



IMMUNOCORE

2021 ANNUAL REPORT

March 2022

DEAR FELLOW SHAREHOLDERS



Bahija Jallal, PhD
Chief Executive Officer

Reflecting on what has been a transformative time for Immunocore, I am extremely pleased with all we have been able to achieve over the last three years, culminating in the FDA approval of our lead product KIMMTRAK® (tebentafusp-tebn) for the treatment of metastatic uveal melanoma (mUM). This was a significant milestone for patients, and for Immunocore, and I am grateful for the dedication and commitment of our employees and healthcare partners.

But most importantly, I would like to thank the patients and their families who have participated in Immunocore clinical trials. KIMMTRAK's U.S. approval is an historic moment for the hundreds of people diagnosed with uveal melanoma every year, for whom the prognosis has been very poor.

U.S. approval was only the first step for Immunocore and for patients. We plan to pursue regulatory approvals in Europe and beyond. One month after FDA approval, we announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had adopted a positive opinion recommending KIMMTRAK® (tebentafusp) for the treatment of HLA-A*02:01-positive adult patients with unresectable mUM. The CHMP opinion will now be reviewed by the EMA, which will provide a final decision on Immunocore's Marketing Authorisation Application in the coming weeks.

Additional marketing authorization applications are under review in the United Kingdom, Canada, and Australia. Our goal is to obtain regulatory approval outside the U.S. and make KIMMTRAK available to more patients in 2022.

We will continue the commercial roll-out of KIMMTRAK, striving to ensure that those who need treatment, and are eligible, have access to it.

We are not stopping there. To date, we have dosed over 700 patients with our ImmTAC platform in melanoma and other solid tumors and look forward to helping even more patients going forward.

ESTABLISHING A PLATFORM FOR GROWTH

During 2021, we also made progress with two other off-the-shelf bispecific t-cell engager candidates in oncology:

- We reported clinical activity for our MAGE-A4 program at the ESMO IO conference. Our candidate (IMC-C102C) demonstrated initial signs of clinical activity with confirmed durable responses in ovarian cancer and a confirmed durable response in head and neck squamous cell carcinomas (HNSCC), with a manageable safety profile. We have initiated an expansion arm in ovarian cancer, while we continue



- ✓ Breakthrough therapy designation
- ✓ RTOR & Project Orbis Initiative
- ✓ Data presentations AACR & ASCO
- ✓ US, UK & EMA accept BLA/MAA's

KIMMTRAK 2021 MILESTONES

- ✓ ctDNA data published at ESMO
- ✓ New data in mCM at SITC
- ✓ FDA approval (January 2022)
- ✓ Positive CHMP opinion (February 2022)

to signal search and explore optimal dosing in multiple solid tumors.

- We continued to progress our third clinical stage candidate, IMC-F106C, an ImmTAC molecule targeting a PRAME antigen, in a first-in-human, Phase 1/2 trial. PRAME is overexpressed in many solid tumors, including non small cell lung cancer, small cell lung cancer, and endometrial, ovarian, melanoma and breast cancers. At year-end 2021, we have enrolled 39 patients into the dose escalation study and we plan to report initial Phase 1 data in the third quarter of 2022.

OUR VALIDATED PLATFORM OPENS DOORS TO MANY POSSIBILITIES FOR IMMUNOCORE

KIMMTRAK's U.S. approval provides an important validation of our ImmTAX platform and offers opportunities for the development of further ground-breaking discoveries in cancer and other diseases with high unmet need.

We continue to advance our T-cell engager candidates for infectious diseases, specifically Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV). We believe our approach has the potential of providing a functional cure in these chronic viral illnesses by redirecting non-exhausted T cells to attack the viral reservoir. Our clinical trial application for the HIV program was accepted in December 2021, and we aim to dose the first patient in the second quarter of 2022.

LOOKING AHEAD

We go into 2022 with energy and optimism that we can build on the amazing progress we have already made. Financially, we are in a strong position.

In February 2021, we raised approximately \$300 million in our upsized initial public offering, along with a concurrent private placement. These capital increases brought us new and engaged investors and have strengthened our balance sheet, providing us with sufficient resources to fund the commercial roll-out of KIMMTRAK and continue the development of our extended pipeline of ImmTAX candidates.

THANK YOU FOR YOUR COMMITMENT

Since I joined Immunocore as CEO in 2019, the team has identified clear goals for Immunocore and delivered on these goals successfully. This consistency and drive to execute our strategy will, I believe, continue to serve the Company, and our patients who are at the heart of what we do, well. We have made extraordinary progress, and to have achieved this much in the midst of the greatest public health crisis in a century, is a testament to the dedication of everyone here at Immunocore. With our entrepreneurial, diverse and performance-driven culture, we did not miss a beat and continually demonstrated our commitment to patients during this unprecedented time.

I am proud of each and every employee and I extend my sincere gratitude to our staff, our partners, my fellow shareholders and all those who have helped us on our mission to pioneer the development of an exciting new class of TCR therapeutics on behalf of patients.

With warm regards,



Bahija Jallal, PhD
Chief Executive Officer

LEADING THE WAY IN TCR THERAPEUTICS

1st

KIMMTRAK
(tebentafusp-tebn):
first approved TCR
therapeutic

1st

First and only
FDA-approved treatment
for metastatic uveal
melanoma

1st

First T-cell engager
to show overall
survival in solid
tumour

Forward Looking Statements

This Annual Report contains “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements regarding future events and our future results that are based on our current expectations, estimates and forecasts about our business, our strategy and clinical development plans, our results of operations and future revenue, the industry in which we operate and the beliefs and assumptions of our management. All statements contained herein which are not statements of historical fact are forward looking statements including, but not limited to, statements regarding our corporate strategy; the future development, timing and potential marketing approval and commercialization of KIMMTRAK including European Commission’s final decision on our Marketing Authorisation Application and regulatory approval of KIMMTRAK in the European Union; our ability to successfully manufacture and commercialize KIMMTRAK in the United States and beyond; the marketing and therapeutic potential of KIMMTRAK for metastatic uveal melanoma (mUM); the expected clinical benefits of KIMMTRAK including extended overall survival benefit; expectations regarding the timing of the commercial launch of KIMMTRAK; the timing and ability to reach patients in a timely manner including expectations regarding the receipt of future regulatory approval in respective European countries, the United Kingdom, Australia and Canada; the potential of our pipeline, clinical development and progress; risks and uncertainties associated with drug development and commercialization; and our future financial and operating results. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “potential,” “possible,” “will,” “would” and other words and terms of similar meaning. Our expectations and beliefs regarding these matters may not materialize, and our actual results in future periods are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval.

We urge investors to review the risks and uncertainties listed or described in our filings with the U.S. Securities and Exchange Commission (the “SEC”), including our most recent Annual Report on Form 20-F for the year ended December 31, 2020 filed with the SEC on March 3, 2022. Investors are cautioned not to place undue reliance on any such forward-looking statements or the scientific data presented. These statements are based on our current beliefs and expectations and speak only as of March 3, 2022. We undertake no duty to update any forward-looking statement, except as required by law.

Note Regarding Trademarks

Immunocore®, ImmTAC®, and KIMMTRAK® are registered trademarks of Immunocore. ImmTAX™ and ImmTAV™ are trademarks of Immunocore. [Other trademarks referenced in this Annual Report are the property of their respective owners.

Corporate Headquarters

Immunocore Holdings plc
92 Park Drive
Milton Park
Abingdon, Oxfordshire OX14 4RY
United Kingdom
+44 1235 438600
info@immunocore.com

Website

<https://www.immunocore.com/>

Market Information

Immunocore's ordinary shares, in the form of American Depositary Shares, or ADSs, are listed on the Nasdaq Global Select Market under the symbol "IMCR" and held by a depository bank, Citibank N.A. Each ADS represents the right to receive one ordinary share.

Depository

Citibank, N.A.
388 Greenwich Street
New York, New York 10013

Legal Counsel

Cooley LLP
55 Hudson Yards
New York, New York 1000

Cooley (UK) LLP
22 Bishopsgate,
London EC2N 4BQ
United Kingdom

Independent Registered Public Accounting Firm

KPMG LLP
London, United Kingdom

Investor Relations

Clayton Robertson, Head of Investor Relations
+1 215 384 4781
ir@immunocore.com

<https://ir.immunocore.com/>

Annual Report on Form 20-F

A copy of our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission is available at sec.gov and upon request to: Investor Relations Department, Immunocore Holdings plc 92 Park Drive, Milton Park, Abingdon, Oxfordshire OX14 4RY, United Kingdom, and by phone at [+44 1235 438600]

**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, 2021
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

92 Park Drive

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: 43,862,850 shares outstanding as of December 31, 2021.

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. ☐

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 \$1.3500 on December 31, 2021. 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 present 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:

- our ability to maintain regulatory approval of KIMMTRAK (tebentafusp-tebn) for metastatic uveal melanoma, or mUM, in the United States;
- the timing of, and our ability to obtain and maintain regulatory approval of, KIMMTRAK in the European Union and respective European countries;
- our expectations regarding the potential commercialization of, the marketing and therapeutic potential of KIMMTRAK for mUM;
- our ability to build a sustainable pipeline of new medicine candidates, including but not limited to future generations of KIMMTRAK;
- the expected clinical benefits of KIMMTRAK including extended overall survival benefit;
- expectations regarding the timing of the commercial launch of KIMMTRAK, the timing of commercial availability and the ability to reach patients in a timely manner;
- the value proposition of KIMMTRAK in mUM and benefit as an orphan indication including expectations regarding the potential market size opportunity;
- our ability to successfully executed our sales and marketing strategy of KIMMTRAK in the United States, 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 market opportunities for our product candidates may be smaller than we estimate and any approval that we obtain may be based on a narrower definition of the patient population;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and related preparatory work and the period during which the results of the trials will become available, as well as our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our expectations regarding timing of regulatory filings for, or our ability to obtain regulatory approval of, tebentafusp in additional jurisdictions, or any of our other product candidates;
- our ability to obtain accelerated approval for current and future product candidates from the FDA and the EMA;
- our ability to identify and develop additional product candidates using our ImmTAX platform;
- business disruptions affecting the initiation, patient enrollment, clinical trial site monitoring, development and operation of our current and proposed clinical trials, including a public health emergency, such as the ongoing coronavirus 2019, or COVID-19, pandemic;
- the potential benefits of our product candidates;
- our business strategies and goals;
- our plans to collaborate, or statements regarding our current collaborations;
- 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;
- the effects of 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;
- 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;
- the loss of key commercial or management personnel;
- whether we are classified as a PFIC for current and future periods;
- our ability to raise additional capital; and
- our estimates regarding the period of time for which our current capital resources will be sufficient to fund our continued operations, future expenses, revenues and needs for additional financing and the accuracy thereof.

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:

- The COVID-19 global pandemic has and may continue to 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.
- 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 generate revenues from KIMMTRAK is subject to attaining significant market acceptance among physicians, patients and healthcare payers.
- Our future prospects are highly dependent on our ability to successfully develop and execute a 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 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.
- The effects of health epidemics, including the ongoing COVID-19 pandemic, in regions where we, or the third parties on which we rely, have business operations could adversely impact our business, including our pre-clinical studies and clinical trials, as well as the business or operations of our CROs or other third parties with whom we conduct business.
- 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.
- Even if we obtain regulatory approvals to market our current and any 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.
- We are subject to manufacturing risks that could substantially increase our costs and limit supply of our products.
- We face substantial competition, which may result in others developing or commercializing drugs before or more successfully than us.
- 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.
- 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 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.
- Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain and motivate qualified personnel.
- As a company based outside of the United States, we are subject to economic, political, regulatory and other risks associated with international operations.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, industry standards and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could negatively affect our operating results and business.

Risks Related to Our Financial Position and Need for Capital

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

We only recently reached our commercial stage as a biotechnology company and have incurred net losses in each year since our inception. Our losses were £131.5 million, £74.1 million and £103.9 million for the years ended December 31, 2021, 2020 and 2019, respectively. We had an accumulated deficit of £481.4 million as of December 31, 2021. We have funded our operations to date primarily with proceeds from private placements of our ordinary and preferred shares, payments from our collaboration partners, debt financing and most recently, our initial public offering.

