interest rate, currency, credit and liquidity risks. Our executive board oversees the management of these risks supported by a financial risk committee that advises on financial risks and the appropriate financial risk governance framework for us. The financial risk committee provides assurance to our executive board that our financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with our policies and risk objectives. The most significant financial risks to which we are exposed include the risks discussed below.

Our principal financial assets include trade and other receivables and cash and security deposits that derive directly from our operations. Our principal financial liabilities comprise our borrowings under the Pharmakon Loan Agreement, lease liabilities and trade and other payables. The main purpose of these financial liabilities is to finance our operations. In connection with our entry into a subscription agreement with the Gates Foundation, we terminated the outstanding note purchase agreement by deed of termination as the terms of the subscription agreement provide that the Gates Foundation would instead subscribe for the remaining amount of the loan as part of a concurrent private placement in connection with our initial public offering in February 2021.

Interest Rate Risk

Our exposure to changes in interest rates relates to investments in deposits and to changes in the interest for overnight deposits. Changes in the general level of interest rates may lead to an increase or decrease in the fair value of these investments. As a result of entering into the Loan Agreement with Oxford Finance, we were exposed to interest rate risk as a variable rate of interest are applied within a defined cap and collar over the term of the debt. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. Following, repayment of the loan with Oxford Finance, under the first tranche of the loan drawn down under the Pharmakon Loan Agreement, we pay a fixed rate of interest.

We are currently not subject to interest rate risks related to any other liabilities shown in the statement of financial position.

Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. Our exposure to the risk of changes in foreign exchange rates relates primarily to fluctuations in value of foreign currency cash and cash equivalent balances held by our main operating subsidiary in the U.K., our operating activities in the United States, and outsourced supplier agreements denominated in currencies other than pound sterling.

Our cash and cash equivalents were £332.5 million and £237.9 million as of December 31, 2022 and 2021, respectively. As of December 31, 2022, 88% of our cash and cash equivalents were held by our U.K. subsidiary, of which 34% were denominated in pounds sterling, 56% were denominated in U.S. dollars and 10% were denominated in euros. The significant remainder of our cash and cash equivalents are held in the United States and denominated in U.S. dollars. Changes in exchange rates had a material impact on U.S. dollar balances held by the Group's main operating subsidiary in the U.K. during September 2022, which resulted in material foreign exchange gains in the Consolidated income statement due to the appreciation of the subsidiary's U.S. dollars in pounds sterling terms. Further movements in exchange rates or returns to previous exchange rate levels have caused, and may continue to cause, material fluctuations or equivalent losses in the Consolidated income statement.

A five percentage point increase in exchange rates would reduce the carrying value of net financial assets and liabilities held in foreign currencies at December 31, 2022 by £5.2 million and as at December 31, 2021 by £2.3 million. A five percentage point decrease in exchange rates would increase the carrying value of net financial assets and liabilities held in foreign currencies at December 31, 2022 by £5.2 million and as at December 31, 2021 by £2.3 million.

Credit Risk

We are exposed to credit risk from our operating activities, primarily trade receivables, and cash, cash equivalents and deposits held with banks and financial institutions. Cash, cash equivalents and deposits are maintained with high-quality financial institutions in the United Kingdom and United States. We are also potentially subject to concentrations of credit risk in our trade receivables. Concentrations of credit risk are with respect to trade receivables owed by a limited number of companies comprising our customer base. Our exposure to credit losses is low, however, owing largely to the credit quality of our distributors, collaboration partners, and other customers, the significant majority of which are considerably larger than us.

We continually monitor our positions with, and the credit quality of, the financial institutions and corporations, which are counterparts to our financial instruments and do not anticipate non-performance. The maximum default risk corresponds to the carrying amount of the financial assets shown in the statement of financial positions. We monitor the risk of a liquidity shortage. The main factors considered here are the maturities of financial assets as well as expected cash flows from equity measures.

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

Citibank, N.A., as depositary bank, registers and delivers our American Depositary Shares, also referred to as ADSs. Each ADS represents one ordinary share (or a right to receive one ordinary share) deposited with Citibank, N.A., London Branch, or any successor, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary's corporate office at which the ADSs are administered is located at 388 Greenwich Street, New York, New York 10013. A deposit agreement among us, the depositary and the ADS holders sets out ADS holder rights as well as the rights and obligations of the depositary. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report.

Fees and Charges

As an ADS holder, you will be required to pay the following fees to the Depositary under the terms of the deposit agreement:

Service	Fee
Issuance of ADSs (*e.g.*, an issuance of ADS upon a deposit of ordinary shares or upon a change in the ADS(s)-to-ordinary shares ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to $0.05 per ADS issued
Cancellation of ADSs (*e.g.*, a cancellation of ADSs for delivery of deposited property or upon a change in the ADS(s)-to-ordinary shares ratio, or for any other reason)	Up to $0.05 per ADS cancelled
Distribution of cash dividends or other cash distributions (*e.g.*, upon a sale of rights and other entitlements)	Up to $0.05 per ADS held
Distribution of ADSs pursuant to (i) share dividends or other distributions, or (ii) exercise of rights to purchase additional ADSs	Up to $0.05 per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (*e.g.*, upon a spin-off)	Up to $0.05 per ADS held
ADS services	Up to $0.05 per ADS held on the applicable record date(s) established by the depositary

As an ADS holder, you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;

- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary in the conversion of foreign currency;
- the fees and expenses incurred by the depositary in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depositary, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs.

In the event of refusal to pay the depositary fees or charges, the depositary may, under the terms of the Deposit Agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees and charges from any distribution to be made to the ADS holder. Note that the fees and charges holders may be required to pay may vary over time and may be changed by us and by the depositary. Holders will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADSs, by making available a portion of the ADS fees charged in respect of the ADSs or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

A. Not applicable.

B. Not applicable.

C. Not applicable.

D. Not applicable.

E. Use of Proceeds.

Not applicable.

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 Securities Exchange Act of 1934, as amended, or 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, 2022. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2022, 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. Exchange Act Rules 13a-15(f) and 15d-15(f) define this as a process designed by, or under the supervision of, the Company's chief executive and financial officers and effected by the Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with International Financial Reporting Standards (as adopted by the IASB).

Due to its inherent limitations, internal control over financial reporting may not detect all misstatements. Furthermore, projections of any evaluation of the effectiveness of internal controls to future periods may prove invalid due to changes in the Company's circumstances and the risk that compliance with policies, procedures and controls is not sustained.

Management has assessed the effectiveness of internal control over financial reporting as of December 31, 2022 based on the Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) 2013. Based on this assessment, management has concluded that our internal control over financial reporting as of December 31, 2022 was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report that is included herein.

C. Attestation Report of the Registered Public Accounting Firm

Our independent registered public accountant, KPMG LLP, who audited the consolidated financial statements included in this annual report, have audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2022. KPMG LLP's report is included below.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Immunocore Holdings plc:

Opinion on Internal Control Over Financial Reporting

We have audited Immunocore Holdings plc and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2022 and 2021, the related consolidated statements of loss and, other comprehensive (loss)/income, changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes collectively, and our report dated March 1, 2023 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

London, United Kingdom

March 1, 2023

D. Changes in Internal Control Over Financial Reporting

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 period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert.

Our Board has determined that Mr. Coy is an "audit committee financial expert" as defined by SEC rules and has the requisite financial sophistication under the applicable rules and regulations of the Nasdaq Stock Market. Mr. Coy is 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 Code of Business Conduct and Ethics that is applicable to all of our employees, officers and directors and is available on our website at https://ir.immunocore.com/corporate-governance/document-charters. Information contained on, or that can be accessed through, our website does not constitute a part of this report and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. Under Item 16B of Form 20-F, if a waiver or amendment of the Code of Business Conduct and Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

Item 16C. Principal Accountant Fees and Services.

KPMG LLP has served as our independent registered public accountant since 2009 and has audited our consolidated financial statements for the years ended December 31, 2022 and 2021.

The following table shows the aggregate fees for services rendered by KPMG LLP to us and our subsidiaries, in the fiscal year ended December 31, 2022 and 2021.

	Year Ended December 31,	
	2022	2021
	£ '000	£ '000
Audit fees	£ 1,107	£ 775
Total	**£ 1,107**	**£ 775**

Audit fees. Audit fees consisted of fees for the audit of our annual financial statements and other professional services provided in connection with the statutory and regulatory filings or engagements, including fees for the review of our interim financial information, comfort letters and consents.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee reviews and pre-approves the scope and the cost of audit services related to us and permissible non-audit services performed by the independent auditors. All of the services related to us provided by KPMG LLP during the last fiscal year have been pre-approved by the audit committee.

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.

While there has been no change in our certifying accountant, we announced on November 9, 2022 that we intend to propose to shareholders at our 2023 Annual General Meeting in May 2023 that Deloitte LLP be appointed to serve as our U.K. statutory auditor and our independent registered public accounting firm for the fiscal year ending December 31, 2023. This decision was taken following a competitive audit tender. KPMG LLP, our current independent registered public accounting firm, is expected to resign before the 2023 Annual General Meeting to be held in May 2023. Upon KPMG LLP's resignation, the board of directors will appoint Deloitte LLP as our U.K. statutory auditor and independent registered public accounting firm, subject to shareholder approval at the 2023 Annual General Meeting.

During the two fiscal years ended December 31, 2022 and 2021 and any subsequent interim period there were: (1) no disagreements with KPMG LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements if not resolved to their satisfaction would have caused them to make reference in connection with their opinion to the subject matter of the disagreement, and (2) no reportable events as defined under Item 16F(a)(1)(v).

The audit reports of KPMG LLP on the consolidated financial statements of Immunocore Holdings plc and subsidiaries as of and for the years ended December 31, 2022 and 2021, did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

The Company has requested that KPMG LLP furnish it with a letter addressed to the SEC stating whether or not it agrees with the above statements. A copy of such letter, dated March 1, 2023, is filed as Exhibit 16.1 to this annual report.

Item 16G. Corporate Governance.

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with Nasdaq rules, we comply with home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. We voluntarily follow most Nasdaq corporate governance rules, but 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 securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- Exemption from quorum requirements for shareholder meetings. In accordance with usual practice in England and Wales, our articles of association will provide alternative quorum requirements that are generally applicable to shareholder meetings;
- Exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to 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 responsibilities 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 requirements that director nominees are selected, or recommended for selection by our board, either by (1) independent directors constituting a majority of our board's independent directors in a vote in which only independent directors participate, or (2) a committee comprised solely of independent directors, and that a formal written charter or board resolution, as applicable, addressing the nominations process is adopted.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as we, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625), the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to U.K. requirements in lieu of many of the Nasdaq corporate governance rules, we comply with the Nasdaq corporate governance rules applicable to foreign private issuers.

Accordingly, our shareholders do not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure.

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 17. Financial Statements.

See pages F-1 through F-47 of this Annual Report.

Item 18. Financial Statements.

Not applicable

Item 19. Exhibits

Exhibit	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
1.1	Articles of Association of Immunocore Holdings plc.	20-F	001-39992	1.1	03/25/21
2.1	Deposit Agreement.	20-F	001-39992	2.2	03/25/21
2.2	Form of American Depositary Receipt (included in Exhibit 2.2).	20-F	001-39992	2.3	03/25/21
2.3	Description of Securities.	20-F	001-39992	2.4	03/25/21
4.1	Subscription Agreement between the Registrant and the Bill & Melinda Gates Foundation, dated February 3, 2021.	F-1/A	333-252166	4.3	02/03/21
4.2†	Research Collaboration and License Agreement, dated as of June 14, 2013, by and among the Registrant, Genentech, Inc. and F. Hoffman-La Roche Ltd, as amended on September 27, 2016.	F-1	333-252166	10.5	01/15/21
4.3†	License Agreement, dated as of September 27, 2016, between the Registrant and Genentech, Inc.	F-1	333-252166	10.8	01/15/21
4.4†	License and Collaboration Agreement, dated as of November 15, 2018, by and among the Registrant, Genentech, Inc. and F. Hoffman-La Roche Ltd.	F-1	333-252166	10.9	01/15/21
4.5	Amended and Restated Global Access Commitments Agreement, dated as of March 2, 2020, between the Registrant and the Bill & Melinda Gates Foundation.	F-1	333-252166	10.11	01/15/21
4.6†	First Amendment to the Amended and Restated Global Access Commitments Agreement, dated as of February 3, 2021, between the Registrant and the Bill & Melinda Gates Foundation.	F-1/A	333-252166	10.12	02/03/21
4.7	Lease, dated as of March 28, 2017, between the Registrant and MEPC MILTON PARK NO. 1 LIMITED and MEPC MILTON PARK NO. 2 LIMITED, on behalf of MEPC Milton LP.	F-1	333-252166	10.13	01/15/21
4.8	Lease, dated as of December 28, 2017, between the Registrant and MEPC MILTON PARK NO. 1 LIMITED and MEPC MILTON PARK NO. 2 LIMITED, on behalf of MEPC Milton LP.	F-1	333-252166	10.14	01/15/21
4.9	Lease, dated as of March 28, 2017, between the Registrant and MEPC MILTON PARK NO. 1 LIMITED and MEPC MILTON PARK NO. 2 LIMITED, on behalf of MEPC Milton LP.	F-1	333-252166	10.15	01/15/21
4.10†	Assignment and Exclusive License, dated as of January 28, 2015, between the Registrant and Adaptimmune Limited.	F-1	333-252166	10.16	01/15/21

4.11#	Employment Agreement between the Registrant and Bahija Jallal, Ph.D., dated January 29, 2021.	F-1/A	333-252166	10.18	02/01/21
4.12	Form of Deed of Indemnity between the Registrant and each of its directors.	F-1	333-252166	10.1	01/15/21
4.13#	Form of Deed of Indemnity between the Registrant and each of its executive officers.	F-1	333-252166	10.2	01/15/21
4.14#	Immunocore Holdings plc 2021 Equity Incentive Plan. and Non-Employee Sub Plan to the Immunocore Holdings plc 2021 Equity Incentive Plan	20-F	001-39992	4.20	03/25/21
4.15	Registration Rights Agreement, dated July 15, 2022, by and among Immunocore Holdings plc and the investors party thereto.	6-K	0001671927	99.2	07/20/22
4.16	Sales Agreement, dated as of September 9, 2022, by and between the Company and Jefferies LLC.	6-K	0001671927	99.1	09/09/22
4.17†	Loan agreement, dated as of November 8, 2022, among Immunocore Limited, as Borrower, the Registrant, certain additional Credit Parties and Guarantors party thereto, BioPharma Credit PLC, as Collateral Agent, and BPCR Limited Partnership and BioPharma Credit Investments V (Master) LP as Lenders.	6-K	0001671927	99.4	11/09/22
8.1	Subsidiaries of the Registrant.	20-F	001-39992	8.1	03/25/21
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer and the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
15.1*	Consent of KPMG LLP				
16.1*	Letter from KPMG LLP dated [ ], 2023				
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 Document				

101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

† Certain portions of this exhibit (indicated by asterisks) have been redacted in accordance with Regulation S-K, Item 601(b)(10).