In January 2022, we received approval from the U.S. Food and Drug Administration, or the FDA, for KIMMTRAK (tebentafusp-tebn) for the treatment of unresectable or metastatic uveal melanoma, or mUM. We are also pursuing regulatory approval of KIMMTAK for the treatment of mUM in other countries including, but not limited to, the European Union, Canada and Australia. We recently began to generate product revenue for KIMMTRAK, reflecting initial sales since we launched KIMMTRAK in the United States in January 2022. We have initiated initial sales efforts during 2022 focused on ensuring market access to enable healthcare providers to purchase KIMMTRAK including obtaining payor coverage and securing contracts with distributors, group purchasing organizations, physician buying groups and federal government entities. We have not received regulatory approval for tebentafusp in any jurisdictions other than the United States, or regulatory approval for any of 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. 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:

- continue to establish a sales, marketing, manufacturing and distribution capability to 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 five clinical stage programs, including our Phase 1/2 clinical trial of IMC-F106C (PRAME) and our Phase 1/2 clinical trial of IMC-C103C (MAGE-A4) in multiple solid tumors; and our ImmTAV molecules targeting Hepatitis B Virus, or HBV, or HIV;
- initiate pre-clinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek regulatory approvals for tebentafusp in other jurisdictions, and any 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 and scientific 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 eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including marketing and selling KIMMTRAK and any future products for which we may obtain regulatory approval, our global regulatory submissions for tebentafusp and any 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 successfully develop and execute 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.

Substantial resources are focused on the commercialization of KIMMTRAK and any future products for which we may obtain regulatory approval. Our ability to generate significant medicine revenues and to achieve commercial success in the near-term will initially depend on our ability to successfully commercialize KIMMTRAK in the United States. With respect to KIMMTRAK, our commercial strategy includes launching KIMMTRAK globally for HLA-A*02:01 metastatic uveal melanoma patients in the United States, and then expanding into Europe, the United Kingdom, and select other markets.

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. As a newly launched medicine for a disease that had no previously-approved treatments, successful commercialization of KIMMTRAK is subject to many risks. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we have established our commercial team and U.S. field force, we expect to develop the team further in order to successfully commercialize KIMMTRAK. There are many factors that could cause commercialization of KIMMTRAK to be unsuccessful, including a number of factors that are outside our control. Because no medicine has previously been approved by the FDA for the treatment of mUM it is especially difficult to estimate KIMMTRAK's market potential or the time it will take to increase patient and physician awareness and change current treatment paradigms. The commercial success of KIMMTRAK depends on the extent to which patients and physicians accept and adopt KIMMTRAK as a treatment for mUM. For example, if the mUM patient population is smaller than we estimate, if it proves difficult to identify mUM patients or educate physicians as to the availability and potential benefits of KIMMTRAK, or if physicians are unwilling to prescribe or patients are unwilling to take KIMMTRAK, the commercial potential of KIMMTRAK will be limited. We also have limited information regarding how physicians, patients and payers will respond to the pricing of KIMMTRAK. Physicians may not prescribe KIMMTRAK and patients may be unwilling to use KIMMTRAK if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Thus, significant uncertainty remains regarding the commercial potential of KIMMTRAK. If the continued commercialization of KIMMTRAK becomes unsuccessful or 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 generate revenues from KIMMTRAK is subject to attaining significant market acceptance among physicians, patients and healthcare payers.

KIMMTRAK, and other product candidates that we may develop or acquire, may not attain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from KIMMTRAK will depend on a number of factors, including:

- timing of market introduction of KIMMTRAK as well as competitive medicines;
- 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;
- 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;
- the extent and duration of 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.

With respect to KIMMTRAK, our ability to grow 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 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).

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, may 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 the case of certain of our agreements with academic institutions or other companies from whom intellectual property rights underlying their respective programs have been in-licensed or acquired. 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 future product candidates we may identify.

As of December 31, 2021, we had working capital (defined as total current assets less total current liabilities) of £201.5 million (\$272.0 million) and cash and cash equivalents of £237.9 million (\$321.2 million). We expect that our existing cash and cash equivalents will be sufficient to fund our operations until at least the third quarter of 2023. With the inclusion of expected product revenue for KIMMTRAK in the United States reflecting initial sales in 2022 and pre-product revenue in France as a result of our early access program, we estimate we will have sufficient funds to continue to meet its liabilities as they fall due into the second half of 2024. However, while we have received marketing approval for KIMMTRAK to treat mUM patients in the United States, our efforts to successfully commercialize KIMMTRAK could materially differ from our estimates, and it is possible that we may not successfully commercialize KIMMTRAK in the United States or in other countries, 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 successfully 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) and IMC-C103C (MAGE-A4) in multiple solid tumors, and IMC-I109V targeting HBV;
- 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 building 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 from our existing 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;
- 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 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. 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.

The elimination of LIBOR could adversely affect our business, operating results, and financial condition.

We are subject to risks related to uncertainty regarding the London Interbank Offered Rate, or LIBOR. LIBOR is the subject of recent national, international, and other regulatory guidance and proposals for reform, which may cause LIBOR to cease to exist after 2021 or to perform differently than in the past. The current administrator of LIBOR will cease to publish the settings relevant to our agreements on June 30, 2023. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, has identified the Secured Overnight Financing Rate, or SOFR, a new index calculated by short-term repurchase agreements, backed by Treasury securities, as its preferred alternative rate for LIBOR. At this time, it is not possible to predict how markets will respond to SOFR or other alternative reference rates as the transition away from LIBOR is anticipated in coming years. There is currently no definitive information regarding the future utilization of LIBOR or of any particular replacement rate. A transition away from LIBOR as a benchmark for establishing the applicable interest rate may adversely affect our outstanding variable-rate indebtedness.

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 commercialize KIMMTRAK, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities. As of December 31, 2021, we have over 20 sales and market access employees in the United States. 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. In addition, 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.

In January 2022, we received approval from the FDA for KIMMTRAK for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM. In February 2022, we received notification that the Committee for Medicinal Products for Human Use, or CHMP, of the EMA has adopted a positive opinion recommending the approval of KIMMTRAK for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM. The CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission, which has the authority to approve medicines for use throughout the European Union. 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-C103C and IMC-F106C in Phase 1 dose escalation trials in patients with advanced or metastatic solid tumors who express MAGE-A4 and 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-C103C and IMC-F106C programs is approximately 100,000 and 200,000, respectively. There is no assurance, however, as to what percentage of this population might benefit from these monotherapies.

We will soon be evaluating the safety and tolerability of I109V/HBV in a Phase 1 dose escalation clinical trial in patients with chronic HBV who test positive for HLA-A*02:01. We estimate that there are approximately 16 to 24 million chronic HBV patients who test positive for HLA-A*02:01. There is no assurance, however, as to what percentage of this population might benefit from this monotherapy.

The total addressable market opportunity for KIMMTRAK and our programs will ultimately depend upon, among other things, the diagnosis criteria included in the final label, if our product candidates are approved for sale for these indications, 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 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, we are not permitted to market or promote any of our product candidates before 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.

While we have recently developed sales, marketing and distribution capabilities, we may not be able to effectively market, sell and distribute KIMMTRAK or any of other product candidates, if approved.

We recently obtained marketing approval for KIMMTRAK in the United States. We have applied for marketing approval of tebentafusp in Europe and other territories. We have developed, and continue to develop, arrangements to sell, market and distribute KIMMTRAK and tebentafusp. We may not be able to effectively market and distribute tebentafusp. We have invested, and expect to continue to invest, significant amounts of financial and management resources to further develop internal and contracted sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that tebentafusp will be approved in a territory. We have engaged third parties and may also engage additional third parties to provide these services. In addition, third parties can terminate our agreement under certain circumstances. If third parties fail to hire, train, and retain qualified field 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 will 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 persuade adequate numbers of physicians to prescribe 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.

The COVID-19 global pandemic has and may continue to 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 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. Since December 2019, a novel strain of coronavirus, COVID-19, has spread to multiple countries. Our company headquarters is located in Oxfordshire, United Kingdom, we have U.S. offices in Conshohocken, Pennsylvania and Rockville, Maryland, and our CROs and contract manufacturing organizations, or CMOs, are operating in Europe, United States and Asia. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. Government-imposed travel restrictions on travel between the United States, Europe and certain other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response.

In response to these public health directives and orders, we have 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 implemented a number of measures to ensure employee safety and business continuity. Employees who can work from home have been doing so, while those needing to work in laboratory facilities are divided into shifts to reduce the number of people gathered together at one time. Business travel has been suspended, and online and teleconference technology is used to meet virtually rather than in person. We have taken measures to secure our research and development project activities, while work in laboratories and facilities has been organized to reduce risk of COVID-19 transmission.

The effects of the 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 could occur, related to COVID-19 or other infectious diseases 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.

To date, the COVID-19 pandemic and its related variants have resulted in periodic short-term delays in progressing our early-stage pipeline programs. Our current and planned clinical trials have been affected by the COVID-19 pandemic, including (i) patients becoming exposed to COVID-19 or having to interrupt treatment, (ii) delays in accessing patients during surges of the COVID-19 pandemic or variants, which can adversely impact enrollment, ongoing treatment, dosing, and protocol-mandated assessments and other procedures, and (iii) CRO and trial site staffing shortages due to illness, isolation and hiring challenges, which can impact data enrollment, data entry, timely response to queries, study timelines and operational milestones.

The continued effects of the COVID-19 pandemic may also further negatively impact our clinical trials in the future, including potential longer delays and restrictions on our ability to recruit and retain patients, principal investigators and healthcare employees. The COVID-19 pandemic could also affect the operations of our CROs or CMOs, which may result in delays or disruptions in our clinical trials or in the supply of product candidates.

In addition, our planned clinical trials may be further affected by the COVID-19 pandemic, 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 COVID-19, 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 COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, and because, who, as healthcare providers, may have heightened exposure to COVID-19 and 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 heightened impact from the COVID-19 coronavirus, 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 coronavirus outbreak 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 spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our ordinary shares.

The COVID-19 pandemic has impacted, and 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, 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. We may experience a material impact on our operations, and we continue to monitor the COVID-19 situation closely

Even though KIMMTRAK has received FDA approval, and even if tebentafusp receives approval in other countries, or 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 commercial success.

Even though KIMMTRAK has received FDA approval and a positive CHMP opinion, 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 clinical stage product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. 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. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

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

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

We may be unable to successfully complete additional large-scale, pivotal clinical trials for any product candidates we develop after tebentafusp. In addition, we may be unable to obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. We have two programs, IMC-C103C and IMC-F106C, in Phase 1 clinical development and, in the case of IMC-I109V, we have received clearance to begin a Phase 1 clinical trial in Australia, Belgium, Hong Kong, New Zealand, Poland, South Korea, Spain and the United Kingdom and submitted for Health Authority approvals to begin clinical development in Romania. We cannot be sure that issues will not arise that require us to suspend or terminate our Phase 1 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 we 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 contract research organizations, or 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. Furthermore, it is impossible to predict when or if IMC-C103C, IMC-F106C and IMCI109V 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 expect to rely 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 anticipate that we will have to rely 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 other countries. 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 in the United States. 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 and abroad, 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;
- 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 or similar regulatory authorities outside the United States. 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 the ongoing COVID-19 pandemic and we do not know the extent and scope of such delays at this point.

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 has 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 IMC-C103C and IMC-F106C programs, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop our IMC-C103C and IMC-F106C programs, and may develop future product candidates, for use in combination with one or more currently approved cancer therapies. Even if any product candidate we 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-C103C and 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-C103C and IMC-F106C 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-C103C and IMC-F106C programs, or any product candidate we develop.

If we do not achieve our projected development and commercialization goals in 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, receipt of regulatory approval, or the commercial launch of a product. The achievement of many of these milestones may be 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, 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 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 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;
- 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 geo-political actions, including war and terrorism.

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

We are subject to manufacturing risks that could substantially increase our costs and limit supply of our products.

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.

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.

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.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and 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 placed on partial clinical hold in 2020 due to insufficient specifications on a drug release assay in the corresponding IND. The partial clinical hold was later lifted and the trial has resumed.

Challenges we may face could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, cause a lack of patient participation in clinical trials and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Even though KIMMTRAK has received FDA approval, and even if tebentafusp receives approval in other countries, or 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 commercial success.

Even though KIMMTRAK has received FDA 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 clinical stage product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. 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. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

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

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, Gritstone Oncology, 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, Gilead Sciences, Inc., bluebird Bio, Inc., or bluebird bio, AgenTus Therapeutics, Inc., Takara Bio Inc., Bristol-Myers Squibb Company, GSK, Kite Pharma, Lion TCR, TCR Cure, CBMG, Eureka and Bellicum Pharmaceuticals, Inc. who are developing TCR-based cell therapies; Immatics, AbbVie, Inc, Regeneron, F. Hoffmann-La Roche Ltd, Amgen, Inc., Genmab, Inc., Molecular Partners and MorphoSys AG 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 MAGE-A4 and PRAME, including Adaptimmune, who is developing a MAGE-A4 directed cellular therapy, which has entered pivotal testing for various forms of sarcoma and has initiated Phase 2 trials for other solid tumors. 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.

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

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. 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 pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective.

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

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. 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 limited capabilities for drug development and do not yet have any capability for sales, marketing or distribution. We have entered into collaborations with other companies that we believe can provide such capabilities, including for example with Genentech and Eli Lilly and Company, or Lilly. These collaborations have also provided us with important funding for our development programs and technology platforms, and we expect to receive additional funding under these 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, it 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 and Phase 3 pivotal clinical trials of tebentafusp, our Phase 1 clinical trials of IMC-C103C and IMC-F106C, and our imminent 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 and Phase 3 pivotal clinical trials of tebentafusp, our Phase 1 clinical trials of IMC-C103C and IMC-F106C, our imminent Phase 1 clinical trial of IMC-I109V 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 expect to continue to do so for commercialization. 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 have any plans to establish in the future, 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, as well as for the commercial manufacture of our products if any of our product candidates receive marketing approval. 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 economic conditions or potential global health concerns such as the COVID-19 pandemic 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-C103C, IMC-F106C, IMC-I109V, GSK01 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-C103C, IMC-F106C, GSK01 and IMC-I109V, 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 nonprofit 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 has 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 whom 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. For example, the European Union General Data Protection Regulation, or the EU GDPR, and the United Kingdom equivalent to the EU GDPR (“UK GDPR”), and other similar laws and regulations impose strict requirements for processing personal data. These laws and regulations also provide for monetary fines and processing penalties. For example, under the UK GDPR, the government may impose temporary and definitive bans on personal data processing as well as fines of up to £17.5 million or 4% of the total annual worldwide turnover in the preceding financial year, whichever is higher. Further, relevant stakeholders may initiate litigation related to our processing of personal data.

The UK’s decision to leave the European Union, often referred to as Brexit, and ongoing developments in the UK have created uncertainty with regard to data protection regulation in the UK. Going forward, there may be an increasing scope of divergence in application, interpretation and enforcement of data protection laws as between the UK and EU. In addition to the parallel UK and EU regimes, following the expiry of the post-Brexit transitional arrangements agreed between the UK and EU, the UK Information Commissioner’s Office is not able to be our “lead supervisory authority” in respect of any ‘cross-border personal data processing’ for the purposes of the EU GDPR. Because we did not designate a lead supervisory authority in an EU member state with effect from January 1, 2021, we are not able to benefit from the EU GDPR’s “one stop shop” mechanism. Among other things, this means that, in the event of a violation of the applicable data protection laws affecting data subjects across the UK and the EU, we could be investigated, and ultimately fined by, the UK Information Commissioner’s Office and the supervisory authority in each and every EU member state where data subjects have been affected by such violation.

In addition, certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. For example, absent appropriate safeguards, the EU GDPR and UK GDPR generally restrict the transfer of personal data to countries outside of the European Economic Area (“EEA”) and UK, such as to the United States, which government regulators have respectively found not to provide an adequate level of data privacy and security protection. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and United Kingdom to the United States, uncertainty remains about compliance with such data protection laws and such mechanisms may not be available or applicable with respect to our personal data processing activities. For example, the “Standard Contractual Clauses” that are designed to be a valid mechanism by which parties can transfer personal data out of the EEA and UK to jurisdictions that are not found to provide an adequate level of protection, must be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country. Specifically, the parties to the cross-border personal data transfer must evaluate the importing jurisdiction’s laws and implement supplemental security measures as necessary to protect the at-issue personal data. It is likely that there will continue to be some uncertainty regarding the mechanisms by which parties transfer personal data out of the EEA and UK to jurisdictions such as the United States. If we cannot implement and maintain a valid mechanism for cross-border personal data transfers, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing (including prohibitions on transferring personal data out of the UK and EEA). The inability to export personal data to other jurisdictions could negatively impact our business operations (including by limiting our ability to conduct clinical trial activities globally); and limit our ability to collaborate with parties that operate in foreign jurisdictions.

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.

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. However, 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, including Trade Control laws, or prevent future material weaknesses or deficiencies. 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.

Tebentafusp was granted breakthrough therapy designation by the FDA for unresectable or metastatic uveal melanoma. We may seek a breakthrough therapy designation for some of our future 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. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed repeal legislation to date, the TCJA, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. 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 through 2031, unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, and other COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% 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 proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule and guidance on September 24, 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services, or CMS, issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. 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. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives.

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 our products, once 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.

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 will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future 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 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 or 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 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 Affordable Care Act, require 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 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.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our lead product candidate or any other current or future product candidates outside the United States.

If we succeed in developing any products, we intend to market them in non-U.S. jurisdictions in addition to the United States or we may also apply for non-U.S. regulatory approval at the same time as we apply for U.S. regulatory approval. For example, KIMMTRAK recently received marketing approval from the FDA, and we are currently seeking further approval of tebentafusp in Europe following our MAA submission to the EMA. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of any of our product candidates by regulatory authorities in another country we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. 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. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be negatively affected.

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 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, 2021, we had 324 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 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 processed 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 limit our flexibility in operating our business and adversely affect our financial health and competitive position.

We have a \$100.0 million loan and security agreement with Oxford Finance, or the Loan Agreement, that is secured by a lien covering substantially all of our assets, including intellectual property. As of December 31, 2021, the outstanding principal balance under the Loan Agreement was \$50.0 million. An additional \$25.0 million is available to us at our option following BLA approval for tebentafusp, and a further \$25.0 million is available at our option and at the discretion of Oxford Finance. The Loan Agreement contains customary covenants and events of default applicable to us.

In addition, the agreement governing 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 guarantee 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 to collateralize 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, power shortages, telecommunications failures, water shortages, floods, hurricanes or other extreme weather conditions, medical epidemics, labor disputes, war or other business interruptions. 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 current COVID-19 pandemic has, at points, 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 impact and may continue to impact our research activities. Moreover, at the end of 2021 and into 2022, tensions between the United States and Russia escalated when Russia amassed large numbers of military ground forces and support personnel on the Ukraine-Russia border and, in February 2022, Russia invaded Ukraine. In response, North Atlantic Treaty Organization, or NATO has deployed additional military forces to Eastern Europe, including to Lithuania, and the Biden administration announced certain sanctions against Russia. The invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise 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. For example, our ongoing IMCgp100-202 trial currently includes trial sites located in Ukraine and Russia and we are currently treating one patient in Russia. Currently, we have plans in place to continue study treatment for this individual; however, the invasion of Ukraine will likely impact our ability to conduct the trial in Ukraine, Russia and potentially in other Eastern European countries, and may prevent us from continuing treatment or follow-up for patients currently enrolled or enrolling future patients 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 our clinical trials and/or analyses of clinical results, including our IMCgp100-202 Trial, and negatively impact our plans to commercialise our product (subject to regulatory approval) in this region, which could harm our business.

Clinical sites involved may not be able to enroll patients into our trials as they have to keep free or use capacities for the treatment of COVID-19 patients. Any of the sites where we conduct clinical trials may announce that they will not enroll further patients into clinical trials until further notice. We currently do not know, how substantial the delay for the development of our product candidates will be. Even if the situation improves in the United States and/or Europe, the impact on supply chains and patient recruitment may last longer.

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.

Our current operations are located in Oxfordshire, England, Pennsylvania and Maryland and we or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in Oxfordshire, England, Pennsylvania and Maryland. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, including any potential effects from the current global spread of COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, 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. Natural disasters or pandemics such as the COVID-19 outbreak could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. For example, certain staff members presently work from home on a part- or full-time basis and it is possible that this could have a negative impact on the execution of our business plans and 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. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

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, at the end of 2021 and into 2022, tensions between the United States and Russia escalated when Russia amassed large numbers of military ground forces and support personnel on the Ukraine-Russia border and, in February 2022, Russia invaded Ukraine. In response, NATO has deployed additional military forces to Eastern Europe, including to Lithuania, and the Biden administration announced certain sanctions against Russia. The invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise 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. For example, our ongoing IMCgp100-202 trial currently includes trial sites located in Ukraine and Russia and we are currently treating one patient in Russia. Currently, we have plans in place to continue study treatment for this individual; however, the invasion of Ukraine will likely impact our ability to conduct the trial in Ukraine, Russia and potentially in other Eastern European countries, and may prevent us from continuing treatment or follow-up for patients currently enrolled or enrolling future patients 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 our clinical trials and/or analyses of clinical results, including our IMCgp100-202 Trial, and negatively impact our plans to commercialise our product (subject to regulatory approval) in this region, which could harm our business.

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.

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 we are based in the United Kingdom, we source research and development, manufacturing, consulting and other services from the United States and the European Union. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the euro, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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 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, 2021, the closing price of our ADSs ranged from a high of \$56.34 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;
- 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 ongoing impact of the COVID-19 pandemic;
- sales of our ADSs or ordinary shares by us or our shareholders in the future; and
- 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 the effects of the ongoing COVID-19 pandemic on the global economy, 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, 2021, 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 43% 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.

Additionally, the holders of an aggregate of approximately 43 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 following the expiration of the initial public offering lock-up period, as well as to cooperate in certain public offerings of such ordinary shares. If we were to register the resale of these shares, they could be freely sold in the public market. 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 are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our ADSs less attractive to investors.

We are an emerging growth company, or EGC, and we will remain an emerging growth company until the earlier to occur of (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenues of at least \$1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” under the rules of the U.S. Securities and Exchange Commission, or SEC, which means the market value of our equity securities that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, or EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404;
- not being required to comply with any requirement that has or may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- an exemption from the requirement to seek nonbinding advisory votes on executive compensation or golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Annual Report. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our ADSs less attractive if we rely on certain or all of these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our ADS price may be more volatile.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” if the market value of our ordinary shares held by non-affiliates is below \$250 million (or \$700 million if our annual revenue is less than \$100 million) as of June 30 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We have incurred, and will continue to incur, increased costs, and we will continue to place increasing demands upon management as a result of being a public company, and our management will be required to devote substantial time to new compliance initiatives.

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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to 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. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently, will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an emerging growth company.

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. A company's internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's 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 IFRS. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

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.

In the fourth quarter of 2020, we enhanced our overall control environment, including adding finance, accounting and procurement 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.

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.