# 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.

IMMUNOCORE HOLDINGS PLC

By: /s/ Bahija Jallal
Bahija Jallal, Ph.D.
Chief Executive Officer
(*Principal Executive Officer*)

Date: March 1, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Immunocore Holdings plc

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statement of financial position of Immunocore Holdings plc and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of loss and other comprehensive (loss)/income, changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2022, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 1, 2023 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Evaluating deductions from revenue related to rebates and chargeback accruals

As discussed in Note 2 to the consolidated financial statements, the Group records net product revenue by deducting rebates and chargebacks, among other items. The rebates and chargebacks relate to future payments to government agencies and are estimated and accrued with a corresponding reduction of gross product revenues when revenue is recognized. As at December 31, 2022, the Group recorded total accrued revenue deductions within trade and other payables and non-current accruals in the consolidated statement of financial position of £25.5 million, of which £22.5 million was subject to greater estimation uncertainty due to ongoing negotiations with the relevant local authorities.

We identified the evaluation of deductions from revenue related to rebates and chargebacks accruals as a critical audit matter because evaluating the Group's assumptions of the expected rebate and chargeback percentages involved challenging auditor judgment. In particular, specialized skills and knowledge was required in evaluating the regulatory legislation and ongoing pricing negotiations within each jurisdiction and challenging auditor judgement was required in evaluating the relevance and reliability of information used in the Group's assumptions.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Group's pre-product revenue and product revenue rebates and chargeback accruals process. We compared the Group's estimate of total expected rebates and chargebacks to the actual payments made to assess the Group's ability to accurately estimate costs. We involved an internal health and life sciences professional with specialist skills and knowledge, who assisted in evaluating the regulatory legislation and ongoing price negotiations within the relevant jurisdictions used in the Group's estimation model. We tested the estimate of the accrued revenue deductions, using a combination of Group internal data and third-party data and compared our estimate to the amount recorded by the Group. We identified and considered the relevance, reliability and sufficiency of sources of data used by the Group in developing the estimate. We also performed sensitivity analyses based on potential changes in certain assumptions and assessed the impact relative to the Group's accruals as of December 31, 2022.

/s/ KPMG LLP

We have served as the Company's auditor since 2009

London, United Kingdom
March 1, 2023

Immunocore Holdings Plc
Annual report and consolidated financial statements
December 31, 2022

Consolidated Statements of Loss and Other Comprehensive (Loss) / Income for the years ended December 31,

	Notes	2022 £'000	2021 £'000	2020 £'000
Product revenue, net	2	108,148	—	—
Pre-product revenue, net		8,661	3,010	—
Total revenue from sale of therapies		116,809	3,010	—
Collaboration revenue		26,928	23,510	30,114
Total revenue		**143,737**	**26,520**	**30,114**
Cost of product revenue		(454)	—	—
Net other operating income/ (loss)	6	3	(57)	4,242
Research and development costs		(89,170)	(73,226)	(74,809)
Selling and administrative expenses		(93,723)	(88,399)	(45,740)
Operating loss		**(39,607)**	**(135,162)**	**(86,193)**
Finance income	7	3,154	47	2,208
Finance costs	8	(7,692)	(5,813)	(3,375)
Non-operating expense		**(4,538)**	**(5,766)**	**(1,167)**
Loss before taxation		**(44,145)**	**(140,928)**	**(87,360)**
Income tax credit	9	2,921	9,405	13,267
Loss for the year		**(41,224)**	**(131,523)**	**(74,093)**
Other comprehensive (loss) / income				
Other comprehensive (loss) / income that is or may be reclassified to profit or loss in subsequent periods (net of tax):				
Exchange differences on translation of foreign operations		(3,186)	(74)	195
Total other comprehensive (loss) / income for the year, net of tax		**(3,186)**	**(74)**	**195**
Total comprehensive loss for the year, net of tax		**(44,410)**	**(131,597)**	**(73,898)**
Basic and diluted loss per share - £	10	**(0.90)**	**(3.10)**	**(2.79)**

The accompanying notes form an integral part of these financial statements.

Immunocore Holdings Plc
Annual report and consolidated financial statements
December 31, 2022

Consolidated Statements of Financial Position as at December 31,

	Notes	2022 £'000	2021 £'000
Non-current assets			
Property, plant and equipment	11	6,472	8,944
Intangible assets		410	—
Right of use assets	12	25,173	22,593
Other non-current assets	13	7,342	4,935
Deferred tax asset	9	4,240	2,575
Total non-current assets		**43,637**	**39,047**
Current assets			
Inventory		943	—
Trade and other receivables	14	46,711	15,208
Tax receivable	9	11,688	9,632
Cash and cash equivalents		332,539	237,886
Total current assets		**391,881**	**262,726**
Total assets		**435,518**	**301,773**
Equity			
Share capital	15	97	88
Share premium	15	123,751	212,238
Foreign currency translation reserve	15	(3,097)	89
Other reserves	15	337,847	386,167
Share-based payment reserve	15, 19	81,411	54,357
Accumulated deficit		(261,253)	(481,392)
Total equity		**278,756**	**171,547**
Non-current liabilities			
Non-current accruals	16	1,479	—
Interest-bearing loans and borrowings	17	39,500	37,226
Deferred revenue	2	4,331	6,408
Lease liabilities	12	28,248	25,355
Provisions		114	57
Total non-current liabilities		**73,672**	**69,046**
Current liabilities			
Trade and other payables	18	75,076	35,436
Deferred revenue	2	6,408	24,450
Lease liabilities	12	1,555	1,255
Provisions		51	39
Total current liabilities		**83,090**	**61,180**
Total liabilities		**156,762**	**130,226**
Total equity and liabilities		**435,518**	**301,773**

The accompanying notes form an integral part of these financial statements.

Immunocore Holdings Plc
Annual report and consolidated financial statements
December 31, 2022

Consolidated Statements of Changes in Equity for the years ending December 31, 2020, 2021 and 2022

	Note	Share capital - adjusted	Share premium - adjusted	Foreign currency translation reserve	Share-based payment reserve	Other reserves - adjusted	Accumulated deficit	Total equity
		£'000	£'000	£'000	£'000	£'000	£'000	£'000
At January 1, 2020	15	**49**	**—**	**(32)**	**10,659**	**283,201**	**(279,106)**	**14,771**
Loss for the year	15,19	—	—	—	—	—	(74,093)	(74,093)
Other comprehensive loss		—	—	195	—	—	—	195
Total comprehensive loss for the year		**—**	**—**	**195**	**—**	**—**	**(74,093)**	**(73,898)**
Conversion of interest-bearing loan	15	—	—	—	—	—	(510)	(510)
Derecognition of derivative liability	15,19	—	—	—	—	—	3,840	3,840
Issue of share capital	15	15	—	—	—	102,966	—	102,981
Equity-settled share-based payment transactions	15,19	—	—	—	8,162	—	—	8,162
At December 31, 2020		**64**	**—**	**163**	**18,821**	**386,167**	**(349,869)**	**55,346**
Loss for the year		—	—	—	—	—	(131,523)	(131,523)
Other comprehensive loss		—	—	(74)	—	—	—	(74)
Total comprehensive loss for the year		**—**	**—**	**(74)**	**—**	**—**	**(131,523)**	**(131,597)**
Issue of share capital	15	24	210,961	—	—	—	—	210,985
Exercise of share options			952	—	—	—	—	952
Equity-settled share-based payment transactions	15,19	—	325	—	**35,536**	—	—	35,861
At December 31, 2021		**88**	**212,238**	**89**	**54,357**	**386,167**	**(481,392)**	**171,547**
Loss for the year		—	—	—	—	—	(41,224)	(41,224)
Other comprehensive income		—	—	(3,186)	—	—	—	(3,186)
Total comprehensive loss for the year		**—**	**—**	**(3,186)**	**—**	**—**	**(41,224)**	**(44,410)**
Issue of share capital	15	7	116,417	—	—	—	—	116,424
Exercise of share options		2	8,139	—	—	—	—	8,141
Capital reduction in Group's parent company	15	—	(213,043)	—	—	(48,320)	261,363	—
Equity-settled share-based payment transactions	15,19	—	—	—	27,054	—	—	27,054
At December 31, 2022	15	**97**	**123,751**	**(3,097)**	**81,411**	**337,847**	**(261,253)**	**278,756**

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Consolidated Statements of Cash Flows for the years ended December 31,

	Notes	2022 £'000	2021 £'000	2020 £'000
Cash flows from operating activities				
Loss for the year		**(41,224)**	**(131,523)**	**(74,093)**
Adjustments for:				
Equity settled share-based payment expenses	19	27,054	35,861	8,162
Depreciation	11,12	6,131	7,012	8,976
Net finance costs		4,538	5,766	1,167
Foreign exchange movements		(6,033)	586	(787)
Other		67	165	(2,863)
Income tax credit	9	(2,921)	(9,405)	(13,267)
Working capital adjustments:				
Increase in receivables and other non-current assets		(32,090)	(5,147)	(532)
Increase in trade and other payables		38,747	9,469	(3,774)
Decrease in deferred revenue	2	(20,119)	(21,128)	(24,497)
Other working capital movements		577	(150)	(41)
Cash used in operations		**(25,273)**	**(108,494)**	**(101,549)**
Net taxation (paid) / received		(618)	12,384	40,299
Net cash used in operating activities		**(25,891)**	**(96,110)**	**(61,250)**
Cash flows from investing activities				
Proceeds from sale of property, plant and equipment		5	77	675
Purchase of property, plant and equipment	11	(1,787)	(1,008)	(3,074)
Purchase of intangible assets		(410)	—	—
Proceeds from investment in sub-leases		—	549	378
Other investing activities		2,385	15	3,164
Net cash flows from / (used in) investing activities		**193**	**(367)**	**1,143**
Cash flows from financing activities				
Gross proceeds from issue of share capital	15	116,812	226,528	83,218
Costs from issue of share capital	15	(388)	(15,543)	(176)
Exercise of share options		8,141	952	73
Non-current interest-bearing loan received	17	43,509	—	37,543
Repayment of principal loan liability	17	(43,509)	—	—
Early settlement and other loan fees	17, 20	(3,280)	—	—
Interest paid on non-current interest-bearing loans		(3,623)	(4,147)	(291)
Repayment of lease liabilities	12	(3,208)	(3,159)	(4,426)
Net cash flows from financing activities		**114,454**	**204,631**	**115,941**
Increase in net cash and cash equivalents		88,756	108,154	55,834
Net foreign exchange difference on cash held		5,897	16	(84)
Cash and cash equivalents at beginning of the year		237,886	129,716	73,966
Cash and cash equivalents at end of the year		**332,539**	**237,886**	**129,716**

Other investing activities primarily relates to interest received, and in 2020 included £2,488,000 of leasehold incentives.

The accompanying notes form an integral part of these financial statements.

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Consolidated Notes to the Financial Statements

1. Accounting policies

General information

Immunocore Holdings plc (the "Company") is a public limited company incorporated in England and Wales and has the following wholly owned subsidiaries: Immunocore Limited, Immunocore LLC, Immunocore Commercial LLC, Immunocore Ireland Limited, Immunocore GmbH, and Immunocore Nominees Limited (collectively referred to as the "Group").

The Company's American Depositary Shares ("ADSs") began trading on the Nasdaq Global Select Market under the ticker symbol "IMCR" on February 5, 2021, following its initial public offering ("IPO"). The IPO and concurrent private placement generated net proceeds of £210,985,000 after underwriting discounts, commissions and directly attributable offering expenses. In July 2022, the Company issued and sold a total of 3,733,333 ADSs and non-voting ordinary shares to certain institutional accredited investors and existing shareholders as a private investment in public entity (the "PIPE") pursuant to a securities purchase agreement with such investors, generating proceeds of £116,812,000 ($140,000,000) before deductions for offering expenses of £388,000.

Prior to completion of the IPO, Immunocore Holdings Limited was incorporated in England and Wales on January 7, 2021. Following a subsequent corporate reorganization, Immunocore Holdings Limited became the ultimate parent company for the Group and was re-registered as a public limited company with the name Immunocore Holdings plc, the registrant. The corporate reorganization was accounted for as a business combination under common control and therefore, Immunocore Holdings plc is a continuation of Immunocore Limited and its subsidiaries. The corporate reorganization was given retrospective effect in the financial statements as at and for the years ended December 31, 2021 and 2020, and the financial statements represent the financial statements of Immunocore Holdings plc.

The principal activity of the Group is pioneering the development and sale of a novel class of TCR bispecific immunotherapies called ImmTAX –**I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **X** disease – designed to treat a broad range of diseases, including cancer, infectious and autoimmune diseases. Leveraging its proprietary, flexible, off-the-shelf ImmTAX platform, the Group is developing a deep pipeline in multiple therapeutic areas, including four clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune disease and multiple earlier pre-clinical programs.

In January and April 2022, the Group received approval from the U.S. Food and Drug Administration ("FDA") and European Commission ("EC"), respectively, for its lead product, KIMMTRAK, for the treatment of unresectable or metastatic uveal melanoma ("mUM"). In June 2022, the UK's MHRA, Health Canada, and the Australian Government Department of Health's TGA have each approved KIMMTRAK for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM. KIMMTRAK is now approved in over 30 countries and we have commercially launched in the United States, Germany and France, among other territories, with further commercial launches underway in additional territories where we have received approval. The Group expects to obtain regulatory approval for KIMMTRAK in further territories in the next year.

Basis of preparation and statement of compliance

The consolidated Group financial statements as of December 31, 2022 and 2021 and for the years ended December 31, 2022, 2021 and 2020 have been prepared in accordance with International Financial Reporting Standards (collectively, "IFRS") as issued by the International Accounting Standards Board.

The consolidated Group financial statements have been prepared under the historical cost basis, as modified by the recognition of certain financial instruments measured at fair value and are presented in sterling which is the Group's presentation currency. All values are rounded to the nearest thousands, except where otherwise indicated.

Date of authorization

These consolidated financial statements were prepared at the request of the Board and were approved by the Board on March 1, 2023, and signed on its behalf by Dr Bahija Jallal, Chief Executive Officer of the Group.

Adoption of New Accounting Standards

There have been no recent new accounting standards that have had a material impact on these consolidated financial statements and no new standards issued but not yet effective that are expected to have a significant impact on the Group.

Going concern

The financial position of the Group, its cash flows and liquidity position and borrowing facilities are described in the primary statements and notes to these sets of financial statements.

The Group reported cash and cash equivalents of £332,539,000 and net current assets of £308,791,000 as at December 31, 2022, with an operating loss for the year the ended December 31, 2022 of £39,607,000. The negative operational cash flow was largely due to the Group's continued focus on research, development, and clinical activities to advance preclinical and clinical programs within the Group's pipeline. The Group generated net product and net pre-product revenue totalling £108,148,000 and £8,661,000 during the year ended December 31, 2022, respectively. In July 2022, the Group received £116,812,000 ($140,000,000) before deduction of attributable expenses of £388,000 following the PIPE.