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, 2021. 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, 2021, we had cumulative carryforward tax losses of £234.2 million. Subject to any relevant utilization criteria and restrictions (including for example, the use of loss carryforwards in relation to U.K. profits incurred on or after April 1, 2017 will be limited each year to £5.0 million per group plus, broadly, an incremental 50% of U.K. taxable profits), 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, 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, to the extent that our projects are grant funded or relate to work subcontracted to the company by third parties, 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 £38.9 million and £12.3 million in the accounting periods ending December 31, 2020 and December 31, 2021, respectively. Under the SME Program, we may be able to surrender the trading losses that arise from our qualifying research and development activities for a cash rebate of up to 33.35% of such qualifying research and development expenditures. The majority of our pipeline research, clinical trials management and manufacturing development activities are eligible for inclusion within these tax credit cash rebate claims. We may not be able to continue to claim payable 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. Where 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 RDEC Program. The cash rebate under the RDEC Program is up to 10.53% of such qualifying research and development expenditures. The U.K. Finance Act 2021 introduced Finance Bill currently progressing through the U.K. Parliament introduces a cap on payable credit claims under the SME Program in excess of £20,000 with effect from April 2021 by reference to, broadly, three times the total PAYE and NICs liability of the company, subject to an exception, which prevents the cap from applying. That exception requires the company to be creating, taking steps to create or managing intellectual property, as well as having qualifying research and development expenditure in respect of connected parties which does not exceed 15% of the total claimed. If such cap comes into force, and such exception does not apply, this could restrict the amount of payable credit that we claim under the SME Program. Additionally, on 27 October 2021, the U.K. Government announced its intention to introduce (following consultation) further restrictions to the U.K. research and development relief programs, refocusing such programs towards innovation in the U.K. A subsequent U.K. Government report proposed restrictions which (if enacted) could, in particular, limit our ability to make claims under the existing relief programs in respect of: (i) research and development subcontracted to a third party (and, in the case of the RDEC Program, in respect of contributions made to a qualifying body) where such third party (or qualifying body) performs the work outside of the U.K., and (ii) expenditure incurred on externally provided workers that are not paid through UK payroll. These and other potential future changes to the U.K. research and development tax relief programs may mean we no longer qualify or may impact on the extent to which we can make claims. Future changes to the R&D tax relief programs may be made which mean we no longer qualify or which 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 research and development 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. research and development 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 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.

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, Her 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 a year.

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 500, 181 Washington Street, Conshohocken, Pennsylvania 19428.

Our actual capital expenditures for the years ended December 31, 2021, 2020 and 2019 amounted to £1.0 million, £3.1 million and £4.3 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 five clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune disease and multiple earlier pre-clinical programs.

On January 26, 2022, the U.S. Food and Drug Administration, or the FDA, approved KIMMTRAK (tebentafusp-tebn) for the treatment of patients with unresectable or metastatic uveal melanoma, or mUM. KIMMTRAK is the first TCR therapeutic to receive regulatory approval from the FDA, the first bispecific T cell engager to receive regulatory approval from the FDA to treat a solid tumor, and the first and only therapy for the treatment of unresectable or mUM to be approved by the FDA.

In February 2022, we announced that the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or the EMA, has adopted a positive opinion recommending the approval of KIMMTRAK for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM. The CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission, which has the authority to approve medicines for use throughout the European Union. Subject to regulatory approval from the European Commission, we anticipate launching KIMMTRAK in Europe in the second quarter of 2022. We plan to pursue regulatory approval for the marketing authorization of KIMMTRAK in all 28-member states of the European Union.

The United Kingdom’s Medicines and Healthcare Regulatory Agency (MHRA), Health Canada, and the Australian Government Department of Health Therapeutic Goods Administration (TGA) have each accepted the submission of the Company’s Marketing Authorisation Application.

KIMMTRAK is manufactured at facilities located in Denmark and Germany. We are supporting the appropriate use of KIMMTRAK in the United States through a well-equipped and fit-for-purpose 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 Pharma to help seek regulatory authorization and commercialize Immunocore's KIMMTRAK in Canada, twenty markets across Central Eastern Europe and Israel. After FDA approval in the United States on January 26, 2021, KIMMTRAK commercial supply was made available shortly after the FDA approval for the treatment of patients with unresectable or metastatic uveal melanoma. KIMMTRAKConnect was launched within three days of FDA approval with the goal to help ensure patients in the United States have access to KIMMTRAK, including financial assistance, personalized support and education, and site of care coordination for eligible patients.

As of December 31, 2021, we have dosed over 700 cancer patients with our ImmTAX product candidates, which we believe is the largest clinical data set of any 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, head and neck and ovarian, among others. We have [three] clinical stage programs within our ImmTAC (Immune mobilizing monoclonal TCRs Against Cancer) platform, including KIMMTRAK. Our other ImmTAX 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, using 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: oncology, infectious, and autoimmune disease. 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. We have five clinical stage assets as well as 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 and autoimmune diseases. Our current pipeline is represented in the diagram below.

Candidate	Target	Indication	Pre-clinical	Phase 1 / 2	Phase 3	Approved	Anticipated Milestones
Oncology							
KIMMTRAK [®]	gp100	Uveal melanoma	<div></div>				✓ FDA Approval 1Q 2022 ✦ Commercial launch 1H 2022
		Cutaneous melanoma	<div></div>				✦ Randomized study 4Q 2022
IMC-C103C ¹	MAGE-A4	NSCLC, gastric, head & neck, ovarian, synovial sarcoma	<div></div>				✓ Initiated ovarian expansion ✦ Ph. 1 update 4Q 2022
IMC-F106C	PRAME	NSCLC, breast, endometrial, ovarian, SCLC, melanoma	<div></div>				✦ Ph. 1 initial data 3Q 2022
Candidate #4	Undisclosed	Multiple solid tumors	<div></div>				
Candidate #5	Undisclosed	Colorectal, gastric, pancreatic	<div></div>				
Infectious Diseases							
IMC-I109V	Envelope	Hepatitis B Virus (HBV)	<div></div>				✦ Enrolling Ph. 1
IMC-M113V ²	Gag	Human Immunodeficiency Virus (HIV)	<div></div>				✦ First patient dosing 2Q 2022

¹ Developed under a co-development/co-promotion collaboration with Genentech. ² Program is wholly owned, development costs being provided by the Bill & Melinda Gates Foundation (BMGF), Immunocore retain all development and commercialization rights in the developed world.

Our ImmTAC Platform (Oncology)

Within our ImmTAC platform, we have three clinical stage programs and additional pre-clinical programs (two of which are shown in the diagram above), 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. KIMMTRAK was approved by the FDA on January 26, 2022 for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM. KIMMTRAK demonstrated monotherapy activity and recently achieved the primary endpoint of superior overall survival in a randomized Phase 3 clinical trial in patients with previously untreated metastatic uveal melanoma against the investigator's choice of treatment. The OS hazard ratio in the intent-to-treat population favored tebentafusp, HR=0.51 (95% CI: 0.37, 0.71); $p < 0.0001$, over investigator's choice (82% pembrolizumab; 13% ipilimumab; 6% dacarbazine). The FDA reviewed KIMMTRAK under the Real-Time Oncology Review pilot program, an initiative of the FDA's Oncology Center of Excellence designed to expedite the delivery of safe and effective cancer treatments to patients, and the FDA's Project Orbis initiative, which enables concurrent review by the health authorities in partner countries that have requested participation.
- **Tebentafusp** regulatory submissions have been submitted to additional regulatory agencies outside the United States requesting marketing authorization of tebentafusp for the treatment of mUM. The EMA, the United Kingdom's MHRA, Health Canada, and the Australian Government Department of Health Therapeutic Goods Administration have each accepted the submission of our MAA. In February 2022, we announced that the CHMP, of the EMA has adopted a positive opinion recommending the approval of KIMMTRAK for the treatment of HLA-A*02:01-positive adult patients with unresectable or mUM. The CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission, which has the authority to approve medicines for use throughout the European Union. Subject to regulatory approval from the European Commission, we anticipate launching KIMMTRAK in Europe in the second quarter of 2022. We plan to pursue regulatory approval for the marketing authorization of KIMMTRAK in all 28-member states of the European Union.
- Continue to promote our global early access program to make KIMMTRAK readily available to mUM patients. We are focused on continuing to treat these patients with KIMMTRAK as regulatory approval is sought in the European Union and their respective European countries. There are currently over 200 patients in 13 countries enrolled in our global early access program.
- **Tebentafusp** is also being developed in metastatic cutaneous melanoma (mCM). In 2021, Immunocore presented data from Phase 1b trial in metastatic cutaneous melanoma (mCM) at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting. Preliminary evidence of KIMMTRAK (tebentafusp-tebn) clinical activity in mCM patients who had prior anti-PD(L)1 therapy, currently an unmet medical need, included 1-year overall survival (OS) rate of 76%. We anticipate initiating a mCM Phase 2 randomized trial with and without PD(L)1 therapies in the fourth quarter of 2022.
- **IMC-C103C**, our ImmTAC molecule targeting an HLA-A*02:01 MAGE-A4 antigen, is currently being evaluated in a first-in-human, Phase 1/2 dose escalation trial in patients with solid tumor cancers including non-small-cell lung cancer, or NSCLC, gastric, head and neck, ovarian and synovial sarcoma. In December, we reported initial Phase 1 data from the trial at the European Society of Medical Oncology Immuno-Oncology Congress. IMC-C103C demonstrated a manageable safety profile and clinical activity with confirmed durable responses in ovarian cancer and a confirmed durable response in head and neck squamous cell carcinoma, or HNSCC. We initiated an expansion arm in high-grade serous ovarian carcinoma at 140 micrograms/week. We anticipate reporting additional data from the Phase 1 trial in the fourth quarter of 2022.
- **IMC-F106C**, our ImmTAC molecule targeting an optimal HLA-A*02:01 PRAME antigen is currently being evaluated in a first-in-human, Phase 1/2 dose escalation trial in patients with multiple solid tumor cancers including NSCLC, SCLC, endometrial, ovarian, cutaneous melanoma, and breast cancers. As of December 31, 2021, we enrolled 39 patients in the Phase 1 clinical trial. Early pharmacodynamic data indicate that IMC-F106C monotherapy is demonstrating biological activity at the doses currently under evaluation. We anticipate reporting Phase 1 initial data from the trial in the third quarter of 2022.

Our ImmTAV Platform (Infectious Diseases)

Using our ImmTAV (Immune mobilizing monoclonal TCRs Against Virus) 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-I109V**, our ImmTAV molecule targeting a conserved hepatitis B virus, or HBV, envelope antigen, is our most advanced ImmTAV program and is currently being evaluated in a Phase 1/2 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 and we initiated dosing the first patient in our Phase 1 single ascending dose, or SAD, trial in the second quarter of 2021.
- **IMC-M113V**, our ImmTAV molecule targeting the human immunosuppression virus, or HIV, gag antigen bispecific TCR molecule, is currently in pre-clinical development. Our goal is to develop a functional cure for HIV and we expect to begin dosing patients in the UK and Europe in 2022. Our clinical trial application in the United Kingdom was accepted in December of 2021, and we anticipate dosing the first patient in this trial during the second quarter of 2022.

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 (Immune modulating monoclonal TCRs Against AutoImmune 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 2022 Strategy and Planned Portfolio Milestones

Our vision is to build a global immuno-therapy business with a portfolio of therapeutics that have the potential to beneficially impact the clinical outcomes of patients across a broad range of diseases, with a near-term focus on the treatment of cancer, infectious and autoimmune diseases. We are pioneering the field of TCR bispecifics by leveraging the power of TCRs to recognize nearly any cellular protein with targeted precision and convert them into potent ImmTAX therapies that can either boost or inhibit the immune system to treat the disease. In order to execute our strategy, we are pursuing the following near-term milestones:

KIMMTRAK® (tebentafusp-tebn)

- The US commercial launch of KIMMTRAK in metastatic uveal melanoma (mUM).
- The European commercial launch of KIMMTRAK in mUM subject to regulatory approval.
- The initiation of a randomized trial in metastatic cutaneous melanoma.

ImmTAC Clinical Candidates targeting oncology targets PRAME and MAGE-A4

- Phase 1 data from IMC-F106C targeting PRAME in multiple solid tumors.
- Phase 1 data from IMC-C103C targeting MAGE-A4 in multiple solid tumors, and expansion arm in ovarian carcinoma.

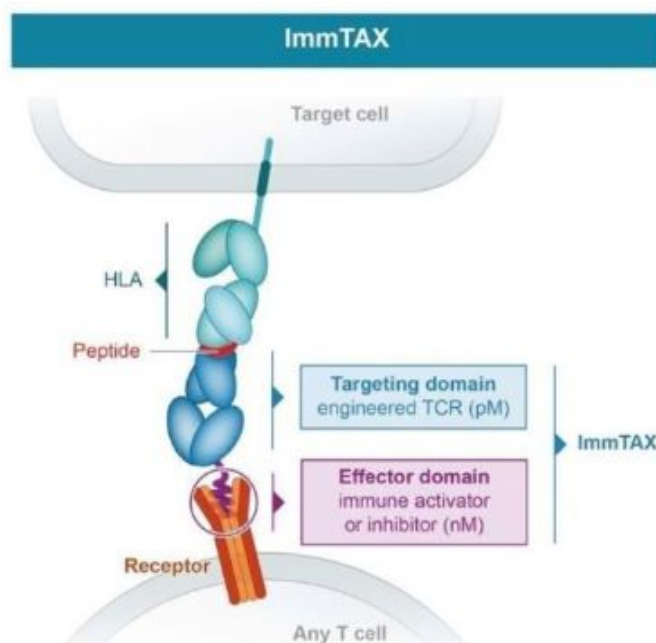
ImmTAV Clinical Candidates for infectious disease

- First patient dosed in IMC-M113V Phase 1 study in HIV.