In assessing the going concern assumptions, the Board has undertaken an assessment of the current business and strategy forecasts covering a three-year period, which includes anticipated KIMMTRAK revenue. In assessing the downside risks, the Board has also considered scenarios incorporating a range of revenue arising from KIMMTRAK sales. As part of considering the downside risks, the Board has considered the impact of the ongoing coronavirus 2019 (''COVID-19'') pandemic and other potential economic impacts including the war in Ukraine and related geopolitical tensions, as well as global inflation, capital market instability, exchange rate fluctuations, and increases in commodity, energy and fuel prices. The Board has concluded that while these may have a future impact on the Group's business and implementation of its strategy and plans, it anticipates that any such impact will be minimal on clinical trials or other business activities over the period assessed for going concern purposes. As of the date of these financial statements, the Group is not aware of any specific event or circumstance that would require the Group to update its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. Actual results could differ from these estimates, and any such differences may be material to the Group's financial statements.

Given the current cash position and the assessment performed, the Board believes that the Group will have sufficient funds to continue to meet its liabilities as they fall due throughout the forecast period outlined above and therefore, the Group has prepared the financial statements on a going concern basis. This scenario is based on the Group's lower range of anticipated revenue levels. As the Group continues to incur significant expenses in the pursuit of its business strategy, including further commercialization and marketing plans for KIMMTRAK, additional funding will be needed before further existing clinical and preclinical programs may be expected to reach commercialization, which would potentially lead to additional operational cash inflows. Until the Group can generate revenue from product sales sufficient to fund its ongoing operations and further develop its pipeline, if ever, it expects to finance its operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements.

Critical accounting estimates and judgments

The preparation of the financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions. These judgments, estimates and assumptions affect the reported assets and liabilities as well as income and expenses in the financial period.

The estimates and associated assumptions are based on information available when the consolidated financial statements are prepared, historical experience and various other factors which are believed to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the Group's control. Hence, estimates may vary from the actual values.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or the period of revision and future periods if this revision affects both current and future periods.

Expected rebates and chargebacks

As outlined below in the "Product revenue, net" policy, the Group recognizes revenue net of estimated deductions for rebates and chargebacks.

Due to its short history of product sales having only recently received regulatory approval for its first product, the Group has limited directly comparable information of actual rebate claims or chargebacks, and the Group's early sales information may have limited predictive value. The Group uses the expected value method to estimate expected rebate and chargeback percentages for revenue deductions, which considers the likelihood of a rebate or chargeback being applicable to sales. The proportion of sales subject to a rebate or chargeback, is inherently uncertain and the Group's estimates are based on internal assumptions, which may change as the Group develops more product experience, and third-party data, which the Group assesses for reliability and relevance.

The Group is subject to state government Medicaid programs and other qualifying federal and state programs in the United States requiring rebates to be paid to participating state and local government entities, depending on the eligibility and circumstances of patients treated with KIMMTRAK after the Group has sold vials to specialty distributors. The Group is also subject to chargebacks from its specialty distributors under the 340B program in the United States, whereby qualifying hospitals are entitled to purchase KIMMTRAK at a lower price. For such sales, the Group's specialty distributors charge back the difference between the wholesale acquisition cost and this lower price. Estimating expected rebate and chargeback percentages for revenue deductions is judgmental due to the time delay between the date of the sale to specialty distributors and the subsequent dates on which the Group is able to determine actual amounts of chargebacks and rebates. The Group forms estimates of 340B chargeback deductions by analyzing sell-through data relating to the hospital mix of onward sales made by specialty distributors. For Medicaid and other rebates, the Group forms estimates based on internal forecasts of the patient mix, information obtained from claims received and other industry data, and external health coverage statistics. Judgment is applied to consider the relevance and reliability of information used to make these estimates.

Judgment is also required in determining expected rebate percentages for the amount of the Group's net pre-product revenue and product revenue in France. Rebates payable to the Economic Committee for Health Products ("CEPS") under compassionate use, early access and commercial programs are subject to a high degree of estimation uncertainty. The Group's estimate of these rebates represents the difference between the expected agreed price for the commercial sale of KIMMTRAK in France, which is subject to negotiation, and the initial price of tebentafusp and KIMMTRAK sold under early access and commercial programs until this price is agreed. Analysis of further legislative requirements, sales volumes and the expected benefit of KIMMTRAK to patients in France is also required in the assessment of rebates payable. The Group applies judgement to assess internal targets, pricing information of other therapies approved for sale in France, information obtained from price negotiations of KIMMTRAK in other countries, and information connected with KIMMTRAK's safety profile when forming its estimated rebate deduction from revenue.

The Group also applies judgment when recording net product revenue in Germany by considering internal targets, KIMMTRAK's benefit rating and the progress of negotiations to estimate the expected rebate percentages for the amounts payable on conclusion of the pricing process following recent legislative changes in the country.

The Group's total accrued revenue deductions at December 31, 2022, including amounts of £22.5 million for the critical estimates subject to greater estimation uncertainty and judgments described above, were £25.5 million. These are included within Accruals in Trade and other payables and within Non-current accruals in the Consolidated statement of financial position at December 31, 2022.

A 20% increase or decrease in the Group's estimates of expected rebate and chargeback percentages for amounts payable to governments or government agencies for the critical estimates described above would have resulted in a £4.5 million reduction or increase, respectively, in Total revenue from the sale of therapies reported in the Consolidated statement of loss for the year ended December 31, 2022. The Group believes its expected values of accruals reported in the Consolidated statement of financial position are materially appropriate; however, due to the uncertainties and judgements outlined above, it is possible eventual amounts could significantly differ to these estimates.

Other estimates and judgments

Management have made other judgements, estimates and assumptions in the preparation of financial statements that do not have as significant a risk of a material adjustment associated with them. These are noted below:

Percentage of completion for performance obligations satisfied over time

Revenue arising on performance obligations satisfied over time are recognized by estimating the percentage of completion which takes into consideration the estimated timelines required to satisfy these obligations and the time since program nomination. The timeline for a project is determined using historical data from previous arrangements and through discussions about each project's plan and progress with project teams and joint steering committees. The measure of progress is therefore based on judgmental assumptions, which could be subject to adjustment in future periods. The Group believes these assumptions to be materially appropriate; however, they may change in future periods and it is possible that other factors may arise which cause estimates in future periods to significantly differ to both current and previous estimates.

Collaboration revenue recognition

Further judgements are made to:

- determine whether promises contained within the collaboration agreements are distinct from the other promises in the contract;
- assess whether milestones or other variable consideration should be included in the transaction price;
- determine whether performance obligations are satisfied at a point in time or over time, and
- identify and consistently apply an appropriate method of measuring progress for performance obligations satisfied over time for the purposes of revenue recognition.

Estimates and assumptions are also made regarding variable consideration included in the transaction price by estimating the most likely amount that will be received. Changes in this estimate would not impact revenue recognized in the period as this constraint is applied to estimated variable consideration to reduce such consideration to the amount which is not probable of being reversed.

Research and development costs

Research and development expenditure which does not meet the criteria for capitalization is expensed as incurred. In preparing the financial statements, the Group may be required to estimate accrued research and development expenditure incurred, the most significant of which is that relating to ongoing clinical trials. These estimates are based on reviews of open contracts, reports provided by the contract research organizations (CROs) and internal reviews to estimate the level of service performed and the associated cost incurred for those services when the Group has not yet been invoiced or otherwise notified of the actual cost. The majority of CROs invoice the Group monthly in arrears for services performed or when contractual milestones are met; however, the level of suppliers for which this is not applicable can be material. The Group makes estimates of accrued expenses as of each statement of financial position date in our financial statements based on facts and circumstances known at that time. The Group confirms the accuracy of estimates with the CROs at the end of each reporting period and adjusts these if necessary.

The financial terms agreed with the CROs 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 the CROs will exceed the level of services provided and result in either a prepayment of the research and development expenses or, where the payments are repaid back to the Group at the end of the clinical trial, a non-current financial asset. In accruing clinical trial expenses, the Group estimates 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 made, the accrual or prepayment expense is adjusted accordingly.

Lease liability discount rate

Since the rate implicit in the lease is not readily determinable the Group uses 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 would have to be paid to borrow on a collateralized basis on 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 the Group does not expect its estimates of the incremental borrowing rates to generate material differences within a reasonable range of sensitivities, judgement is involved in selecting an appropriate rate, and the rate selected for each lease will have an impact on the value of the lease liability and corresponding right-of-use asset in the statement of financial position.

Valuation of share options

The Group operates equity-settled, share-based compensation plans whereby certain of our employees and directors are granted awards over the shares in our company. The grant date fair value of awards granted under these share-based compensation plans is calculated using the Black Scholes valuation model for grants since the Company's IPO, which closed on February 9, 2021. From this point, the Company's share price has been publicly available as an input to the Black Scholes model. For awards prior to our IPO, both the Black Scholes and the Back Solve valuations models were used.

The valuation models used require the input of subjective assumptions, including assumptions about the expected life of share-based awards and share price volatility, which are used to determine the fair value of the Group's ordinary shares. These assumptions used represent management's best estimates at the time of grant, but such estimates involve inherent uncertainties and the application of judgment. The expected life assumption is based on the Group's assessment of the time within which participants are expected to exercise options, which requires consideration of employee groups, expected employee service, and other internal factors, and the degree to which these are expected to shorten the life of options in comparison to contractual expiry dates. The volatility assumption is based on the historical data of a comparator group of companies. While the Group has assessed that these estimates result in share-based payment accounting that is materially appropriate within a reasonable range of sensitivities, applying different assumptions could result in a significantly different expense being recognised in the Consolidated Statement of Comprehensive Loss. Further judgmental assumptions around options expected to vest and the valuation of option modifications also significantly impact the share-based compensation charge associated with granted options.

Significant accounting policies

Basis of consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries as of December 31, 2022 and 2021 and for the years ended December 31, 2022, 2021 and 2020. A subsidiary is an entity controlled, directly or indirectly, by Immunocore Holdings Plc. Control is regarded as the exposure or rights to the variable returns of the entity when combined with the power to affect those returns. The financial results of subsidiaries are consolidated from the date control is obtained until the date that control ceases.

Segment reporting

The Group operates in one operating segment. The Group's chief operating decision maker (the, "CODM"), its Chief Executive Officer, manages the Group's operations on an integrated basis for the purposes of allocating resources. The Group is registered in four geographic regions: the United Kingdom, the Republic of Ireland, Switzerland and the United States. Substantially all of the Group's assets are held in the United Kingdom.

Foreign currencies

Transactions in foreign currencies are translated to the Group companies' functional currencies at the foreign exchange rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the statement of financial position date are retranslated to the functional currency at the foreign exchange rate ruling at that date. Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currencies that are stated at fair value are retranslated to the functional currency at foreign exchange rates ruling at the dates the fair value was determined. Foreign exchange differences arising on translation are recognized.

On consolidation, the assets and liabilities of foreign operations, are translated to the Group's presentational currency, sterling, at foreign exchange rates ruling at the reporting date. The revenues and expenses of foreign operations are translated at an average rate for the year where this rate approximates to the foreign exchange rates ruling at the dates of the transactions. Foreign exchange differences arising on retranslation are recognized in other comprehensive income.

Product revenue, net

Product revenue, net, relates to the sale of KIMMTRAK following marketing approval. The Group recognizes revenue at the point in time that control transfers to a customer, which is typically on delivery. The Group also operates under consignment arrangements where control passes when the Group's distributor takes KIMMTRAK out of consignment inventory. The amount of revenue recognized under its arrangements reflects the consideration to which the Group expects to be entitled to, net of estimated deductions for rebates, chargebacks, levies, other customer fees and product returns. Estimated revenue deductions are updated at the end of each reporting period using the latest available data. The Group considers whether any part of amounts expected to be received should be constrained to ensure that it is highly probable that a significant reversal in the cumulative revenue recognized will not occur. Estimating such deductions involves judgments which are detailed further above under "Critical accounting estimates".

The Group's main customers in the United States and Europe are its distributors. These distributors are invoiced at contractual list prices with standard payment terms typically between one and two months. When the Group has the right to offset chargebacks against trade receivables and the parties have agreed to settle the payments net, chargebacks are recorded as a reduction in trade receivables. Other chargebacks, rebates and deductions are recognized as an accrual in the consolidated statement of financial position.

The Group's customers are hospitals and healthcare providers in certain countries, where KIMMTRAK is sold through an agent acting on the Group's behalf.

Pre-product revenue, net

Pre-product revenue, net, relates to the sale of tebentafusp under a compassionate use and an early access program in France up to September 2022. These programs provided patients with access to tebentafusp before KIMMTRAK became available as a marketed product in France. Pre-product revenue is recognized on delivery of tebentafusp to healthcare providers, which is the point in time when control is transferred. Such revenue is recognized net and represents the prices set by the Group that are expected to be retained after estimated deductions and to the extent that it is highly probable that a significant reversal of revenue will not occur. These variable estimated deductions include both an estimate of government rebates and levies payable, and an estimate of returns in the case of expiry, damage or other instances. The total rebate payable by the Group is dependent on the outcome of price negotiations with the French government, and the Group makes an estimate of these amounts payable each reporting period based on available pricing information and the applicable regulations. Returns are estimated based on industry trends and information provided by the Group's distributors.

The estimates for rebates and returns deducted from pre-product revenue are recorded in the period the related pre-product revenue is recognized and are classified under Accruals within Trade and other payables in the Consolidated Statement of Financial Position. Costs of pre-product revenue are expensed when incurred and include costs associated with previous manufacturing of tebentafusp and other third-party selling expenses. Previous manufacturing costs were recognized in Research and development expenses at the time, and third-party selling expenses are recognized within Selling and administrative expenses.

Cost of product revenue

Cost of product revenue represents production costs including raw materials, external manufacturing costs, and other costs incurred in bringing inventories to their location and condition prior to sale. Due to the Group's manufacturing arrangements, overheads and internal costs of product revenue are minimal. Further information on Cost of product revenue is included within the 'Inventories' policy below.

Collaboration revenue

Revenue arises primarily under the Group's collaboration agreements, which are reviewed and assessed in line with the five-step framework established by IFRS 15 "*Revenue from Contracts with Customers*". The Group considers the promises contained within the collaboration agreements and uses judgment to determine whether those promises are distinct from the other promises in the contract. In addition, the Group uses judgment to determine whether milestones or other variable consideration should be included in the transaction price, whether performance obligations are satisfied at a point in time or over time, and for performance obligations satisfied over time, the appropriate method of measuring progress for the purposes of revenue recognition.

Within these collaboration agreements, the Group grants licensing rights and access to the Group's technology to develop specified targets and commercialize future product candidates for specified targets defined in the respective collaboration agreements, in addition to research and development services, participation on a joint steering committee and the option to obtain exclusive rights to the associated intellectual property license either through the collaborator exercising an option to do so, or at the Group's election. In each of the collaboration agreements, these promises are combined with each relevant target as one combined performance obligation, because the promises are mutually dependent and the collaborator is unable to derive significant benefits from its access to these targets for their intended purpose without receipt of the remaining promises, which are highly specialized and cannot be performed by other organizations. These single combined performance obligations are satisfied over time and deemed fully satisfied when the collaborator is contractually entitled to benefit from the exclusive rights to the associated intellectual property license either through the collaborator exercising an option to do so or at the Group's election. This occurs at different stages of the research and development process within each of the collaboration agreements and is set out in Note 2. Once the collaborator has obtained exclusive rights to the associated intellectual property, the Group has no further contractual obligations relating to the performance obligation and accordingly the performance obligation is deemed satisfied and complete at this point. The Group accounts for each target under collaboration agreements as having one combined performance obligation with the mutually dependent rights noted above.

Where the Group receives development milestones at key inflection points specified within the collaboration agreements, these are considered variable consideration and are assessed at contract inception and each subsequent reporting period and not recognized in the transaction price until it is highly probable that the recognition of such revenue will not be reversed. The Group determines the variable consideration to be included in the transaction price by estimating the most likely amount that will be received and then applying a constraint to reduce the consideration to the amount which is not probable of being reversed. The determination of whether a milestone is probable includes consideration of the following factors:

- whether achievement of a development milestone is highly susceptible to factors outside the entity's influence, such as milestones involving the judgment or actions of third parties, including regulatory bodies or the customer;
- whether the uncertainty about the achievement of the milestone is not expected to be resolved for a long period of time;
- whether the Company can reasonably predict that a milestone will be achieved based on previous experience; and.
- the complexity and inherent uncertainty underlying the achievement of the milestone.

Any development milestone revenue adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Under collaboration agreements, depending on the terms, the Group may also receive commercialization milestones and royalties. These amounts have not been included within the transaction price as of December 31, 2022, 2021 and 2020 because they are sales-based royalties which will be recognized when the subsequent sale occurs.

Revenue is recognized as the programs progress through the various stages of research and development using an estimate of percentage completion which takes into consideration the estimated timelines required to satisfy the performance obligation and the time taken since program nomination. The determination of the percentage of completion requires the estimation of when the performance obligation will be completed, and this is reviewed and re-assessed quarterly, typically by the joint steering committee for the contract, based on the latest project plan and discussions with project teams and will consider progress achieved to date, historical experience on similar programs and other internal factors as may be available. If a change in facts or circumstances occurs, the estimate of percentage completion is adjusted, and revenue recognized based on the revised estimate.

The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate is recognized as an adjustment to revenue in the period in which the change in estimate occurs.

Under certain collaboration agreements, research and development costs incurred either in excess of a defined amount, or in accordance with a cost sharing agreement, are reimbursed. These amounts are considered variable consideration and are assessed at contract inception and each subsequent reporting period and not recognized in the transaction price until it is highly probable that the recognition of such revenue will not be reversed. The Group determines the variable consideration to be included in the transaction price by estimating the expected value that will be received and then applying a constraint to reduce the consideration to the amount which is highly probable of not resulting in a significant reversal in the cumulative amount of revenue recognized. The determination of whether reimbursed costs are highly probable to not be reversed includes the following:

- past history and experience with similar contracts.
- unexpected fluctuations in planned spend.
- changes to project timelines

The Group's collaboration revenue arrangements have standard payment terms and do not contain a significant financing component.

Further information about judgements involved in the Group's revenue recognition are described further above in this note under the section 'Percentage of completion for performance obligations satisfied over time' within the 'Other estimates and judgments' section.

Deferred revenue

The Group's deferred revenue primarily relates to the collaboration agreements outlined above.

Deferred revenue is classified as current when the Group expects to recognize revenue within a year from the balance sheet date, and non-current when the period of revenue recognition is expected to be longer than a year from the balance sheet date.

The Group recognizes deferred revenue when the amount of unconditional consideration is in excess of the value of satisfied, or part satisfied, performance obligations.

Changes in deferred revenue typically arise due to:

- adjustments arising from a change in the estimate of when the performance obligation will have been completed.
- a change in the estimate of the transaction price due to changes in the assessment of whether variable consideration is constrained because it is not considered probable of being received; and
- the recognition of revenue.

The Group also has deferred product revenue following a non-refundable upfront receipt from Medison Pharma under an amended agreement entered into in November 2022. The Group determined that this receipt relates to the distribution of KIMMTRAK in South America and assessed there is a single performance obligation to provide KIMMTRAK to Medison for onward sale under exclusive distribution license. The deferred revenue is expected to be released with the sale of products following regulatory approval in the territory.

Trade Receivables

Trade receivables include amounts invoiced or contractually accrued where only the passage of time is required before payment is received under the Group's collaboration agreements and other revenue arrangements. Trade receivables are assessed for impairment using the simplified approach under IFRS 9, *Financial Instruments*, which requires lifetime expected losses to be recognized with the initial recognition of the receivable. As of December 31, 2022, the amount of expected credit losses is not material.

Inventories

Inventories include finished goods manufactured for commercial sale, items in the process of being manufactured for commercial sale, and the materials to be used in the manufacturing process. The principal costs in manufacturing the Group's inventories are raw materials, external manufacturing costs, and other costs incurred in bringing inventories to their location and condition prior to sale.

Inventories are measured at weighted average cost and presented as assets in the Consolidated Statement of Financial Position to the extent that they are recoverable. Inventories are stated at the lower of cost and net realizable value, and the Group assesses whether an expense should be recognized to write down inventory values at each reporting period. Where this expense relates to inventories sold following marketing approval of KIMMTRAK, the Group recognizes the expense within Cost of product revenue. Approximately £409,000 of manufacturing costs associated with KIMMTRAK sold in the year ended December 31, 2022 were previously recognised in Research and development expenses as the vials were not originally manufactured for sale in the ordinary course of business. There are approximately £690,000 of such manufacturing costs previously recognized in Research and development expenses associated with our inventory on hand at December 31,2022, and the Group expects to sell the majority of these vials in 2023. While Cost of product revenue may increase in future periods, due to the low costs involved in manufacturing KIMMTRAK, inventory costs and Cost of product revenue are not material at this time.

After regulatory submission and prior to receiving marketing approval, the Group recorded the expense for prelaunch inventory expected to be sold in the ordinary course of business within Research and development expenses. Reversals of previous write-downs of inventories are recognized within Cost of product revenue or Research and development expenses, depending on where the write-down was originally recognized.

Research and development costs

Research and development expenditure is expensed as incurred. The Group makes estimates of accrued expenses as of each statement of financial position date based on facts and circumstances known at that time. There may be instances in which payments made to CROs or other parties will exceed the level of services provided and result in either a prepayment of the research and development expenses or, where the payments in substance represent deposits to be repaid back to the Group at the end of the clinical trial, a non-current financial asset. In accruing clinical trial expenses, the Group estimates 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 made, the accrual or prepayment expense is adjusted accordingly.

Share-based payments

The Group operates equity-settled, share-based compensation plans whereby certain employees of the Group are granted equity awards in the Company. The grant date fair value of these employee share plan awards are calculated using the Black Scholes valuation model for awards granted following the Group's IPO, which closed on February 9, 2021, and for awards prior to IPO, both the Black Scholes valuation model and the Back Solve valuation model. The resulting cost is recognized in the Consolidated Statement of Loss over the vesting period of the awards, which is the period in which the services are received. The value of the charge is adjusted to reflect actual levels of awards vesting, except where the failure to vest is as a result of not meeting a market condition in the case of certain awards prior to our IPO.

The various assumptions used in determining the grant date fair value of the awards and the resulting cost recognized in the profit and loss account are set out in Note 19. Further information about the judgements involved in forming these assumptions is also described further above under 'Valuation of share options' within the 'Other estimates and judgments' section.

Taxation

Uncertainties exist with respect to the interpretation of complex tax regulations, changes in tax laws, and the amount and timing of future taxable income. Given the wide range and complexity of existing contractual agreements, differences arising between the actual results and the assumptions made, or future changes to such assumptions, could necessitate future adjustments to tax income and expense already recorded. The U.K. Research and Development Tax Credit calculation incorporates an estimate of employee time spent on qualifying research and development activities which are reviewed and updated annually.

Tax on the loss for the year comprises current and deferred tax. Tax is recognized in the profit and loss account, except to the extent that it relates to items recognized directly in equity, in which case it is recognized directly in equity.

Current tax is provided at the amounts expected to be paid applying tax rates that have been enacted or substantively enacted by the statement of financial position date. Current tax includes tax credits, which are accrued for the period based on calculations that conform to the U.K. Research and Development Tax Credit scheme applicable to Small and Medium sized Enterprises. Research and development costs which are not eligible for reimbursement under this scheme, such as expenditure incurred on research projects for which we receive income, are considered for reimbursement under the U.K. R&D expenditure credit ("RDEC") scheme.

Deferred tax is provided in full, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Deferred tax assets are recognized to the extent that it is probable that future taxable profits will be available against which the temporary differences can be utilized. Deferred tax is provided on temporary differences arising on investment in subsidiaries, associates and joint ventures, except where the timing of the reversal of the temporary difference can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future. Deferred tax is provided using rates of tax that have been enacted or substantively enacted by the statement of financial position date.

Leases

The Group's 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.

The Group assesses whether a contract is or contains a lease at inception of the contract. The Group recognizes a right of use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the Group recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease.

The right-of-use assets comprise leasehold property and reflect the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day and any initial direct costs less lease incentives that may have been received. They are subsequently measured at cost less accumulated depreciation, impairment losses and remeasurements of the underlying lease liability. Depreciation is charged to the profit and loss account on a straight-line basis over the expected life of each lease agreement. The Group assesses at each reporting date whether the right-of-use assets are impaired.

The lease liability is initially measured at the present value of the lease payments that are not paid at commencement date. Where the terms of the lease agreement include increases to the rent charge, the minimum guaranteed increase is included in the lease liability. They are subsequently measured by increasing the carrying amount to reflect interest of the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made. The lease liability will also be remeasured to reflect changes in the underlying lease agreement such as the expected lease length.

Since the rate implicit in the lease is not readily determinable the Group uses 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 would have to be paid to borrow on a collateralized basis on 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.

The Group previously entered into sub-lease arrangements which were assessed at inception. For operating leases, the associated income is recognized in the profit and loss account on a straight-line basis over the term of the lease.

Property, plant and equipment

Property, plant and equipment are stated at cost less accumulated depreciation and accumulated impairment losses. Where parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items of property, plant and equipment. The Group assesses at each reporting date whether property, plant and equipment is impaired.

Depreciation is charged to the profit and loss on a straight-line basis over the estimated useful lives of each item of property, plant and equipment. The estimated useful lives are as follows:

- Leasehold improvements - over the expected lease term
- Plant and equipment - 3 to 5 years
- Right-of-use assets - over the expected lease term

Depreciation methods, useful lives and residual values are reviewed at each financial year end and adjusted prospectively where applicable.

Impairment of non-financial assets

Non-financial assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units).

Intangible assets

Acquired intangible assets under development are recognized at their cost and evaluated for impairment annually and when indicators of potential impairment are present.

Cash and cash equivalents

Cash and cash equivalents comprise cash balances and short-term money market funds with an original maturity of less than three months.

Loans and borrowings

Loans and borrowings are classified as financial liabilities and are initially recorded at fair value minus transaction costs directly attributable to the issue of the loan. After initial recognition, any such loans and borrowings are measured at amortized cost using the effective interest method, with the amortization recognized in finance costs. Embedded derivatives identified under loan arrangements are assessed for their potential to be material or to give rise to a derivative liability, and separately recognized where the Group determines these possibilities may reasonably be expected to occur.

The Group entered into a long-term loan under an agreement with Pharmakon in November 2022, which is classified as a non-current liability at December 31, 2022. The Group previously had a loan with Oxford Finance which was repaid in November 2022.

Fair value measurements

Where financial and non-financial assets and liabilities are measured at fair value, the Group uses appropriate valuation techniques for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The Group recognizes transfers between levels of the fair value hierarchy at the end of the reporting period during which the changes have occurred. The carrying amount of cash and cash equivalents, trade receivables, short and long-term deposits, trade payables, accruals and other current liabilities in the Group's consolidated statement of financial position approximates their fair value because of the short maturities of these instruments.

2. Revenue and segmental reporting

Revenue recognized during 2022 arose primarily from Product revenue following regulatory approval of KIMMTRAK in the United States and Europe. Revenue recognized during 2021 and 2020 arose primarily from collaboration agreements with GlaxoSmithKline Intellectual Property Development Ltd ("GSK"), Eli Lilly and Company ("Eli Lilly") and Genentech, Inc. ("Genentech").

Revenue from sale of therapies	**2022 £'000**	**2021 £'000**	**2020 £'000**
Product revenue	108,148	—	—
Pre-product revenue	8,661	3,010	—
Total revenue from sale of therapies	116,809	3,010	—
Collaboration revenue			
GSK	—	6,083	6,356
Eli Lilly	7,361	—	3,522
Genentech	19,567	17,427	20,236
Total collaboration revenue	**26,928**	**23,510**	**30,114**
Total revenue	**143,737**	**26,520**	**30,114**

Of the Group's collaboration customers, Eli Lilly and Genentech are based in the United States. GSK is based in the United Kingdom. The revenue figure for Genentech in the table above represented more than 10% of the Group's revenue during 2022. During 2021, the figures for both GSK and Genentech in the table above each represented more than 10% of the Group's revenue. In 2020, all figures above for the Group's collaboration customers represented more than 10% of the Group's revenue.

The following table shows amounts of revenue recorded for individual customers representing more than 10% of the Group's total revenue from the sale of therapies during 2022.

	2022 £'000
Customer A	30,804
Customer B	29,225
Customer C	20,419
Customer D	20,054
Customer E	13,724
	114,226

Net product revenue from the sale of KIMMTRAK, and net pre-product revenue from the sale of tebentafusp as part of a compassionate use and early access program are presented by region based on the location of the customer below.

	2022 £'000	**2021 £'000**	**2020 £'000**
United States	80,448	—	—
Europe	35,490	3,010	—
Rest of World	871	—	—
Total revenue from sale of therapies	**116,809**	**3,010**	**—**

Product revenue, net

During the year ended December 31, 2022, the Group recognized £108,148,000 of net product revenue relating to the sale of KIMMTRAK primarily in the United States and Europe after estimated deductions for rebates, chargebacks, other customer fees and returns, which are recognized in accruals as set out in the Group's accounting policies.

Pre-product revenue, net

During the year ended December 31, 2022 and 2021, the Group recognized £8,661,000 and £3,010,000 of net pre-product revenue, respectively, relating to the sale of tebentafusp under compassionate use and early access programs in France after estimated deductions for rebates and returns, which are recognized in accruals as set out in the Group's accounting policies. In September 2022, the Group began selling KIMMTRAK as a commercial product in France, and these sales are reflected in Product revenue, net.

Collaboration revenue

For the year ended December 31, 2022, a total of £24,450,000 of revenue recognized was included in deferred revenue at January 1, 2022 (2021: £21,128,000 recognized included in deferred revenue at January 1, 2021).

Trade receivables and deferred revenue from contracts with customers

Trade receivables were £27,736,000 as at December 31, 2022, compared to £6,047,000 as at December 31, 2021, mainly due to the increase in Product revenue following approval of KIMMTRAK in 2022. As at December 31, 2022, the amount of expected credit losses on Trade receivables was not material.