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.

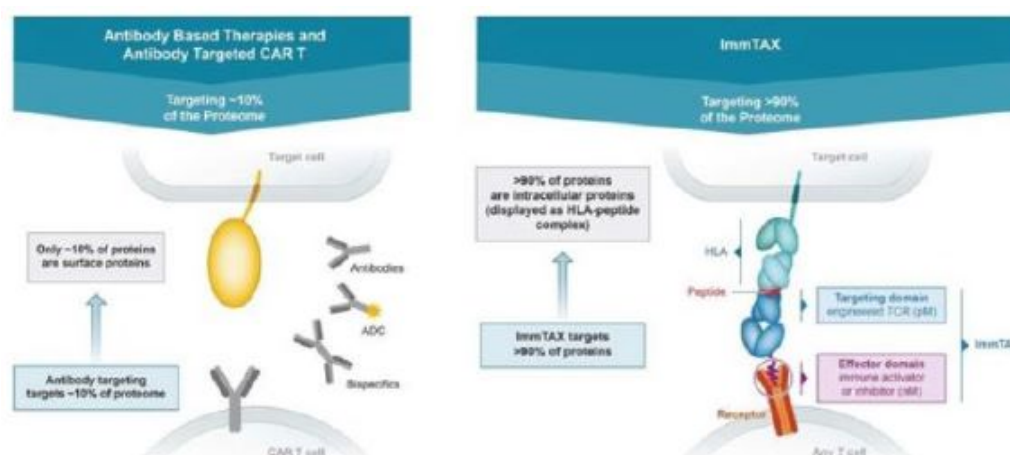
We believe the flexibility of our approach will allow us to develop therapeutics designed to treat a broad range of diseases. While we have focused our initial efforts on oncology, we are broadening our development efforts to infectious and autoimmune diseases. We have named each of these platforms according 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 are in the early commercialization stages of KIMMTRAK and are focused on driving awareness and adoption of KIMMTRAK as a treatment for mUM amongst mUM patients and their healthcare providers. During the first quarter of 2022, our first quarter of commercial launch, our initial focus is to utilize our commercial capabilities to meet patient demand in the United States.

We utilize a hybrid model that includes in-house and contracted resources in the United States and Europe. We have entered into a strategic partnership with Syneos Health, Inc., or Syneos and an exclusive multi-regional agreement with Medison Pharma to help seek regulatory authorization and commercialize Immunocore's KIMMTRAK in Canada, twenty markets across Central Eastern Europe and Israel.

Reimbursement

Coverage in the United States

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. We are currently approaching the U.S. commercial third-party payor community in efforts to establish coverage for KIMMTRAK.

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
- 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, Gritstone Oncology, 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, Gilead Sciences, Inc., bluebird Bio, Inc., or bluebird bio, AgenTus Therapeutics, Inc., Takara Bio Inc., Bristol-Myers Squibb Company, GSK, Kite Pharma, Lion TCR, TCR Cure, CBMG, Eureka and Bellicum Pharmaceuticals, Inc. who are developing TCR-based cell therapies; Immatics, AbbVie, Inc, Regeneron, F. Hoffmann-La Roche Ltd, Amgen, Inc., Genmab, Inc., Molecular Partners and MorphoSys AG 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 MAGE-A4 and PRAME, including Adaptimmune, who is developing a MAGE-A4 directed cellular therapy, which has entered pivotal testing for various forms of sarcoma and has initiated Phase 2 trials for other solid tumors. 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.

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 our MAA has been accepted for review by 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.

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.

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.

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 processes, 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 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 candidates and technology platform, generally including but not limited to the United States, Europe, Australia, Brazil, Canada, China, India, Israel, Japan, Mexico, New Zealand, Russia, South Africa and South Korea. We also intend to rely on data exclusivity, market exclusivity and patent term extensions when available, including any relevant exclusivity through supplementary protection certificates and orphan or pediatric drug designation.

As of December 31, 2021, we solely own seven issued U.S. patents, 75 issued foreign patents, 14 pending U.S. patent applications, 153 pending foreign patent applications and five pending Patent Cooperation Treaty, or PCT, patent applications. We also co-own with Adaptimmune 16 issued U.S. patents, 155 issued foreign patents, 31 pending U.S. patent applications, and 36 pending foreign patent applications. These patents and patent applications include claims directed to our soluble TCR bispecific therapeutic candidates, required intermediates in the preparation of our soluble TCR bispecific therapeutic candidates, our platform technology used to identify and generate soluble TCR bispecific therapeutic candidates, targets, formulations and methods of treatment.

While we own issued composition of matter patents relating to tebentafusp and pending patent applications relating to our other product candidates, including IMC-C103C (MAGE-A4), IMC-F106C (PRAME), GSK01 and IMC-I109V (HBV), 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.

ImmTAC platform

Tebentafusp, our ImmTAC product candidate

As of December 31, 2021, we own granted patents and patent applications covering the composition of matter of our lead ImmTAC, tebentafusp, and required intermediates in the preparation of tebentafusp. The patent claims extend to cover additional TCR variants with similar biological properties in addition to the specific candidate sequence. 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, subject to further patent term adjustments, patent term extensions and/or supplementary protection certificates. Further protection may be achieved if further pending patent applications covering the expected label dosing regimen and formulation of tebentafusp are granted. The dosing regimen patents and patent applications include one granted in South Africa, one pending in the United States and nine pending in foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Japan, Hong Kong, Mexico, Russia and South Africa. The formulation patent family currently includes pending patent applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia and South Africa. The issued South African dosing regimen patent is expected to expire in 2037, and, if granted, the pending patent applications in the dosing regimen family would expire in 2037 and the formulation patent application family would expire in 2040, each excluding any additional term for patent term adjustments or patent term extensions.

Further soluble TCR bispecific candidates

As of December 31, 2021, we own issued composition of matter patents and pending composition of matter patent applications, including four pending U.S. patent applications, two issued foreign patents in Colombia and Indonesia, 50 pending foreign patent applications and three PCT applications, covering further clinical and pre-clinical stage soluble TCR bispecific therapeutic candidates for oncology, including IMC-C103C, IMC-F106C, and GSK01 targeting MAGE-A4, PRAME and NY-ESO. 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 Colombian and Indonesia patents are expected to expire in 2037 and, if granted, patents derived from these applications or applications that claim priority from these applications would expire in 2036 for GSK01, 2037 for IMC-C103C, 2038 for IMC-F106C and 2041 for IMC-J110C, excluding any additional term for patent term adjustments or patent term extensions. National patent applications for GSK-01, IMC-C103C and IMC-F106C have been filed in the United States and foreign jurisdictions, including Europe, Australia, Canada, China, Japan, Mexico and Russia.

ImmTAV platform

IMC-I109V clinical program

As of December 31, 2021, we own 19 pending composition of matter PCT patent application relating to our IMC-I109V clinical program. The IMC-I109V patent family currently includes pending patent applications in the United States, Europe, Australia, Brazil, Canada, China, Indonesia, Japan, South Korea, Mexico, Malaysia, New Zealand, Philippines, Russia, Singapore, Thailand and South Africa. Such pending patent applications, if granted, are expected to expire in 2040, excluding any additional term for patent term adjustments or patent term extensions.

Our ImmTAX platform

As of December 31, 2021, we own a number of patents and patent applications related to our ImmTAX platform. These include platform technology composition-of-matter patents and patent applications that aim to cover a disulphide bond stabilization approach for obtaining soluble TCRs, phage display methodology for the production of TCRs with supraphysiological affinity and specificity for target antigen, and a TCR bispecific format with potent T cell redirection activity. Granted patents for these core platform technologies have been obtained in major territories including nine issued patents in the United States and 124 patents in a mixture of foreign jurisdictions, including Europe, Australia, Brazil, Canada, China, Eurasia, Hong Kong, Israel, India, Japan, South Korea, Norway, New Zealand, Mexico, Russia, Singapore and South Africa. The earliest of these patents will begin to expire in 2022 and 2023, for soluble TCRs with disulphide bond stabilization and phage display technology, respectively, excluding any additional term for patent term adjustments or patent term extensions. Patents relating to the TCR bispecific format required for enhanced potency will expire starting in 2030, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2021, we own 28 pending composition-of-matter platform technology patent applications relating to TCR bispecifics with improved therapeutic properties, including formats with extended in vivo half-life and improved anti-CD3 effector functions. Each patent family currently includes pending applications in the United States, Europe, Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia and South Africa. We also own 14 pending composition-of-matter patent applications relating to a TCR-PD1 agonist bispecific platform for tissue/organ specific immunosuppression for the treatment of autoimmune and 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.

The platform patents and patent applications relating to soluble TCRs with disulphide bond stabilization and phage display methodology, as well as certain other technology patents, are jointly owned in 50% equal share with Adaptimmune. We control the prosecution of these jointly owned patents and patent applications. A field restricted cross license limits each company's exploitation of the technology to their respective fields. 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."

Target patent applications

As of December 31, 2021, we own, in equal share with Adaptimmune, four issued U.S. patent, 28 pending U.S. patent applications, eight issued foreign patents and 25 pending foreign patent applications 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. In addition, we also own one pending PCT patent application relating to non-classical HLA antigens suitable for the isolation and affinity maturation of non-classically HLA restricted TCRs and methods for production of such antigens. If granted, national applications derived from the PCT application are expected to expire in 2040, excluding any additional term for patent term adjustments or patent term extensions.

Patent term

Typically, we submit an initial priority application at the U.K. Intellectual Property Office, or UKIPO, and/or at the U.S. Patent and Trademark Office, 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). 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 154 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 PCT 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

Furthermore, 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, 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, 2021, our trademark portfolio contains registrations or registration applications including for Immunocore, ImmTAC, ImmTAX and ImmTAV 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 are responsible for development of the IMC-C103C program through the completion of the Phase 1 clinical trial, with costs being shared equally with Genentech, and are required to use diligent efforts with respect to our development and commercialization obligations. After completion of the Phase 1 clinical trial, we have a limited time period in which to decide to either continue co-development (including co-funding) of our IMC-C103C program or withdraw from our co-funding commitment and thereby convert our co-exclusive license to a full out-license to Genentech of the program, in exchange for future milestone and royalty payments to us. Unless we decide to withdraw co-funding and co-development of our IMC-C103C program following completion of the Phase 1 clinical trial, we and Genentech would be jointly responsible for further clinical development of the asset, with costs shared equally between us. We would retain co-exclusive rights and joint responsibility for commercialization of our IMC-C103C program; although Genentech would have sole rights to book sales. We have already agreed to an equal sharing of funding and profits in regards to our IMC-C103C program. Within six months of starting the first Phase 3 registrational trial of our IMC-C103C program, we are obligated to negotiate a co-promotion agreement with Genentech to define the remaining co-promotion activities.

If we elect to withdraw from co-funding of our IMC-C103C program after completion of the Phase 1 clinical trial, then Genentech shall acquire an exclusive worldwide license to the MAGE-A4 soluble TCR bispecific therapeutic candidate compounds and shall be fully responsible for all further development and commercialization of such candidate compounds, at its expense. These licenses, if granted, do not include any rights to affinity-enhanced TCRs or TCR therapeutic compounds directed to different target peptides. From the point of co-funding withdrawal, we will be eligible to receive over \$700 million in aggregated development and commercial milestone payments plus royalties from Genentech on all sales of products arising from our IMC-C103C program under the 2018 Genentech Agreement, with a rate varying between a high single-digit percentage and a low-teens percentage of net sales, subject to certain agreed reductions, dependent on the cumulative annual net sales for each calendar year. 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. We are required to notify Genentech as soon as reasonably practicable in the event that we experience a change of control prior to the completion of the first Phase 1 clinical trial, and Genentech could treat such a change of control as a co-funding withdrawal notice.