Deferred revenue as at December 31, 2022 and 2021 was as follows:

	2022 £'000	2021 £'000
Current deferred revenue	6,408	24,450
Non-current deferred revenue	4,331	6,408
	10,739	**30,858**

Deferred revenue in the Consolidated statement of financial position is primarily in respect of the upfront fee and development milestone consideration received from the various collaboration agreements in advance of services performed by the Group. Deferred revenue decreased by £20,119,000 as a result of the revenue recognised under our collaboration agreements detailed above. The Current deferred revenue of £6,408,000 in the Consolidated statement of financial position, represents the amount of transaction price allocated to performance obligations that are unsatisfied or partially satisfied as at December 31, 2022, and is expected to be recognized as revenue within one year.

Non-current deferred revenue in the Consolidated statement of financial position at December 31, 2022, relates to a revised distribution agreement with Medison Pharma Ltd ("Medison") entered into in November 2022. Under the revised agreement, the Group received a non-refundable payment of £4,331,000 in the year ended December 31, 2022, in exchange for granting Medison exclusive distribution rights in South America. The Group has determined that the deferred revenue relates to the Group's single, combined performance obligation to supply KIMMTRAK to Medison and to grant Medison the exclusive right to distribute KIMMTRAK in South America. The Group expects to recognize this revenue with the sale of products following regulatory approval in the territory. The Group estimates that Product revenue recognition of this Non-current deferred revenue will commence in 2024 or later.

No revenue was recognized in 2022 relating to performance obligations satisfied in previous years (2021: no revenue; 2020: £705,000).

Accruals for rebates and chargebacks

Information on estimated revenue deductions for rebates and chargebacks included under Accruals within Trade and other payables in the Consolidated statement of financial position is provided within *Critical accounting estimates and judgements* in Note 2.

Genentech Collaboration

Under the Genentech agreement signed in November 2018, the Group received aggregate non-refundable payments totaling $100 million consisting of an initial upfront payment of $50 million and $50 million paid upon an investigational new drug filing for the first clinical trial of the product candidate compound, in exchange for granting Genentech rights to co-develop/co-promote the Group's IMC-C103C program and the co-exclusive worldwide license to the Group's intellectual property rights in MAGE A4 soluble TCR bispecific therapeutic candidate compounds. The Group is responsible for development of the IMC-C103C program over the period of time to estimated completion of the Phase 1 clinical trial, with costs being shared equally with Genentech. In February 2023, as the Group elected to withdraw from co-funding with Genentech the MAGE-A4 HLA-A02 program, IMC-C103C, Genentech shall acquire an exclusive worldwide license to the MAGE-A4 HLA-A02 soluble TCR bispecific therapeutic candidate compounds and shall be fully responsible for all further development and commercialization of such candidate compounds, at its expense. For more information, please see "Item 4B. Business overview—Our Collaborations and License Agreements—Genentech Collaboration."

The total payments of $100 million (£77.4 million) were recorded as deferred revenue on receipt in November 2018 and allocated to a single combined performance obligation covering the granting of the co-exclusive worldwide license, the provision of development services and participation on a joint steering committee. This deferred revenue is recognized as the Group satisfies the combined performance obligation over the estimated period of time to when the Group has completed substantially all of its responsibilities associated with its withdrawal from the co-funding and the Phase I clinical trial. Following the Group's withdrawal from co-funding the MAGE-A4 HLA-A02 program, IMC-C103C, Genentech shall acquire an exclusive worldwide license to the MAGE-A4 HLA-A02 soluble TCR bispecific therapeutic candidate compounds and shall be fully responsible for all further development and commercialization of such candidate compounds, at its expense. Research and development costs reimbursed under the 2018 Genentech Agreement are considered variable consideration and not recognized in the transaction price until it is highly probable that the recognition of such revenue will not be reversed.

During the year ended December 31, 2022, the Group recognized £19,567,000 revenue relating to the 2018 Genentech Agreement (2021: £17,427,000; 2020: £20,236,000). The revenue recognized represents both deductions from deferred revenue and research and development costs reimbursed, predominantly for clinical trial costs. Such reimbursements arise in order to ensure that research and development costs are shared equally in accordance with the 2018 Genentech agreement. Of the revenue recognised in the year ended December 31, 2022, £2,478,000 represented research and development cost reimbursements (2021: £338,000; 2020: £2,785,000), and £17,089,000 represented revenue that was included in the deferred revenue balance at January 1, 2022. As at December 31, 2022, £6,408,000 of transaction price was allocated to the unsatisfied performance obligation under the agreement. The Group estimates that the remaining revenue relating to this performance obligation would be satisfied within one year.

GSK Collaboration

In June 2013, the Group entered into a collaboration and license agreement with GSK pursuant to which the Group and GSK agreed to collaborate in the development of soluble TCR bispecific therapeutic compounds (the "GSK Agreement"). Under the GSK Agreement, the Group granted GSK the right to nominate up to four exclusive targets. The first target, GSK01/NY-ESO, was nominated at the time of execution of the GSK Agreement. A second target was nominated in July 2017. GSK subsequently had no further ability to nominate additional targets under the terms of the agreement. Following a review of the targets in the year ended December 31, 2021, the parties elected not to proceed further with the second target and the GSK Agreement was terminated in January 2022.

As at December 31, 2022, the Group had received a total of £22,900,000 in non-refundable payments, none of which were received during the years ended December 31, 2022 and 2021. Those previous payments were recorded as deferred revenue on receipt and allocated to a single combined performance obligation for each target covering the provision of research and development services and participation on a joint steering committee. This deferred revenue was recognized as the Group satisfied the combined performance obligation over the estimated period of time to when GSK could exercise the option to obtain an exclusive worldwide license for the therapeutic candidate compounds. Research and development costs reimbursed under the GSK Agreement were considered variable consideration and assessed at contract inception and each subsequent reporting period and not recognized in the transaction price until it was highly probable that the recognition of such revenue would not be reversed.

During the year ended December 31, 2022, the Group recognized no revenue relating to the GSK Agreement (2021: £6,083,000; 2020: £6,356,000) following termination of the agreement. In 2021, GSK and the Group elected not to progress with the final program under the agreement and therefore released the remaining deferred revenue attributed to the GSK Agreement during the year ended December 31, 2021.

Lilly Collaboration

The Group released the remaining deferred revenue attributed to the third target under the Lilly Collaboration after the parties agreed to terminate the agreement in March 2022. No further revenue under the collaboration is expected.

In July 2014, the Group entered into a development and license agreement with Eli Lilly, or the Lilly Agreement, pursuant to which the Group and Eli Lilly agreed to collaborate in the development, manufacture and commercialization of soluble TCR bispecific therapeutic compounds. Under the Lilly Agreement, Eli Lilly paid an initial non-refundable upfront fee payment of $45 million in exchange for options to three targets. Following termination of the agreement, Eli Lilly no longer has any rights to the targets or the ability to nominate any further targets under the initial agreement. In December 2016, the Group and Eli Lilly agreed to swap an existing antigen target, selected by Eli Lilly, for a new, well known neo-antigen target. Lilly has no further obligations with respect to the initial target that was replaced. In September 2017, the Group and Eli Lilly agreed to swap a second antigen target, selected by Eli Lilly, for a second neo-antigen target. Similarly, Eli Lilly has no further obligations with respect to the initial target that was replaced.

Under the Lilly Agreement, the Group was responsible for developing soluble TCR bispecific therapeutic pre-clinical candidates to each target with Eli Lilly responsible for GMP manufacture of Phase 1 material at its expense. On a collaboration target-by collaboration target basis, at the point of clinical candidate nomination, Eli Lilly had the right to opt in to gain exclusive co-development/co-promotion rights to the target program.

The $45.0 million upfront payment was recorded as deferred revenue on receipt and allocated to a single combined performance obligation for each target covering the provision of research and development services and participation on a joint steering committee. This deferred revenue was recognized as the Group satisfied the combined performance obligations over the estimated period of time to when Eli Lilly could exercise the option to obtain exclusive co-development/co-promotion rights to the target and the Group could opt-out of the co-development of the target.

During the year ended December 31, 2022, the Group recognized £7,361,000 of revenue relating to the Lilly Agreement (2021: no revenue; 2020: £3,522,000). The Group released the remaining deferred revenue attributed to the third target under the collaboration after the parties agreed to terminate the agreement during the year ended December 31, 2022. No further revenue under the Eli Lilly Collaboration is expected.

Other segmental reporting information

The total of non-current assets other than financial instruments and deferred tax assets located in the United Kingdom as at December 31, 2022 is: £6,079,000. The total located in other countries (primarily the United States) is £2,241,000.

3. Operating loss is stated after charging (crediting)

The following items have been included in operating loss:

	2022 £ '000	2021 £ '000	2020 £ '000
(Gain) / loss on disposal of property, plant and equipment	(3)	180	1,064
Profit on derecognition of leases	—	—	(3,700)
Remeasurement of leases	—	(15)	(227)
Depreciation of property, plant and equipment (Note 11)	4,304	5,511	6,446
Depreciation of right-of-use assets (Note 12)	1,827	1,501	2,530
Write-down of inventories recognised as an expense	28	871	—
Reversals of inventory write-downs	(197)	—	—
Operating lease income (Note 6)	—	108	460

Research and development costs in the Consolidated Statements of Loss and Other Comprehensive Income are stated net of the Research and Development Expenditure Credit, totalling £184,000 for 2022 (2021: £358,000; 2020: £227,000).

4. Staff numbers and costs

The average number of persons employed by the Group (including the Board) during the year, analysed by category, was as follows:

	2022 No. of employees	2021 No. of employees	2020 No. of employees
Research	133	154	177
Development	137	88	96
Corporate	105	73	56
Total	**375**	**315**	**329**

The aggregate staff costs of these persons were as follows:	2022 £'000	2021 £'000	2020 £'000
Wages and salaries	36,235	27,337	29,038
Social security costs	4,169	2,258	2,131
Share-based payments (Note 19)	27,054	35,861	8,162
Contributions to defined contribution plans (Note 21)	1,355	1,001	1,035
	68,813	**66,457**	**40,366**

During the year ended December 31, 2020, the Group undertook a corporate restructure incurring costs of £1.2 million. The restructure was completed in the second quarter of 2020 and reduced the overall headcount, at that time, by 78 employees.

5. Selling and administrative expenses

There were £12,125,000 of foreign exchange gains, which the Group classifies within Selling and administrative expenses, for the year ended December 31, 2022, compared to gains of £457,000 and £5,000 in the years ended December 31, 2021 and 2020, respectively. These gains arise on a number of foreign currency items, including the translation of monetary foreign currency balances in the Group's main operating subsidiary in the United Kingdom, which was significantly impacted by changes in exchange rates between pounds sterling and U.S. dollars in the year ended December 31, 2022.

6. Net other operating income / (loss)

	2022 £'000	2021 £'000	2020 £'000
Profit on derecognition of leases	—	—	3,700
Gain / (loss) on disposal of property, plant and equipment	3	(180)	(1,064)
Settlement agreement	—	—	810
Sub-lease income	—	108	460
Remeasurement of leases	—	15	227
Other	—	—	109
	3	**(57)**	**4,242**

During the year ended December 31, 2020, the Group terminated the lease term fortwo leasehold properties giving rise to a profit on disposal of £3,700,000 which included £1,400,000 received as an incentive for exiting one of the leasehold agreements.

During the year ended December 31, 2020, the management of the Group conducted an internal investigation as a result of receiving a whistleblower complaint alleging employee misconduct and other improper activities related to a kickback scheme involving an employee and two third-party vendors. After the investigation, the one remaining open contract with the third-party vendors was terminated and the Group undertook proceedings against the involved parties. The Group estimated the amount in question to be in the range of £1.1 million to £1.8 million and recovered £1.8 million from the employee and third-party vendors in December 2020 of which £810,000 was reflected within other operating income.

Sub-lease income comprised income from sub-lease arrangements on operating leases on certain leasehold properties.

7. Finance income

	2022 £'000	2021 £'000	2020 £'000
Interest on cash and cash equivalents and other receivables	3,154	21	668
Gain on entering into sub-leases on leasehold properties	—	—	215
Interest on investment in sub-lease	—	26	38
Gain from change in fair value of derivative liability	—	—	1,287
	3,154	**47**	**2,208**

The derivative liability represented a foreign exchange call option over certain series B shares which was settled in full in March 2020, resulting in a gain of £,287,000 based on the fair value as at derecognition, and a credit to equity of £3,840,000.

8. Finance costs

	2022 £'000	2021 £'000	2020 £'000
Interest on lease liabilities (Note 12)	1,796	1,732	2,401
Interest expense on financial liabilities measured at amortized cost	4,503	4,081	708
Loss from change in fair value of embedded derivative asset	—	—	266
Loss on derecognition of financial liabilities measured at amortized cost	1,393	—	—
	7,692	**5,813**	**3,375**

Interest expenses on financial liabilities measured at amortized cost in the year ended December 31, 2022, and 2021 primarily relate to the Oxford Finance debt agreement entered into in November 2020. Following repayment of the loan to Oxford Finance in November 2022, the Group began to incur interest expenses under a new loan agreement with Pharmakon. The loss on derecognition of financial liabilities measured at amortised cost in the year ended December 31, 2022, primarily represents the loss arising on the early repayment of the loan to Oxford Finance compared to the amortized cost carrying value.

9. Income tax

The major components of the income tax expenses for the years ended December 31, 2022, 2021 and 2020 are:

	2022 £'000	2021 £'000	2020 £'000
Profit or loss			
Current tax:			
R&D tax credit for the year	(2,209)	(9,322)	(12,432)
Foreign corporation tax on profits for the year	783	—	84
Adjustments in respect of prior years	20	370	(100)
Total current tax	**(1,406)**	**(8,952)**	**(12,448)**
Deferred tax:			
Current year	(1,352)	(459)	(439)
Effect of changes in tax rates	(13)	—	(1)
Originating and reversal of timing differences, including adjustments in respect of prior years	(150)	6	(379)
Total deferred tax	**(1,515)**	**(453)**	**(819)**
Total income tax credit	**(2,921)**	**(9,405)**	**(13,267)**

Reconciliation of tax expense and accounting profit for 2022, 2021 and 2020:	2022 £'000	2021 £'000	2020 £'000
Loss before tax	**(44,145)**	**(140,928)**	**(87,360)**
Tax credit using the UK Corporation tax rate of 19% (2021: 19% and 2020: 19%)	**(8,388)**	**(26,776)**	**(16,598)**
Effect of:			
Non-deductible expenses	11,268	12,836	9,120
Additional deduction for R&D expenditure	(16,408)	(12,354)	(16,286)
Surrender of tax losses for R&D tax credit refund	3,099	12,354	16,286
R&D expenditure credits	(3,418)	(10,210)	(13,424)
Share-based compensation plans deduction	(4,552)	—	—
Movement in deferred tax not recognized	15,895	14,315	8,084
Adjustments to tax charge in respect of previous periods - deferred tax	(150)	18	(379)
Adjustments to tax charge in respect of previous periods	20	370	(100)
State taxes	(435)	—	7
Effects of overseas tax rates	161	42	24
Effects of changes in tax rates	(13)	—	(1)
Total tax credit included in loss for the year	**(2,921)**	**(9,405)**	**(13,267)**

The components of income tax are as follows:

	2022 £'000	2021 £'000	2020 £'000
Current tax:			
United States:			
Federal	692	106	(16)
State	75	—	—
United Kingdom	(2,173)	(9,058)	(12,432)
Ireland	—	—	—
Total current tax	**(1,406)**	**(8,952)**	**(12,448)**
Deferred tax:			
United States:			
Federal	(1,488)	(453)	(819)
State	—	—	—
United Kingdom	—	—	—
Ireland	(27)	—	—
Total deferred tax	**(1,515)**	**(453)**	**(819)**
Total income tax credit	**(2,921)**	**(9,405)**	**(13,267)**

On May 24, 2021, the U.K. 2021 Finance Bill was substantively enacted and subsequently received Royal Assent on June 10, 2021. Under this bill, the rate of U.K. corporation tax will increase to 25% in 2023, with lower rates and tapered relief to be applied to companies with profits below £250,000.

A deferred tax asset of £4,240,386 has been recognized in 2022 (2021: £2,575,000) primarily representing unused tax credits and capitalised research and development expenditure carried forward for Immunocore LLC following an assessment of all available and applicable information, including its forecasts of costs and future profitability and the resulting ability to reverse the recognized deferred tax assets over a short period of time.

In addition to the deferred tax asset above, the Group has unrecognized deferred tax assets of £60,336,000 (2021: 58,093,000) on tax losses £241,344,000 (2021: £232,372,000) which do not expire. Deferred tax assets have not been recognized in respect of these losses as they may not be used to offset taxable profits elsewhere in the Group and there are no other tax planning opportunities or other evidence of recoverability in the near future. If the Group were able to recognize all unrecognized deferred tax assets, including deferred tax on losses and share-based payment, the income tax credit would increase by £55,605,000 (2021: £49,283,000).

10. Basic and diluted loss per share

	2022	2021	2020
Loss for the year (£000's)	**(41,224)**	**(131,523)**	**(74,093)**
Basic and diluted weighted average number of shares	45,714,923	42,488,579	26,523,411
Basic and diluted loss per share (£) [(1)]	**(0.90)**	**(3.10)**	**(2.79)**

(1) The basic and diluted loss per share for the years ended December 31, 2021 and 2020 are adjusted for the (i) the exchange of shares of Immunocore Limited for shares of Immunocore Holdings Limited on a 1 for 100 basis, and (ii) the reorganization of the share capital of Immunocore Holdings plc, resulting in a consolidation with the effect of a 20 to 1 reverse stock split on the Company's ordinary shares and non-voting ordinary shares, all of which took place in connection with the Company's initial public offering which closed on February 9, 2021.

Basic loss per share is calculated by dividing the loss for the period attributable to the equity holders of the Group by the weighted average number of ordinary shares outstanding during the period. The dilutive effect of potential shares through share options are considered to be anti-dilutive as they would decrease the loss per share and are therefore excluded from the calculation of diluted loss per share.

11. Property, plant and equipment

	Leasehold properties and improvements £'000	Plant and equipment £'000	Assets under construction £'000	Total £'000
Cost:				
At January 1, 2021	**15,810**	**25,983**	**120**	**41,913**
Additions	—	933	75	1,008
Transfers	59	85	(144)	—
Effect of foreign currency translation	7	(60)	—	(53)
Disposals	(231)	(139)	(35)	(405)
At December 31, 2021	**15,645**	**26,802**	**16**	**42,463**
Additions	60	1,345	382	1,787
Transfers	—	42	(42)	—
Effect of foreign currency translation	72	21	—	93
Disposals	—	(138)	—	(138)
At December 31, 2022	**15,777**	**28,072**	**356**	**44,205**
Depreciation and impairment:				
At January 1, 2021	**7,835**	**20,324**	**—**	**28,159**
Depreciation charge for the year	2,386	3,125	—	5,511
Effect of foreign currency translation	4	(44)	—	(40)
Disposals	(41)	(70)	—	(111)
At December 31, 2021	**10,184**	**23,335**	**—**	**33,519**
Depreciation charge for the year	2,083	2,221	—	4,304
Effect of foreign currency translation	38	10	—	48
Disposals	—	(138)	—	(138)
At December 31, 2022	**12,305**	**25,428**	**—**	**37,733**
Carrying value:				
At December 31, 2022	**3,472**	**2,644**	**356**	**6,472**
At December 31, 2021	5,461	3,467	16	8,944
At January 1, 2021	7,975	5,659	120	13,754

At December 31, 2022 and 2021,none of the Group's property, plant and equipment was held under finance leases or similar hire purchase agreements. The Group's property, plant and equipment is pledged as security under the Group's loan agreement entered into with Pharmakon in November 2022.

12. Leases

The Group leases its corporate headquarters in the United Kingdom, where its facilities contain research and development, laboratory and office space of approximately 114,000 square feet. In addition, the Group leases approximately 20,000 square feet of office space in the USA, and a small office in both Ireland and Switzerland. The Group's United Kingdom leases expire between 2037 and 2042, although there are points at which it may terminate the leases prior to this.

Information about leases for which the Group is a lessee and a lessor is presented below. The lease payments for short-term leases and leases of low value assets are immaterial. The Group's leases have terms that may include:

- Options to terminate the lease early at the right of the tenant
- Variable lease payments with a guaranteed minimum increase and capped maximum increase

In addition, there is a leasehold property to which the Group is committed to assume the lease should the property become vacant. The future contingent liabilities associated with these leases are set out in Note 22.

Leases in which the Group is a Lessee

Right-of-use assets: leasehold properties

	2022 £'000	2021 £'000
Balance at January, 1	22,593	23,093
Additions	2,575	31
Remeasurements	1,710	970
Depreciation charge for the year	(1,827)	(1,501)
Effect of foreign currency translation	122	—
Balance at December, 31	**25,173**	**22,593**

The right-of-use asset additions during the year ended December 31, 2022 primarily relate to the lease of additional space at the Group's facilities in the United Kingdom.

The Group entered into two guarantee agreements on December 23, 2020 associated with the termination of the lease term for one of the leasehold properties. These agreements indemnify the lessor for certain costs in the event of the new lessee defaulting under their lease agreement for the leasehold property. As at December 31, 2022, the Group does not expect to make future payments as a result of these agreements.

Lease liabilities

Maturity analysis – contractual undiscounted cash flows

	2022 £'000	2021 £'000
Less than one year	3,504	2,929
One to five years	11,639	10,289
More than five years	33,890	30,126
Total undiscounted lease liabilities	**49,033**	**43,344**

Lease liabilities included in the Consolidated Statements of Financial Position

	2022 £'000	2021 £'000
Current	1,555	1,255
Non-current	28,248	25,355
Total lease liabilities	**29,803**	**26,610**

Amounts recognized for lease liabilities in the Consolidated Statements of Loss	2022 £'000	2021 £'000	2020 £'000
Interest on lease liabilities	1,796	1,732	2,401

Amounts recognized in the Consolidated Statement of Cash Flows	2022 £'000	2021 £'000	2020 £'000
Total cash outflow for leases	3,208	3,159	4,426

13. Other non-current assets

	2022 £'000	2021 £'000
Long-term security deposits	941	786
Prepayments	6,264	3,984
Other	137	165
	7,342	**4,935**

The long-term security deposits represent lease security deposits for buildings.

Prepayments are those amounts paid in advance for clinical trials or commercial services that may be repaid at the end of the associated agreements or received as services. These services or repayments are estimated to be received in a period greater than twelve months from December 31, 2022.

14. Trade and other receivables

	2022 £'000	2021 £'000
Trade receivables	27,736	6,047
Other receivables	7,682	1,470
Prepayments and accrued income	11,293	7,691
	46,711	**15,208**

Included within prepayments and accrued income are amounts paid in advance for clinical trials that are expected to be received in services or repaid within 12 months.

15. Capital and reserves

Private investment in public equity ("PIPE")

In July 2022, the Company issued and sold 2,000,000 ADSs, with each ADS representing one ordinary share of nominal value £0.002 and 1,733,333 non-voting ordinary shares of nominal value £0.002 each, to certain institutional accredited investors and existing shareholders (the "Investors") at a purchase price of $37.50 per ADS / non-voting ordinary share pursuant to a securities purchase agreement with such Investors dated July 15, 2022, generating gross proceeds of £116,812,000 ($140,000,000) before deducting offering expenses payable by the Company of £388,000.

Capital Reduction

In April 2022, the Company completed a reduction of its share capital, as contemplated in the registration statement for the Company's initial public offering, whereby (i) the whole of the amount standing to the credit of the Company's share premium account was cancelled and (ii) 23,702,856,974 ordinary shares and 457,338,326 non-voting ordinary shares (which were issued by way of a bonus issue on April 25, 2022 for the purpose of capitalising the Company's merger reserve) were cancelled. The distributable reserves created by the reduction of capital amounted to £261.4 million.

IPO and Impact of Corporate Reorganization

On January 7, 2021, Immunocore Holdings Limited was incorporated as a private limited company under the laws of England and Wales with nominal assets and liabilities for the purpose of becoming the holding company of Immunocore Limited.

On January 22, 2021, each holder of series A preferred shares, series B preferred shares, series C preferred shares, Growth Shares and ordinary shares in Immunocore Limited, sold and transferred their shares to Immunocore Holdings Limited in exchange for 100 shares of the same class at par value of 0.01 pence in Immunocore Holdings Limited. Following this share exchange, Immunocore Limited became a wholly owned subsidiary of Immunocore Holdings Limited.

All Immunocore Limited share options granted to directors and employees under share option plans that were in existence immediately prior to the reorganization were exchanged for share options in Immunocore Holdings Limited on a one-for-100 basis.

Following the share exchange, Immunocore Limited undertook a reorganization of its share capital to re-designate its series A preferred shares, series B preferred shares, series C preferred shares and Growth Shares into a single class of ordinary shares and subsequently undertook a share capital reduction, cancelling all amounts standing to the credit of its share premium account and cancelling 6,414,412 ordinary shares.

On February 1, 2021, Immunocore Holdings Limited was re-registered as a public limited company ("plc") with the name Immunocore Holdings plc. The Company's consolidated assets and liabilities immediately following the reorganization were the same as Immunocore Limited immediately before the reorganization.

Effective immediately prior to completion of the IPO, the Company re-organized its share capital whereby all of the outstanding series A preferred shares, series B preferred shares and series C preferred shares were re-designated as ordinary shares of the Company on a one for one basis. A total of 16,632,540 of the ordinary shares, following the re-designation of the series C preferred shares, were converted to a separate class of non-voting ordinary shares. A total of 6,250,000 Growth Shares were re-designated of which 4,324,000 of the Growth Shares were re-designated as deferred shares of the Company. The remaining 1,926,000 Growth Shares were re-designated in the ratio of one ordinary share, issued for non-cash consideration and three deferred shares.

Immediately following these re-designations referred to above every 20 ordinary shares of £0.0001 and every 20 non-voting ordinary shares of £0.0001 in the Company were consolidated into one ordinary share and one non-voting ordinary share of £0.002.

On February 9, 2021, the Company completed an IPO of 11,426,280 ADSs representing 11,426,280 ordinary shares with a nominal value of £0.002 per ordinary share for gross proceeds of $297,083,000. In addition to the ADSs sold in the IPO, the Company completed the concurrent sale of an additional 576,923 ADSs, representing 576,923 ordinary shares with a nominal value of £0.002 per ordinary share, at the initial offering price of $26.00 per ADS, for gross proceeds of approximately $15.0 million, in a private placement to the Gates Foundation. The total aggregate gross proceeds were $312,083,000 (£226,528,000). A total of £15,543,000 representing underwriting discounts and commissions and other offering expenses incurred incrementally and directly attributable to the offering of securities were deducted from the gross proceeds of the IPO.

Under the terms of the Company's agreement with the Gates Foundation, the Group is required to develop, manufacture and commercialize soluble TCR bispecific therapeutic candidates targeted to mutually agreed neglected diseases, currently HIV, with the potential to treat people at an affordable price in developing countries. In the event of certain defaults by the Group under the agreement, the Gates Foundation has the right to sell, or require the Group to buy back, any of the shareholdings in the Group held by the Gates Foundation. In such an event, if within 12 months after such redemption or sale, the Group experiences a change in control at a valuation of more than 150% of the valuation used for the redemption or the sale of the shares, the Group has agreed to pay the Gates Foundation compensation equal to the excess of what it would have received in such transaction if it still held its shares at the time of such change of control over what it received in the sale or redemption of its shares.

The table below reflects the number of growth, ordinary, and deferred shares issued and outstanding at December 31, 2022.

	Growth shares	Ordinary shares	Deferred shares
Issued and fully paid share capital (0.2p per share, except deferred shares which are 0.01p per share)			
At January 1, 2021	**391**	**31,782,885**	**5,793,501**
Repurchased and cancelled	(391)	—	—
New shares issued for cash	—	12,003,203	—
Exercise of share options	—	76,762	—
At December 31, 2021	**—**	**43,862,850**	**5,793,501**
Repurchased and cancelled	—	—	—
New shares issued for cash	—	3,733,333	—
Exercise of share options	—	492,163	—
At December 31, 2022	**—**	**48,088,346**	**5,793,501**

The impact of the corporate reorganization reflects the combined effect of each of the steps of the corporate reorganization set out in this Note 15. A total of 391 Growth Shares with a nominal value of £0.0001 per Growth Share were repurchased and cancelled. Included within ordinary shares are2,164,960 ordinary shares with no voting rights. All ordinary shares are entitled to receive dividends and assets available for distribution. Deferred shares have no voting rights and are not entitled to dividends and are only entitled to receive amounts paid up on the deferred shares out of assets available for distribution after all payments have been made to holders of ordinary shares for amounts paid up or payable on such shares.

	2022 £	2021 £
Allotted, called up and fully paid		
Ordinary shares	96,177	87,726
Deferred shares	579	579
	96,756	**88,305**

On February 3, 2021, the Company passed an ordinary resolution which authorises the Directors, or any duly authorised committee of the directors, to allot shares in the Company or grant rights to subscribe for or convert any security into shares in the Company up to an aggregate nominal value of £150,000 for a period expiring five years (up to February 3, 2026). This amount may be renewed, varied or revoked by the Company in a general meeting.

Nature and purpose of reserves

The share-based payments reserve is used to recognize the value of equity-settled share-based payments provided to employees. All other reserves are as stated in the consolidated statement of changes in equity.

The other reserve arose as a result of the corporate reorganization described above.

The treasury reserve represents those unvested awards granted to certain employees and members of the Board under the Growth Share Plan (Note 19). As at December 31, 2022, the treasury reserve totaled nil (2021: nil; 2020: £2.80).

No dividends were paid or declared in the years ended December 31, 2022, 2021 and 2020.

Capital management

The capital structure of the Group consists of shareholders' equity, debt, cash and investments in money market funds. For the foreseeable future, the Board will maintain a capital structure that supports the Group's strategic objectives through:

- managing the budgeting process;
- managing funding and liquidity risk; and
- maintaining strong investor relations.

The Group monitors capital to maintain an appropriate structure that fulfils its strategic objectives, considers the needs of shareholders, and ensures it maintains sufficient funds to continue as a going concern.