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 pHLA-A2, 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 June 2013, we entered into a collaboration and license agreement, or the GSK Agreement, with GlaxoSmithKline Intellectual Property Development Ltd, or GSK, pursuant to which we and GSK agreed to collaborate in the development of soluble TCR bispecific therapeutic compounds.

We received an upfront payment upon execution and one additional payment in connection with GSK's nomination of the second collaboration target. As of December 31, 2021, we had received payments totaling £22.9 million in upfront payments and early development milestones.

Under the GSK Agreement, we granted GSK the right to nominate up to four targets as being exclusive to GSK under our collaboration. The first target, GSK01/NY-ESO, was nominated at the time of execution of the GSK Agreement. Following a portfolio review, we, in collaboration with GSK, jointly elected not to proceed further with the first target. Consequently, GSK relinquished its option to acquire an exclusive license to the NY-ESO program and we retained ownership of the asset.

A second target was nominated in July 2017. Following a portfolio review in 2021, we, in collaboration with GSK, elected not to proceed further with this second target.

Under the terms of the GSK Agreement, GSK does not have an option to nominate any further targets, and the GSK Agreement was subsequently terminated in January 2022.

Lilly Collaboration

In July 2014, we entered into a development and license agreement, referred to, as subsequently amended, as the Lilly Collaboration, with Eli Lilly and Company, or Lilly, pursuant to which we and Lilly agreed to collaborate in the development, manufacture and commercialization of soluble TCR bispecific therapeutic compounds.

Under the Lilly Collaboration, Lilly paid us an initial upfront fee payment of \$45 million in exchange for options to three targets. Lilly no longer has the ability to nominate any further targets under the initial agreement. In the year ended December 31, 2019, the parties agreed not to proceed with the first target under the agreement, and no further obligations remain with respect to this target. In September 2017, we and Lilly agreed to swap a second antigen target, selected by Lilly, for another neo-antigen target. No further obligations remain with respect to the initial second target that was replaced. The focus of the programs associated with Lilly's second and third nominated targets under the agreement is currently under review and there were no significant changes to the Lilly Collaboration in the year ended December 31, 2021.

From the designation of each selected target until the expiration or termination of any exclusive license Lilly may obtain by exercising its option rights, we are prohibited from directly or indirectly conducting any development or commercialization activities relating to such target selected under the Lilly Collaboration or epitopes derived from such target or any compounds directed to such target, other than as provided under the Lilly Collaboration.

Under the Lilly Collaboration, we are responsible for developing soluble TCR bispecific therapeutic pre-clinical candidates to each target with Lilly being 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, Lilly has the option to pay a \$10 million option fee to gain exclusive co-development/co-promotion rights to the target program. Following exercise of its option, Lilly will provide to us a clinical development plan and budget plan for the advancement of the selected candidate through clinical Phase 1 development. Upon receipt of the proposed development plan and Phase 1 budget, we have a limited time period in which to elect to contribute either 25% or 50% costs to reach the next clinical phase or to opt-out of further development. Similar provisions are available at the start of Phase 2 clinical trials and registrational clinical trials. Should we elect to contribute towards registrational trials, then, within six months of the start of the first registrational trial, we would agree with Lilly on the terms of a co-promotion agreement that establishes how co-promotion activities would be divided and receive either a 25:75 or 50:50 profit split that aligns with the funding contributions established in development. Should we opt-out of co-development on a collaboration target-by-collaboration target basis, Lilly would obtain an exclusive worldwide license to develop and commercialize the compound at its sole expense.

We are eligible to receive differing development milestones, commercial milestones and royalties dependent on whether we exercise our opt-out right at the time when a product is Phase 1-ready, Phase 2-ready or registrational trial-ready and if we have contributed either 0%, 25% or 50% of clinical expenses prior to the point of opt-out. The maximum aggregate amount of milestone payments we are eligible to receive for a product (in the case of such product treating a single indication) is \$336 million and the tiered royalties we are eligible to receive range from a mid-single-digit to a mid-teens percentage. Royalties are payable while there is a jointly owned or solely owned valid patent claim covering the licensed product in the country in which the relevant product is sold, which, if applicable patent application are granted, is expected to be at least 2041 for the first neoantigen program, and, in each case, for a minimum of 10 years from first commercial sale of the relevant licensed product.

The Lilly Collaboration is effective until all payment obligations expire, including any ongoing royalty payments due in relation to Lilly's sale of any licensed product. The Lilly Collaboration can also be terminated on a program-by-program basis by Lilly if a selected target or any product or selected candidate is not viable or will not otherwise obtain regulatory approval. Both parties have rights to terminate the Lilly Collaboration in whole or in part for uncured material breach upon 90 days' written notice or immediately upon insolvency of the other party. Lilly has additional rights to terminate either the Lilly Collaboration or any specific program for convenience on provision of 90 days' notice to us. We also have rights to terminate any license where Lilly ceases development on any compound or withdraws any licensed product in specified circumstances. Where we continue any development of any compound resulting from a terminated collaboration program where Lilly has exercised its option to obtain an exclusive license, we would agree with Lilly on a royalty that reflects the value to the program contributed by Lilly prior to the date of termination.

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.

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, 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 (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.

In Europe, we are subject to the EU GDPR, in relation to our processing and other use of personal data. We may in the future process personal data in relation to participants in our clinical trials in the EEA, including the health and medical information of these participants. The EU GDPR imposes a multitude of obligations on us as part of its mandated privacy governance framework. For example, these obligations include, to be transparent and disclose to individuals how their personal information will be used; to retain personal data only as necessary; to provide data breach notifications; and to demonstrate valid consent for certain data processing activities.

EU Member States 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 addition, the EU GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the EU GDPR are uncertain as the result of legal proceedings in the EU, including the efficacy and legality of using standard contractual clauses. This may increase the complexity of transferring personal data across borders out of the EEA.

Fines for certain breaches of the EU GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the EU GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders change our use of data, enforcement notices, or potential civil claims including class action type litigation.

Further, Brexit, and ongoing developments in the United Kingdom have created uncertainty with regard to data protection regulation in the United Kingdom. Following the United Kingdom's withdrawal from the EU, the data protection obligations of the GDPR continue to apply to United Kingdom-related processing of personal data in substantially unvaried form and fashion under the so-called 'UK GDPR' (i.e., the GDPR as it continues to form part of United Kingdom law by virtue of section 3 of the European Union (Withdrawal) Act 2018, as amended (including by the various Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations)). However, going forward, there will be increasing scope for divergence in application, interpretation and enforcement of data protection laws as between the United Kingdom and the EU. In addition, the relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear. For example, it is still unclear whether the transfer of data from the EU to the United Kingdom will in the future remain lawful under the EU GDPR. Additionally, as noted above, the United Kingdom has transposed the EU GDPR into domestic law by way of the UK GDPR, which exposes us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. In addition to such parallel United Kingdom and EU regimes, following the expiry of the post-Brexit transitional arrangements agreed between the United Kingdom and EU, the United Kingdom Information Commissioner's Office is not able to be our 'lead supervisory authority' in respect of any "cross border processing" for the purposes of the EU GDPR. Because we did not designate a lead supervisory authority in an EU member state with effect from January 1, 2021, we are not able to benefit from the GDPR's "one stop shop" mechanism. Among other things, this means that, in the event of a violation of the applicable data protection laws affecting individuals across the United Kingdom and the EU, we could be investigated and ultimately fined by, the United Kingdom Information Commissioner's Office and the supervisory authority in each and every EU member state where data subjects have been affected by such violation.

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, 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. Among the provisions of the ACA of importance to our business are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for most branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, effective January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and delaying the implementation of certain ACA-mandated fees. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. 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. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how such efforts to repeal and replace the ACA and the healthcare reform measures of the Biden administration will impact the ACA and our business.

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 through 2031 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and other COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% 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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule and guidance on September 24, 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. 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. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. 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

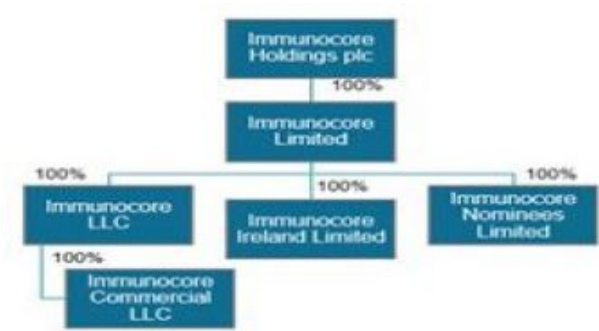
We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the UK Bribery Act 2010 and the UK Proceeds of Crime Act 2002 and possibly other state and national anti-bribery 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:



Immunocore Holdings Plc, Immunocore Limited and Immunocore Nominees Limited are incorporated in the United Kingdom. Immunocore LLC and Immunocore Commercial LLC are incorporated in the United States. Immunocore Ireland Limited is incorporated in Ireland.

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 102,000 square feet. Our leases expire between 2037 and 2040, 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 4,000 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 Dublin, Ireland.

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, 2021 into U.S. dollars on December 31, 2021, which was £1.00 to \$1.3500. 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 previously 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.

For a discussion related to our financial condition, changes in financial condition, results of operations for 2019, and a comparison of results of operations for 2020 compared to 2019, you should review 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, 2020, which was filed with the SEC on March 25, 2021.

A. Operating Results

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 five clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune disease and multiple earlier pre-clinical programs.

On January 26, 2022, the U.S. Food and Drug Administration, or the FDA, approved KIMMTRAK (tebentafusp-tebn) for the treatment of patients with unresectable or metastatic uveal melanoma, or mUM. KIMMTRAK is the first TCR therapeutic to receive regulatory approval from the FDA, the first bispecific T cell engager to receive regulatory approval from the FDA to treat a solid tumor, and the first and only therapy for the treatment of unresectable or mUM to be approved by the FDA.

We have three clinical stage programs within our ImmTAC (**I**mmune **m**obilizing **m**onoclonal **T**CRs **A**gainst **C**ancer) platform, including KIMMTRAK. Our clinical programs are being conducted with patients with a broad range of cancers including melanoma, lung, gastric, head and neck and ovarian, among others. As of December 31, 2021, we have dosed over 700 cancer patients with our 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 ImmTAX 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.

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. We have not yet generated revenue from any marketed products. We may never be able to develop or commercialize a marketable product. Our ability to develop product revenue 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 \$1,135.1 million through private placements of our ordinary and preferred shares, debt financing, payments from our collaboration partners, and most recently, borrowings under our debt facility with Oxford Finance Luxembourg S.A.R.L., or Oxford Finance, 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 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 250 employees. We have also established relationships with three pharmaceutical collaborators, Genentech, Inc., or Genentech, GlaxoSmithKline Intellectual Property Development Ltd, or GSK, and Eli Lilly and Company, or Lilly.

We have incurred significant operating losses and expect to continue to incur significant expenses and operating losses for the near future. Losses were £131.5 million, £74.1 million and £103.9 million, for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, our accumulated deficit was £481.4 million. We expect to continue to incur significant and increasing expenses and 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 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, we have only recently commenced the sale 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. 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

Commercialization of KIMMTRAK

KIMMTRAK is manufactured at facilities located in Denmark and Germany. We are supporting the appropriate use of KIMMTRAK in the United States through a well-equipped and fit-for-purpose 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 Pharma to help seek regulatory authorization and commercialize Immunocore's KIMMTRAK in Canada, twenty markets across Central Eastern Europe and Israel. After FDA approval in the United States on January 26, 2022, KIMMTRAK commercial supply was made available shortly after the approval for the treatment of patients with unresectable or mUM. KIMMTRAKConnect was launched within three days of FDA approval with the goal to help ensure patients in the United States have access to KIMMTRAK, including financial assistance, personalized support and education, and site of care coordination for eligible patients.

On February 25, 2022, following an accelerated review and one month after the regulatory approval of KIMMTRAK by the FDA, KIMMTRAK received a positive CHMP opinion for the treatment of unresectable or mUM. The CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission, which has the authority to approve medicines for use throughout the European Union. Subject to regulatory approval from the European Commission, we anticipate launching KIMMTRAK in Europe in the second quarter of 2022. We plan to pursue regulatory approval for the marketing authorization of KIMMTRAK in all 28-member states of the European Union.

The United Kingdom's Medicines and Healthcare Regulatory Agency (MHRA), Health Canada, and the Australian Government Department of Health Therapeutic Goods Administration (TGA) have each accepted the submission of the Company's Marketing Authorisation Application.

COVID-19 Business Update

To date, the coronavirus 2019, or COVID-19, pandemic has resulted in periodic short-term delays in progressing our early-stage pipeline programs.

In addition, our current and planned clinical trials have been and may in the future be affected by the COVID-19 pandemic, including (i) patients becoming exposed to COVID-19 or having to interrupt treatment, (ii) delays in accessing patients during surges of COVID-19, which can adversely impact enrolment, ongoing treatment, dosing, and protocol-mandated assessments and other procedures (iii) 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 if quarantines impede patient movement or interrupt healthcare services; (iv) delays or difficulties in clinical site initiation, including difficulties in recruiting and retaining clinical site investigators and clinical site staff; (v) diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials and, because as healthcare providers, may also have a heightened exposure to COVID-19 and adversely impact our clinical trial operations; (vi) interruption of our future 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 (vii) limitations in employee resources that would otherwise be focused on the conduct of our planned clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people, which can impact enrollment, data entry, timely responses to queries, study timelines and operational milestones.

The COVID-19 pandemic remains a rapidly evolving situation and we will continue to closely monitor, assess and mitigate the effects of the COVID-19 pandemic on our business.

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. We refer to these two initial targets as the Negotiated Targets. For each of the Negotiated Targets, we were responsible for developing a soluble TCR bispecific therapeutic pre-clinical candidate compound, and Genentech was responsible for all GMP manufacture, clinical development and commercialization of those compounds, upon which we would be entitled to receive future milestone and royalty payments.

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 September 2016, following achievement of formal nomination of the pre-clinical candidate compound, we and Genentech amended the 2013 Genentech Agreement. We refer to this amendment as the 2016 Genentech Amendment. The 2016 Genentech Amendment provided that the Negotiated Targets, including MAGE-A4, ceased to be considered eligible targets under the 2013 Genentech Agreement. On the same day, we entered into a license agreement with Genentech, or the 2016 Genentech Agreement. Pursuant to the 2016 Genentech Agreement, we regained control of the initial two programs covering the Negotiated Targets in existence at the time of execution, including MAGE-A4, and Genentech granted us an exclusive worldwide license to use its background intellectual property rights to advance such programs. Under the 2016 Genentech Agreement, we had sole responsibility for the development, manufacture and commercialization of the soluble TCR bispecific therapeutic compounds of the Negotiated Targets at our own expense, and are 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 under the 2016 Genentech Agreement, 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 of the Negotiated Targets, should we seek to license the rights to develop and/or commercialize either program to a third party. The 2016 Genentech Agreement is effective on a country-by-country basis, and shall expire on the later of (i) the expiration of the last to expire patent containing a valid claim which covers the sale of the applicable soluble TCR bispecific therapeutic compounds of the Negotiated Targets and (ii) the tenth anniversary of the date of the first commercial sale of such compounds. Either party is entitled to terminate the 2016 Genentech Agreement for an uncured material breach of the other party upon 90 days' written notice, or 30 days' written notice, in the case of payment defaults, or immediately upon insolvency of the other 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 are responsible for development of the IMC-C103C program through the completion of the Phase 1 clinical trial, with costs being shared equally with Genentech, and are required to use diligent efforts with respect to our development and commercialization obligations. For more information, please see "Item 4B. Business overview—Our Collaborations and License Agreements—Genentech Collaboration."

GSK Collaboration

In June 2013, we entered into a collaboration and license agreement, or the GSK Agreement, with GlaxoSmithKline Intellectual Property Development Ltd, or GSK, pursuant to which we and GSK agreed to collaborate in the development of soluble TCR bispecific therapeutic compounds.

Under the GSK Agreement, we received an upfront payment upon execution and one additional payment in connection with GSK's nomination of the second collaboration target. As of December 31, 2021 we had received payments totaling £22.9 million in upfront payments and early development milestones. For more information, please see "Item 4.B Business overview—Our Collaborations and License Agreements—GSK Collaboration."

Under the GSK Agreement, we granted GSK the right to nominate up to four targets as being exclusive to GSK under our collaboration. The first target, GSK01/NY-ESO, was nominated at the time of execution of the GSK Agreement. Following a portfolio review, we, in collaboration with GSK, jointly elected not to proceed further with the first target. Consequently, GSK relinquished its option to acquire an exclusive license to the NY-ESO program and we retained ownership of the asset.

A second target was nominated in July 2017. Following a portfolio review in 2021, we, in collaboration with GSK, elected not to proceed further with this second target. Under the terms of the GSK Agreement, GSK does not have an option to nominate any further targets, and the GSK Agreement was subsequently terminated in January 2022. No further payments or revenue are expected from the GSK Agreement as a result.

Lilly Collaboration

In July 2014, we entered into a development and license agreement with Lilly, referred to, as subsequently amended, as the Lilly Collaboration, pursuant to which we and Lilly agreed to collaborate in the development, manufacture and commercialization of soluble TCR bispecific therapeutic compounds.

Under the Lilly Collaboration, Lilly paid us an initial upfront fee payment of \$45 million in exchange for options to three targets. Lilly no longer has the ability to nominate any further targets under the initial agreement with Lilly. In December 2016, we and Lilly agreed to swap an existing antigen target, selected by 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, we and Lilly agreed to swap a second antigen target, selected by Lilly, for a second neo-antigen target. Similarly, Lilly has no further obligations with respect to the initial target that was replaced. From the designation of each selected target until the expiration or termination of any exclusive license Lilly may obtain by exercising its option rights, we are prohibited from directly or indirectly conducting any development or commercialization activities relating to such target selected under the Lilly Collaboration or epitopes derived from such target or any compounds directed to such target, other than as provided under the Lilly Collaboration. For more information, please see "Item 4B. Business overview—Our Collaborations and License Agreements—Lilly Collaboration."

Components of Results of Operations

Revenue

To date, we have generated revenue primarily from our collaboration agreements. In 2021, we made sales of tebentafusp for the treatment of mUM under a compassionate use program in France. In 2022, following FDA approval in January 2022, we will sell KIMMTRAK for the treatment of mUM in the United States.

Collaboration Revenue

Collaboration revenue is primarily derived from our collaboration agreements with Genentech, GSK and Lilly, and previously pursuant to our collaboration agreement with MedImmune plc (now known as AstraZeneca plc), or MedImmune, which terminated during 2019. Our revenue from collaboration agreements 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, 2021, we have received a total of \$216.8 million in collaboration revenue consisting 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 “Critical Accounting Estimates” and the notes to the consolidated financial statements.

Pre-Product Revenue

Pre-product revenue relates to the sale of tebentafusp under a compassionate use program in France. We did not generate any revenue from the sale of marketed pharmaceutical products prior to December 31, 2021.

Product Revenue

We will recognize product revenue in the year ended December 31, 2022 following approval from the FDA for KIMMTRAK for the treatment of mUM on January 26, 2022. We began selling KIMMTRAK in the United States in February 2022. If tebentafusp receives marketing approval to be sold in Europe, following the receipt of a positive CHMP opinion in February 2022, we will also recognize product revenue for sales in Europe in the year ended December 31, 2022.

Operating Expenses

Costs of Product Revenue

We will recognize costs of product revenue in the year ended December 31, 2022 following regulatory approval of KIMMTRAK in the United States in January 2022.

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 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. Research and development expenses incurred with external organizations 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 typically 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 remain significant in the future as we advance existing and future product candidates into and through clinical studies and pursue 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:

- 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;
- 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 regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

Administrative Expenses

Administrative expenses consist primarily of personnel-related costs, including salaries and share-based compensation expense, for corporate and other administrative and operational functions including finance, legal, human resources, pre-commercial expenses and information technology, as well as facility-related costs. These costs relate to the operation of the business, unrelated to the research and development function or any individual program.

Due to our substantial increase in planned research and development expenses, as explained above, we also expect that our administrative expenses will increase. We expect that we will continue to incur increased accounting, audit, legal, regulatory, compliance, director, and officer insurance costs as well as investor and public relations expenses associated with being a public company. We anticipate that the additional costs for these services will substantially increase our administrative expenses. Additionally, we have seen an increase in expenses as a result of our preparation for the U.S. commercial launch of KIMMTRAK and our transition to a commercial-stage company, and expect further costs as we look to launch in other countries.

Net Other Operating (Loss) / Income

Net other operating (loss) / income and consist primarily of profit 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 and gains arising on changes in the fair value of a derivative liability.

Finance Costs

Finance costs consist of the movement in fair value of an embedded derivative asset and derivative liability and interest expenses related to financial liabilities and lease liabilities.

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. 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.

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. Where 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.

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 £232.4 million as of December 31, 2021. 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.

In future, we may benefit from the U.K.'s "patent box" regime, 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, 2021 and 2020

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

	Year ended December 31,			
	2021		2020	
	\$ '000	£ '000	£ '000	'000
Revenue	35,802	26,520	30,114	
Research and development expenses	(98,855)	(73,226)	(74,809)	
Administrative expenses	(119,339)	(88,399)	(45,740)	
Net other operating (loss) income	(77)	(57)	4,242	
Operating loss	(182,469)	(135,162)	(86,193)	
Finance income	63	47	2,208	
Finance costs	(7,848)	(5,813)	(3,375)	
Non-operating expense	(7,785)	(5,766)	(1,167)	
Loss before taxes	(190,254)	(140,928)	(87,360)	
Income tax credit	12,697	9,405	13,267	
Loss for the period	(177,557)	(131,523)	(74,093)	

Revenue

	Year ended December 31,			
	2021		2020	
	\$ '000	£ '000	£ '000	'000
Collaboration revenue				
GSK	8,212	6,083	6,356	
Eli Lilly	—	—	3,522	
Genentech	23,526	17,427	20,236	
Total collaboration revenue	31,738	23,510	30,114	
Pre-product revenue	4,064	3,010	—	
Total revenue	35,802	26,520	30,114	

For the year ended December 31, 2021, collaboration revenue decreased to £23.5 million from £30.1 million for the year ended December 31, 2020. The decrease is primarily driven by the Lilly Collaboration, for which no revenue has been recognized during the year ended December 31, 2021 while a portfolio review was undertaken of the two ongoing programs. In addition, revenue under the Genentech collaboration decreased by £2.8 million due to a reduction in reimbursable costs incurred under the respective cost sharing arrangements. During the year ended December 31, 2021, we also elected with GSK not to progress the remaining programs under the GSK Agreement, and recognized in full the balance of deferred revenue, representing the final revenue expected from GSK pursuant to the GSK Agreement. The GSK agreement was subsequently terminated in January 2022.

The decrease in collaboration revenue was partially offset by pre-product revenue relating to the sale of tebentafusp under a compassionate use program in France during the year ended December 31, 2021, which provides patients with access to tebentafusp prior to receipt of regulatory marketing approval. Pre-product revenue is recognized net and includes deductions for both an estimate of government rebates payable and an estimate of returns in the case of expiry, damage or other instances.

Research and Development Expenses

	Year ended December 31,			
	2021		2020	
	\$ '000	£ '000	£ '000	
<i>External research and development expenses:</i>				
Tebentafusp	33,724	24,981	31,373	
IMC-F106C (PRAME)	6,850	5,074	2,388	
IMC-C103C (MAGE-A4)	6,376	4,723	4,519	
IMC-I109V (HBV)	2,232	1,653	3,264	
Other expenses	10,323	7,647	7,258	
Research expenses	636	471	485	
Total external research and development expenses	60,141	44,549	49,287	
<i>Internal research and development expenses:</i>				
Headcount related expenses	30,610	22,674	19,539	
Laboratory consumables	5,574	4,129	4,331	
Laboratory equipment expenses	2,406	1,782	1,589	
Other	124	92	63	
Total internal research and development expenses	38,714	28,677	25,522	
Total research and development expenses	98,855	73,226	74,809	

For the year ended December 31, 2021, our research and development expenses were £73.2 million, as compared to £74.8 million for the year ended December 31, 2020. This decrease of £1.6 million was attributable to a decrease in external research and development expenses of £4.7 million, partially offset by an increase in internal research and development expenses of £3.2 million.