The Group's borrowings under the Pharmakon Loan Agreement detailed in Note 17, contain customary representations and warranties and customary affirmative and negative covenants applicable to the Group, including limitations on the Group's ability to dispose of assets, enter into merger, consolidation or acquisition transactions, and incur additional debt. The Group monitors compliance with these covenants during the year and is in compliance.

16. Non-current accruals

Non-current accruals include estimates for rebates, chargebacks and other customer fees, and returns in respect of Product revenue, net and Pre-product revenue, net. Further details of the amounts and judgements involved in the determination of these accruals is provided under the Group's Critical accounting estimates and judgments in Note 2.

17. Non-current interest-bearing loans and borrowings

	2022 £'000	2021 £'000
Long-term borrowings	39,500	37,226
	39,500	**37,226**

In November 2022, the Group entered into an agreement with Pharmakon for the provision of a facility of up to $100 million. The Group used the proceeds after drawing down the first tranche of $50 million under the Pharmakon Loan Agreement to repay the Group's loan at the time with Oxford Finance. The total payments made for the exit fee on the loan with Oxford Finance and attributable fees to the agreement with Pharmakon were £3,280,000. The Group is also required to pay a further fee of £1,035,000 ($1,250,000) at the latest by June 2024, regardless of whether it elects to draw down on the second $50m tranche under the Pharmakon Loan Agreement. The first $50 million tranche of the loan under the agreement with Pharmakon bears interest at a fixed rate of 9.75%, which is payable quarterly in arrears, with payments commencing in 2023.

The Group has pledged financial assets, which include Cash and cash equivalents and Trade receivables, the values of which are presented in the consolidated statement of financial position at December 31, 2022, and Note 14, respectively, as collateral for the loan drawn down under the Pharmakon Loan Agreement. In the event the Group was unable to repay the loan, these pledged assets would instead be used to repay the outstanding amount of loan and interest.

The Group originally entered into its loan and security agreement with Oxford Finance in November 2020 for the provision of up to $100 million debt financing to be provided under three tranches, of which the first tranche of $50 million was received on signing the agreement.

18. Trade and other payables

	2022 £'000	2021 £'000
Trade payables	11,716	7,499
Other taxation and social security	927	532
Pension liability	34	23
Accruals	62,399	27,382
	75,076	**35,436**

Accruals include estimates for rebates, chargebacks and other customer fees, and returns in respect of Product revenue, net and Pre-product revenue, net. Further details of the amounts and judgements involved in the determination of these accruals is provided under the Group's Critical accounting estimates and judgments in Note 2.

19. Share-based payments

The Group operates employee share schemes that grant equity settled awards to employees and directors to acquire shares in the Group at a specified exercise price. Grants are normally exercisable over a four-year period with 25% vesting at the end of the first year and the remaining award vesting quarterly over the following three years. All awards lapse on the tenth anniversary from the date of grant and are not entitled to dividends.

The total charge for such share-based payment plans in 2022 was £27,054,000 (2021 – £35,861,000; 2020 – £8,162,000), all of which relate to equity settled awards.

Equity Incentive Plan ("EIP")

Under the Group's EIP, awards are granted to certain employees and members of the Board to acquire shares in the Company at a specified exercise price. Those awards granted from 2017 normally vest over a four-year period with 25% of the award vesting at the end of the first year and the remaining award vesting quarterly over the following three years. Awards granted prior to 2017 normally vest over a four-year period with 25% of the award vesting after each complete year.

Immediately prior to completion of the IPO, the Group undertook a corporate reorganization (see Note 15), and the following changes were undertaken in respect of share options and growth share awards in existence immediately prior to the reorganization.

All Immunocore Limited share options and Growth Shares granted to directors and employees under share incentive arrangements that were in existence immediately prior to the reorganization were exchanged for share options and Growth Shares in the Company on a one-for-100 basis with no change in any of the vesting terms and exercise prices.

Immediately prior to completion of the IPO, the Company reorganized its share capital which included the re-designation of 6,250,000 Growth Shares, or 312,500 Growth Shares reflecting the consolidation of every 20 ordinary shares into one ordinary share of £0.002, as both ordinary shares and deferred shares (see Note 15). Previously awarded Growth Shares were replaced with an award of share options in the Company on a one-for-one basis. For 216,200 of these replacement share option awards, the vesting terms and exercise prices were substantially unchanged. For the remaining 96,300 replacement share option awards, the vesting terms and exercise prices were revised to the extent that these Growth Shares were considered cancelled for the purpose of determining the share-based payment charge, prior to the replacement share options being awarded. In addition, the replacement ordinary shares that arose from the re-designation of Growth Shares resulted in an incremental fair value of £325,000, attributed to share premium.

Immediately following these re-designations referred to above, every 20 share options over ordinary shares of £0.0001 in the Company was consolidated into one share option over an ordinary share of £0.002. At the same time, the exercise price for each of the outstanding share options was adjusted to reflect the reorganization, subject to a minimum exercise price equal to the nominal value of a share and was re-designated into U.S. dollars. The adjustment to exercise price did not impact the fair value of the underlying share options, with the exception of the 96,300 replacement share options re-designated from Growth Shares where the exercise price was increased.

Those share options awarded in 2019 were modified at the same time as the corporate reorganization, through the removal of accelerated vesting conditions under certain circumstances. The incremental fair value granted was valued on a consistent basis to other awards made within the Group and was valued at $5.19 per share and was applied to those unvested awards as at the date of modification. Fair value inputs for the purposes of calculating the incremental fair value of the modification in January 2021 included an exercise price of $17.46, a share price of $26.00, an expected life of 3 years, expected volatility of 90% and a risk-free rate of -0.13%.

During March 2020, those share options awarded in 2019 were modified through a reduction in the associated exercise price from $30.93 to $17.46 per share. The incremental fair value granted was valued on a consistent basis to other awards made within the Group and was valued at $3.84 per share and was applied to those unvested awards as at the date of modification. Fair value inputs for the purposes of calculating the incremental fair value of the modification in March 2020 included an exercise price and share price of $17.46, an expected life of 1.6 years, expected volatility of 93% and a risk-free rate of 0.11%.

During the year ended December 31, 2022, and December 31, 2021, options over a total of 1,507,581 shares and 4,702,027 shares respectively were awarded, the majority of which vest over a four-year period from the date of grant, with 25% of the award vesting at the end of the first year and the remaining award vesting quarterly over the following three years. Of the above awards in the year ended December 31, 2022, there were 66,972 options awarded to our non-executive directors, 56,704 of which vest one year from the date of grant and 10,268 of which vest monthly over a three-year period. The Group's awards are not entitled to dividends prior to exercise.

The number and weighted average exercise prices of share options are as follows:

Number of shares issuable	Number of share options (#)	Weighted average exercise price ($)
Outstanding at January 1, 2020	**3,579,115**	**36.26**
Awards granted	1,122,680	17.46
Awards exercised	(13,880)	5.98
Awards forfeited	(136,556)	22.29
Outstanding at December 31, 2020	**4,551,359**	**17.16**
Awards granted	4,702,027	26.56
Awards exercised	(76,762)	17.01
Awards forfeited	(290,664)	31.24
Awards replaced with options	312,500	38.72
Outstanding at December 31, 2021	**9,198,460**	**22.31**
Awards granted	1,507,581	27.50
Awards exercised	(492,163)	19.72
Awards forfeited	(320,634)	26.41
Outstanding at December 31, 2022	**9,893,244**	**23.10**
Exercisable at December 31, 2022	**4,967,607**	**20.97**

The weighted average fair value of options granted in 2022 was $16.93 (2021: $16.48; 2020: $9.11). The weighted average share price at the date of exercise of the options during the year was $46.17 (2021: $33.97; 2020: $17.46).

The number and weighted average hurdle rate of growth shares previously held were as follows:

Number of shares issuable	Number of growth shares	Weighted average hurdle rate $
Outstanding at December 31, 2020	314,456	37.53
Awards forfeited	(1,956)	40.95
Awards replaced with options	(312,500)	37.49
Outstanding at December 31, 2021	—	—
Outstanding at December 31, 2022	—	—

For share options outstanding at December 31, 2022, the range of exercise prices and weighted average remaining contractual life are as follows:

	Share options	
Exercise price £	Number of options	Weighted average remaining contractual life
11.83	221,258	2.3
17.46	3,790,348	6.3
24.66	1,122,956	9.1
25.83	56,704	9.4
26.00	4,077,400	8.1
29.87	113,559	9.3
32.98	16,545	3.1
34.44	10,268	9.5
34.83	28,800	9.0
36.79	144,875	8.8
37.25	2,100	9.5
39.02	3,000	8.5
40.93	64,965	6.9
41.74	42,223	8.3
46.39	56,415	8.1
46.86	141,828	9.8

Awards granted in the year ended December 31, 2022, and 2021, have been valued using the Black-Scholes option pricing model. The assumptions used in the models for share options granted during year ended December 31, 2022 and 2021, are as follows:

	2022	2021
Share price at grant date	$ 24.66 - $46.86	$ 26.00 - $41.74
Exercise price	$ 24.66 - $46.86	$ 26.00 - $41.74
Expected volatility	73.02% - 87.81%	83.88% - 88.76%
Expected life (years)	4 years - 5 years	4 years
Risk free rate	1.12% - 4.12%	-0.05% - 0.52%
Fair value	$ 15.10 - $29.41	$ 16.16 - $26.18

As the Group completed its IPO on February 9, 2021, there is insufficient trading history at this time to derive historical volatility from the Group's own ADS price. Accordingly, the expected volatility is determined by reference to both the period for which trading activity is available for the Group's own price and the historical volatility of similar listed entities. The expected volatility used reflects the assumption that the historical volatility over a period similar to the life of the awards is indicative of future trends, which may not necessarily be the actual outcome. The expected life of the share options is based on expectations and is not necessarily indicative of exercise patterns that may occur. The risk-free rate is based on the Bank of England's estimates of gilt yield curve as at the respective grant dates.

Previous awards granted under the Share Option Plan were valued using the Black-Scholes option pricing model, those awards granted under the Growth Share Plan were valued using the Back Solve model, reflecting the different rights available to holders of Growth Shares. The assumptions used in the models for previous awards granted are as follows and adjusted to reflect our corporate reorganisation and IPO outlined further above.

	Growth shares		Share options			
	Apr-20	Jun-20	Apr- 20	Jun- 20	Oct-20	Nov- 20
Share price at grant date	$ 17.46	$ 17.46	$ 17.46	$ 17.46	$ 17.46	$ 17.46
Exercise price	—	—	$ 17.46	$ 17.46	$ 17.46	$ 17.46
Hurdle rate	$ 17.46 - 46.39	$ 17.46	—	—	—	—
Expected volatility	91%	102%	79%	85%	87%	87%
Expected life (years)	1	1	3	3	3	3
Risk free rate	0.03%	(0.02%)	0.03%	(0.03)% – 0.02%	(0.07)%	(0.01%)
Fair value	$ 0.58 - 1.92	$ 1.92	$ 8.84	$ 9.36 - 9.37	$ 9.59	$ 9.55

	Growth shares	Share options	Share options	Share options
	Apr-17	May-19	Apr-17	2016
Share price at grant date	$ 40.93	$ 17.46	$ 40.93	$ 38.20
Exercise price	—	$ 40.93	$ 40.93	$ 11.83 - 40.93
Hurdle rate	$ 46.39	—	—	—
Expected volatility	65%	67%	65%	60%
Expected life (years)	2.7	1.9 yrs - 3 yrs	5	5
Risk free rate	0.15%	0.69% - 0.71%	0.42%	0.62% - 1.41%
Fair value	$ 15.98	$ 3.26	$ 22.00	$ 21.06 - 29.45

Share options and growth shares are not entitled to dividends.

The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the awards is indicative of future trends, which may not necessarily be the actual outcome. The expected life of the share options is based on historical data and current expectations and is not necessarily indicative of exercise patterns that may occur. The risk-free rate is based on the Bank of England's estimates of gilt yield curve as at the respective grant dates.

20. Financial instruments

Financial instruments risk management objectives and policies

The Group's principal financial assets include cash and cash equivalents, trade receivables and cash and security deposits that derive directly from its operations or from financing activities. The Group's principal financial liabilities comprise the drawn down debt under the loan agreement with Pharmakon, lease liabilities, and the majority of trade and other payables. The main purpose of these financial liabilities is to finance the Group's operations.

	2022 Carrying amount £'000	2021 Carrying amount £'000
Financial assets at amortized cost:		
Current financial assets		
Cash and cash equivalents	332,539	237,886
Trade receivables	27,736	6,047
Prepayments and accrued income	769	—
Non-current financial assets		
Long-term security deposits	941	786
Other	137	165
Total financial assets	**362,122**	**244,884**
Financial liabilities at amortized cost:		
Current financial liabilities		
Trade and other payables	74,149	35,436
Lease liabilities	1,555	1,255
Non-current financial liabilities		
Non-current accruals	1,479	—
Interest-bearing loans and borrowings	39,500	37,226
Lease liabilities	28,248	25,355
Total financial liabilities	**144,931**	**99,272**

The Group is exposed to interest rate, currency, credit and liquidity risks. The Group's Board oversees the management of these risks supported by a financial risk committee that advises on financial risks and the appropriate financial risk governance framework. The financial risk committee provides assurance to the Board that the Group's financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with its policies and risk objectives. The most significant financial risks to which the Group is exposed are set out below.

Liquidity risk

The Group's exposure to liquidity risk arises from its ongoing operational expenditure required to perform its principal activity. The Group continuously monitors the risk of a shortage of funds by assessing expected cash flows, which are used to generate forecast levels of cash and cash equivalents. The Group also considers its foreign currency receivables and the foreign currency cash levels required in dollars and euros as part of these forecasts in order to ensure it has sufficient resources to settle its payable balances. The Group's objective is to maintain a balance between continuity of funding and flexibility through the use of capital increases or other sources of financing to ensure it continues to have sufficient liquidity.

The following are the contractual maturities of financial liabilities, including estimated interest payments in respect of the interest-bearing loans and borrowings:

At December 31, 2022	Carrying amount £ '000	Contractual cash flows £ '000	One year or less £ '000	1 - 3 years £ '000	3 - 5 years £ '000	Greater than 5 years £ '000
Financial liabilities						
Trade payables and accruals	74,149	74,149	74,149	—	—	—
Interest-bearing loans and borrowings (Note 17)	39,500	61,238	4,084	9,212	32,068	15,874
Non-current accruals	1,479	1,479	—	1,479	—	—
Total financial liabilities	**115,128**	**136,866**	**78,233**	**10,691**	**32,068**	**15,874**

At December 31, 2021	Carrying amount £'000	Contractual cash flows £'000	One year or less £'000
Financial liabilities			
Trade payables	32,393	32,393	32,393
Interest-bearing loans and borrowings (Note 17)	37,226	37,226	—
Total financial liabilities	**69,619**	**69,619**	**32,393**

The maturity of contractual cashflows for the majority of financial liabilities isone year or less except for interest-bearing loans and borrowings which have been calculated in accordance with the Group's loans and borrowings accounting policy which states that all such balances are classified as financial liabilities and are initially recorded at the amount of proceeds received, net of transaction costs. Loans and borrowings are subsequently measured at amortized cost, with the difference between the proceeds, net of transaction costs, and the amount due on redemption being recognized as an expense to the profit and loss account over the period of the relevant loan and borrowings. Interest payable or accrued at the end of each reporting period on these loans is included within Trade and other payables in the Consolidated statement of financial position.

The contractual cash flows represent amounts contractually due to Pharmakon in accordance with the agreement. The contractual amounts for the initial tranche of $50 million drawn down under the agreement are interest-only payments through to November 2026 followed by equal quarterly payments of principal and interest through to the maturity date in November 2028. Contractual maturities for the Group's lease liabilities are presented under "Commitments and contingencies" in Note 22.

Credit risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk from its operating activities, including trade receivables and deposits with banks and financial institutions. The Group has assessed the expected credit loss by considering a number of factors including the credit quality of the Group's counter-parties and the short-term nature of the receivables. The majority of the Group's receivables are with healthcare distributors and healthcare providers, including government hospitals. These receivables arise primarily in the United States, Germany and France, and the Group considers the location of the counterparty in conjunction with the type of counterparty in assessing the level of credit risk involved. Appropriate due diligence is performed on these organizations before agreements are entered into, and the Group implements and monitors appropriate credit limits for each customer. Of the Group's Trade receivables of £27,736,000, £4,194,000 were past due at December 31, 2022. The Group has subsequently received the majority of these amounts for the past due receivables. Trade receivables are assessed for impairment using the simplified approach under IFRS 9, *Financial Instruments*, which requires lifetime expected losses to be recognized with the initial recognition of the receivable. As at December 31, 2022, the amount of expected credit losses recognized in the Consolidated statement of financial position is not material.

The Group held cash and cash equivalents of £332,539,000 at December 31, 2022 (2021: £237,886,000) which are held with multiple highly rated banks. The Group monitors the credit rating of those banks.

The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in this Note 20.

The Group determines whether receivable balances should be written off on an individual basis. Balances are written off when there is no reasonable expectation of recovery. Write-offs were immaterial in the years ended December 31, 2022, 2021 and 2020.

Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: interest rate risk, currency risk and other price risk, such as equity price risk and commodity risk.

Interest rate risk

The Group's exposure to changes in interest rates relates to investments in deposits and to changes in the interest for overnight deposits. Changes in the general level of interest rates may lead to an increase or decrease in the fair value of these investments. As a result of entering into the Loan Agreement with Oxford Finance, the Group was previously exposed to interest rate risk as a variable rate of interest was applied within a defined cap and collar over the term of the debt. The Group repaid this loan to Oxford Finance and entered into a loan with Pharmakon in November 2022. The first tranche of this loan drawn down in the year ended December 31, 2022 is subject to a fixed rate of interest and the Group is no longer exposed to these variable interest rate movements on its loan borrowings.

Financial assets subject to variable interest rates are as follows:

	2022 Carrying amount £'000	**2021 Carrying amount £'000**
Cash and cash equivalents	332,539	237,886
	332,539	**237,886**

An increase in Bank of England base rates by 0.5 percentage points would increase the net annual interest income as of December 31, 2022 by £1,663,000 (2021: £1,189,000). A decrease in Bank of England base rates by 0.5 percentage points would reduce the net annual interest income to all the deposit accounts as of December 31, 2022 by £1,663,000 (2021: £1,189,000).

Financial liabilities subject to variable interest rates are as follows:

	2022 Carrying amount £'000	2021 Carrying amount £'000
Interest-bearing loans and borrowings	—	37,226
	—	**37,226**

The Group's loan drawn down under the Pharmakon Agreement bears a fixed rate of interest and there were no interest-bearing loans and borrowings as at December 31, 2022 bearing a variable rate of interest.

Interest-bearing loans and borrowings as at 31 December, 2021 represented borrowings under the Oxford Finance agreement, which bore interest at an annual rate equal to LIBOR plus 8.85% with a minimum rate of 9.01% and a maximum rate of 12.01%.

Foreign currency risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Group's exposure to the risk of changes in foreign exchange rates relates primarily to the fluctuations in the value of foreign currency cash and cash equivalents held by the Group's main operating subsidiary in the U.K., the Group's operating activities in the United States, and outsourced supplier agreements denominated in currencies other than pound sterling. The Group minimizes foreign currency risk by maintaining cash and cash equivalents of each currency at levels sufficient to meet foreseeable expenditure to the extent practical.

Financial assets and liabilities in foreign currencies are as follows:

	2022 Carrying amount £'000	2021 Carrying amount £'000
Financial assets at amortized cost:		
Cash and cash equivalents	229,981	134,935
Trade and other receivables	27,736	3,628
	257,717	**138,563**
Financial liabilities at amortized cost:		
Trade payables	7,099	15,589
Accruals	50,058	16,174
Interest-bearing loans and borrowings (Note 17)	39,500	37,226
	96,657	**68,989**

A five percentage point increase in exchange rates would reduce the carrying value of net financial assets and liabilities held in foreign currencies at December 31, 2022 by £6,735,000 (2021: £2,598,000 decrease). A five percentage point decrease in exchange rates would increase the carrying value of net financial assets and liabilities held in foreign currencies at December 31, 2022 by £6,735,000 (2021: £2,598,000 increase).

Disclosure of financial assets and liabilities

Fair value of financial assets and liabilities

Cash and cash equivalents, trade receivables, trade and other payables and other short-term assets and liabilities

The majority of the Group's financial assets and liabilities outlined at the start of this Financial instruments note are short-term items for which the nominal value is deemed to reflect fair value.

Non-current financial assets and liabilities

The Group has presented the carrying amount and estimated fair value of its non-current financial assets and liabilities in the table below.

	2022		2021	
	Carrying amount £'000	Fair value £'000	Carrying amount £'000	Fair value £'000
Financial assets at amortized cost:				
Non-current financial assets and other receivables	1,078	1,078	951	951
Total financial assets at amortized cost	**1,078**	**1,078**	**951**	**951**

	2022		2021	
	Carrying amount £'000	Fair value £'000	Carrying amount £'000	Fair value £'000
Financial liabilities at amortized cost				
Non-current accruals	1,479	1,479	—	—
Interest-bearing loans and borrowings (Note 17)	39,500	39,322	37,226	37,226
Total financial liabilities	**40,979**	**40,801**	**37,226**	**37,226**

Interest bearing loans and borrowings

On November 8, 2022, the Group entered into the Pharmakon Loan Agreement, providing for term loans to the Group in an aggregate principal amount of up to $100 million to be funded in two tranches. The first tranche, in the amount of $50 million, bears interest at a fixed rate of 9.75% and will mature in November 2028. The Group used the proceeds from the first tranche, together with cash on hand, to repay in full the Group's existing $50 million loan from Oxford Finance and thereafter no further amounts may be borrowed pursuant to the loan agreement with Oxford Finance. The second tranche, consisting of one or two term loan(s) in an aggregate principal amount of up to $50 million (with a minimum draw of $25 million), is available until June 30, 2024, and may be advanced at the Group's election and, if and when drawn, is intended to be used to support the continued development and commercialization of the Company's pipeline and for other general purposes.

The Group originally entered into a loan and security agreement, or the Oxford Finance Agreement, in November, 2020, for the provision of up to $100 million debt financing to fund the Group's working capital and other general corporate needs. The loan was subject to funding in three tranches, of which the first tranche of $50 million was received on signing the Loan Agreement. Borrowings under the Oxford Finance Agreement bore interest at an annual rate equal to LIBOR plus 8.85%, with a minimum rate of 9.01% and a maximum rate of 12.01% and were repayable in monthly interest-only payments.

Other non-current financial assets

Included within other non-current financial assets are long-term deposits representing lease security deposits for buildings, with a balance at December 31, 2022 of £941,000 (2021: £786,000) and £137,000 for a legal settlement.

Changes in liabilities arising from financing activities

Movements relating to finance costs are set out in Note8 and the changes in cash flows from financing activities related to the Group's liabilities are outlined in the Consolidated Statement of Cash Flows.

The Group's non-current loans increased by £2,274,000 to £39,500,000 in the year ended December 31, 2022, primarily due to foreign exchange differences. The Group recorded foreign currency losses on its loans with Oxford Finance and under the Pharmakon Loan Agreement totalling £4,387,000 in the year ended December 31, 2022. There were also repayment fees on the Group's loan with Oxford Finance and attributable fees in arranging a new facility with Pharmakon, which totalled £3,280,000, and there was a loss of £1,393,000 arising on derecognition of the loan with Oxford Finance.

The potential impact of foreign exchange rates on our financial liabilities is illustrated further above in this note under 'Foreign Currency Risk'.

There was no material change in 2021 on year in the loan liability of £37,226,000 and £36,654,000 as at December 31, 2021, and 2020 respectively.

Lease liabilities increased by £3,193,000 in the year ended December 31, 2022 primarily as a result of lease additions of £2,575,000, lease remeasurements of £1,710,000 and interest costs of £1,796,000 (Note 8 and Note 12), which were offset by lease payments of £3,208,000 as set out in Cash flows from financing activities in the Consolidated statements of cash flows. There were no material changes in leases liabilities in the year ended December 31, 2021 other than interest costs and continued payments for the use of buildings under the relevant agreements.

21. Post-employment benefit plans

The Group operates a defined contribution pension scheme for its directors and employees. The assets of the scheme are held separately from those of the Group in an independently administered fund.

The unpaid contributions outstanding at December 31, 2022 were £5,000 (2021: £23,000; 2020: £2,000). The total expense relating to these plans in the current period was £1,355,000 (2021: £1,001,000; 2020: £1,035,000).

22. Commitments and contingencies

As at December 31, 2022	Less than 1 year	1-3 years	3-5 years	5-10 years	10-15 years	More than 15 years	Total
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Lease liabilities – existing	3,504	5,898	5,741	14,893	15,045	3,952	49,033
Lease liabilities – contingent	107	429	429	161	—	—	1,126
Manufacturing	9,337	1,597	—	—	—	—	10,934
Other	421	438	—	—	—	—	859
Intangible commitments	826	—	—	—	—	—	826
Capital commitments	1,058	—	—	—	—	—	1,058
Total contractual obligations	**15,253**	**8,362**	**6,170**	**15,054**	**15,045**	**3,952**	**63,836**

As at December 31, 2021	Less than 1 year	1-3 years	3-5 years	5-10 years	10-15 years	More than 15 years	Total
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Lease liabilities – existing	2,947	5,407	4,959	12,533	13,172	4,742	43,760
Lease liabilities – contingent	57	840	225	—	—	—	1,122
Manufacturing	919	189	—	—	—	—	1,108
Capital commitments	75	—	—	—	—	—	75
Total contractual obligations	**3,998**	**6,436**	**5,184**	**12,533**	**13,172**	**4,742**	**46,065**

The Group's manufacturing commitments expected to be incurred in less than one year increased to £9,337,000 in the year ended December 31, 2022, primarily as a result of the Group's plans to increase expenditure in relation to its IMC-F106C (PRAME) and other early-stage programs in 2023.

The Group has contractual obligations for a leasehold property under which it is obligated to take on the lease should the property become vacant at specified dates in the future. The Group has assessed this contingent event as at December 31, 2022, and has classified the potential obligation as a contingent liability totaling £1,126,000 (2021: £1,122,000).

23. Related party disclosures

The Group may enter into transactions in the ordinary course of business with unaffiliated companies of which the Group's directors are directors or executive officers. The Group considers such transactions to be on terms comparable with those of other companies with whom the Group does not share a common director or executive officer. The amounts involved in such transactions are not considered material in relation to the Group, the companies, or the directors and executive officers.

Remuneration of key management personnel

The remuneration of the directors and executive officers, who are considered the key management personnel of the Group, is set out below in aggregate for each of the categories specified in IAS 24, 'Related Party Disclosures.

	2022 £'000	2021 £'000	2020 £'000
Short-term employee benefits	3,065	2,222	3,421
Share-based payment	20,137	25,813	5,602
	23,202	**28,035**	**9,023**

Short-term employee benefits above include £41,000 and £29,000 of pension contributions for the years ended December 31, 2022 and 2021, respectively.

24. Events after the reporting period

As the Group has elected in February 2023 to withdraw from co-funding with Genentech the MAGE-A4 HLA-A02 program, IMC-C103C, Genentech shall acquire an exclusive worldwide license to the MAGE-A4 HLA-A02 soluble TCR bispecific therapeutic candidate compounds and shall be fully responsible for all further development and commercialization of such candidate compounds, at its expense. The licenses granted to Genentech do not include any rights to (i) affinity-enhanced TCRs or (ii) TCR therapeutic compounds, in each case (i) and (ii) that are directed to targets other than MAGE-A4.

Exhibit 12.1

Certification by the Principal Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Bahija Jallal, certify that:

1. I have reviewed this annual report on Form 20-F of Immunocore Holdings plc (the "***Company***");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 1, 2023

By: /s/ Bahija Jallal, Ph.D.
Bahija Jallal, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 12.2

Certification by the Principal Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Brian Di Donato, certify that:

1. I have reviewed this annual report on Form 20-F of Immunocore Holdings plc (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 1, 2023

By: /s/ Brian Di Donato
Brian Di Donato
Chief Financial Officer
(Principal Financial Officer)

Exhibit 13.1

Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 20-F of Immunocore Holdings plc (the "***Company***") for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "***Report***"), I, Bahija Jallal, Chief Executive Officer of the Company and Brian Di Donato, Chief Financial Officer of the Company, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each hereby certifies that, to the best of her or his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 1, 2023

/s/ Bahija Jallal, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

/s/ Brian Di Donato
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Immunocore Holdings plc under the Securities Exchange Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-255182 and 333-265000) on Form S-8 and registration statement (No. 333-264105) on Form F-3 of our reports dated March 1, 2023, with respect to the consolidated financial statements of Immunocore Holdings plc and the effectiveness of internal control over financial reporting.

/s/KPMG LLP

London, United Kingdom
March 1, 2023

Exhibit 16.1

March 1, 2023

Securities and Exchange Commission

Washington, D.C. 20549

Ladies and Gentlemen:

We are currently principal accountants for Immunocore Holdings plc and, under the date of March 1, 2023 we reported on the consolidated financial statements of Immunocore Holdings plc as of and for the years ended December 31, 2022 and 2021, and the effectiveness of internal control over financial reporting as of December 31, 2022. On November 9, 2022, we were notified that Immunocore Holdings plc intend to appoint Deloitte LLP as its principal accountant for the fiscal year ended December 31, 2023 and that the auditor-client relationship with KPMG LLP will cease upon receipt by Immunocore Holdings plc of our resignation after the completion of the audit of Immunocore Holdings plc's consolidated financial statements as of and for the year ended December 31, 2022, and the effectiveness of internal control over financial reporting as of and for the year ended December 31, 2022, and the issuance of our reports thereon. We have read Immunocore Holdings plc's statements included under Item 16F of its Form 20-F dated March 1, 2023, and we agree with such statements, except that we are not in a position to agree or disagree with Immunocore Holdings plc's statement that the Board of Directors will appoint Deloitte LLP as their U.K. statutory auditor and independent registered public accounting firm (subject to shareholder approval at the annual general meeting to be held in 2023).

Very truly yours.

/s/ KPMG LLP