For the year ended December 31, 2021, our external research and development expenses decreased by £4.7 million. This was driven by a reduction in spend of £6.4 million incurred for our tebentafusp program due to a reduction in clinical trial activity as we instead focused on plans for anticipated regulatory approval in the United States and preparations for commercial launch in the United States as well as plans to pursue regulatory approval in Europe. In addition, there was a decrease of £1.6 million of costs incurred in connection with activity on our IMC-I109V program due to both clinical study initiation costs incurred during the year ended December 31, 2020, and a reduction in clinical trial activity in the current period partly due to the ongoing impact of the COVID-19 pandemic and completion of manufacturing work earlier in the year ended December 31, 2021. These decreases were partially offset by an increase of £2.7 million in expenses incurred for our IMC-F106C program due to a higher level of clinical trial activity.

For the year ended December 31, 2021, our internal research and development expenses increased by £3.2 million. This was primarily due to an increase of £3.1 million in headcount related expenses comprising £3.9 million of share-based payment charge partially offset by a decrease of £0.8 million in other employee-related costs.

We expect our research and development expenses to increase in future periods as we advance our trials and further develop our clinical and preclinical pipeline.

Administrative Expenses

For the year ended December 31, 2021, administrative expenses were £88.4 million, compared to £45.7 million for the year ended December 31, 2020, an increase of £42.7 million. The administrative expenses for year ended December 31, 2021, of £88.4 million, comprised the following:

	Year ended December 31,			
	2021		2020	
	\$ '000	£ '000	£ '000	
<i>Administrative expenses:</i>				
Share-based payment charge	43,120	31,941	8,162	
Other employee related expenses	19,061	14,119	14,935	
Pre-commercial costs	25,831	19,134	1,781	
Legal and professional fees	9,993	7,402	3,901	
Depreciation expenses	9,466	7,012	9,007	
Other expenses	12,485	9,248	7,959	
Foreign exchange gains	(617)	(457)	(5)	
Total administrative expenses	119,339	88,399	45,740	

Administrative expenses increased by £42.7 million in the year ended December 31, 2021, primarily due to an increase in the share-based payment charge of £23.8 million to £31.9 million compared to the year ended December 31, 2020. This increase was a result of the options granted in 2021 in connection with our IPO. In addition, in the year ended December 31, 2021, there was pre-commercial expenditure related to tebentafusp of £19.1 million, an increase of £17.4 million, reflecting preparations undertaken and costs incurred in 2021 ahead of our commercial launch. In the year ended December 31, 2021, there were also legal and professional fees of £7.4 million, an increase of £3.5 million from the prior year, primarily attributable to the IPO and additional costs incurred as a result of becoming a public company. Other costs increased by £1.3 million, reflecting higher IT and other corporate costs in the year ended December 31, 2021.

These increases were partially offset by a reduction in depreciation of property, plant and equipment and right-of-use assets of £2.0 million. The depreciation expense reduced in the year ended December 31, 2021, following the termination of two leasehold property agreements during the year ended December 31, 2020.

Disregarding the impact of the non-cash share payment charge, we expect our administrative expenses to increase in future periods as we expand our commercial and corporate operations.

Net Other Operating (Loss) / Income

For the year ended December 31, 2021, net other operating loss totaled £0.1 million, compared to net other operating income of £4.2 million for the year ended December 31, 2020. The movement of £4.3 million reflects the termination of two leasehold properties during the year ended December 31, 2020, giving rise to a profit on disposal of £3.7 million (which included £1.4 million received as an incentive for exiting one of the leasehold agreements). A further £0.8 million of other operating income arose in the year ended December 31, 2020, from the settlement agreement reached with a former employee and third-party vendors. Sub-lease income also decreased by £0.4 million in the year ended December 31, 2021, and there was a reduction in the loss on disposal of property, plant and equipment of £0.9 million in the year ended December 31, 2021.

Finance Income

For the year ended December 31, 2021, finance income was £47,000 compared to £2.2 million for the year ended December 31, 2020. This decrease of £2.2 million reflects the movement in fair value of the derivative liability for £1.3 million, a foreign exchange call option over certain series B preferred shares which was settled in full on March 2, 2020. In addition, there was a decrease of £0.6 million in bank and other interest receivable in the year ended December 31, 2021.

Finance Costs

For the year ended December 31, 2021, finance costs amounted to £5.8 million, compared to £3.4 million for the year ended December 31, 2020. This increase of £2.4 million is primarily due to an increase in interest expenses on financial liabilities measured at amortized cost of £3.4 million reflecting our loan from Oxford Finance of \$50 million which was drawn down on November 6, 2020, including £0.5 million relating to a fee arising on completion of the IPO, that was paid to Oxford Finance in the year ended December 31, 2021. During the year ended December 31, 2020, there were interest expenses on financial liabilities of £0.2 million reflecting our outstanding loan from the Gates Foundation, which converted into series B preferred shares on March 2, 2020. This increase is partially offset by a £0.5 million decrease in interest on lease liabilities reflecting the termination of two leasehold properties in the year ended December 31, 2020, and a £0.3 million decrease in the loss from a change in the fair value of the embedded derivative asset also following the conversion of our outstanding loan from the Gates Foundation.

Income Tax Credit

For the year ended December 31, 2021, the income tax credit amounted to £9.4 million compared to £13.3 million for the year ended December 31, 2020. This decrease of £3.9 million relates to reduction in the proportion of operating and research and development costs in the period that are eligible for the U.K. R&D tax credit regime (such as the non-cash share-based payment charge and pre-commercial expenses incurred in the period).

Off-balance sheet arrangements

We have no off-balance sheet arrangements besides a contingent liability in relation to a 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 have assessed this contingent event as at December 31, 2021 and have classified this as a contingent liability totaling £1.1 million. 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

Up to December 31, 2021, while we had recorded pre-product revenue for sales of tebentafusp under a compassionate use program in France, we had not recorded product revenues from the sales of any marketed pharmaceutical products. For periods up to and including the year ended December 31, 2021, we have incurred operating losses and negative cash flows from our operations since our inception. In January 2022, the FDA approved KIMMTRAK (tebentafusp-tebn) for the treatment of patients with unresectable or mUM.

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 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, 2021, we have raised an aggregate of \$1,135.1 million through private placements of our ordinary and preferred shares, payments from our collaboration partners, debt financing and most recently, the completion of our IPO where we listed our ADSs on the Nasdaq Global Select Market and raised gross proceeds of \$297.1 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 \$15.0 million, in a private placement to the Gates Foundation.

As of December 31, 2021, and 2020, we had cash and cash equivalents of £237.9 million and £129.7 million, respectively.

Other than our Loan Agreement with Oxford Finance described below, 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,					
	2021			2020		
	\$	'000	£	'000	£	'000
Cash and cash equivalents at beginning of the year		175,117		129,716		73,966
Net cash flows used in operating activities		(129,749)		(96,110)		(61,250)
Net cash flows from / (used in) investing activities		(495)		(367)		1,143
Net cash flows from financing activities		276,252		204,631		115,941
Net foreign exchange difference on cash held		22		16		(84)
Cash and cash equivalents at end of the year		321,147		237,886		129,716

Operating Activities

Net cash used in operating activities increased to £96.1 million for the year ended December 31, 2021, from £61.3 million for the year ended December 31, 2020. This increase of £34.8 million in the year ended December 31, 2021, is primarily due to a £40.3 million net income tax credit received during the year ended December 31, 2020, compared to £12.4 million in the year ended December 31, 2021. Tax credits received in 2020 related to both 2018 and 2019. Excluding the non-cash increase of £27.7 million in the share-based payment charge, operating losses were £21.3 million higher in the year ended December 31, 2021. In addition, working capital movements in the year ended December 31, 2021 were £11.9 million more favourable when compared to the year ended December 31, 2020. This was largely as a result of an increase in trade and other payables of £9.5 million in the year ended December 31, 2021, compared to a decrease of £3.8 million in the year ended December 31, 2020. This payables increase was partially offset by an increase in trade receivables of £5.1 million compared to an increase of £0.5 million in the year ended December 31, 2020. Trade receivables increased largely as a result of amounts billed under a compassionate use program in France, which we received in January 2022.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2021, was £0.4 million compared to net cash generated from investing activities of £1.1 million for the year ended December 31, 2020. The change was primarily related to a decrease in capital expenditure on property, plant and equipment of £2.1 million offset by a £1.0 million lease capital contribution and a £0.2 million increase in sub-lease proceeds.

Financing Activities

Net cash from financing activities during the year ended December 31, 2021, was £204.6 million primarily reflecting the net proceeds we received of £211.0 million from the IPO which closed in February 2021. These inflows were partially offset by £7.3 million of lease payments and interest payments related to our debt facility with Oxford Finance. We also received £1.0 million from the exercise of share options in the year ended December 31, 2021.

Net cash from financing activities during the year ended December 31, 2020, was £115.9 million. This resulted from funding of £37.5 million from the Oxford Finance facility in November 2020 and £83.0 million from the second and final closing of the series B preferred share financing in March 2020 and series C preferred share financing in December 2020. This was partially offset by the repayment of lease liabilities of £4.4 million.

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 £481.4 million as of December 31, 2021. 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 commercialize KIMMTRAK and continue research and development and clinical activities for our product candidates. In addition, due to our initial public offering in February 2021, we have and expect to continue to incur additional costs associated with operating as a public company. Our expenses will also increase if, and as, we:

- pursue further approval and commercialization of tebentafusp outside the United States.;
- 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 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 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 2040 under our largest leases in the United Kingdom. These obligations and potential obligations could result in payments of up to £44.9 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 at certain break-points prior to expiry. We expect to continue to incur expenses for such leases for the foreseeable future. If the company continues to grow, launches further products or expands its 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, primarily related to the manufacture of KIMMTRAK in the United States following FDA approval in January 2022. We also anticipate tebentafusp will receive marketing approval to be sold in Europe, based upon the receipt of a positive CHMP opinion in February 2022. While we have already incurred costs in preparation for commercial launches in the United States and beyond, 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 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 2023 onward, repayments of principal borrowings under our facility with Oxford Finance, until at least 2025. The loan liability at December 31, 2021, was £37.2 million, and further details are provided in Note 16 to our consolidated financial statements. We have the option to draw down a further \$25 million under our facility with Oxford Finance. We may also have the option to draw down an additional \$25 million; however, this is contingent on future events. If we determine that further borrowing is required, we could enter into new or amended agreements.

Since inception, we have raised an aggregate of \$1,135.1 million through private placements of our ordinary and preferred shares, payments from our collaboration partners, debt financing and most recently, the completion of our IPO where we listed our ADSs on the Nasdaq Global Select Market and raised gross proceeds of \$297.1 million. Our net cash used in operations for the years ended December 31, 2021, 2020 and 2019 was £96.1 million, £61.3 million and £102.9 million, respectively. 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, 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 in the Group 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 £237.9 million as at December 31, 2021. Having considered downside scenarios incorporating the impact of a delay or failure in successfully commercializing KIMMTRAK in the United States and in receiving regulatory approval for tebentafusp outside the United States, we believe that our existing cash and cash equivalents is sufficient to enable us to fund our planned operating expenses and capital expenditure requirements until at least the third quarter of 2023. With the inclusion of expected revenue for KIMMTRAK in the United States and pre-product revenue for sales of KIMMTRAK pursuant to the compassionate use program in France, we believe that we will have sufficient funds to continue to meet our liabilities as they fall due into 2024. This estimation of funding requirements includes a rigorous assessment of the forecasts and identified reasonable risks and mitigating actions referred to elsewhere in the Annual Report, including the ongoing impact of the COVID-19 pandemic. We have based this estimation of capital requirements on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. In addition, while we have received approval from the FDA for the sale of KIMMTRAK in the United States for the treatment of mUM, our efforts to successfully commercialize KIMMTRAK could materially differ to our estimates, and it is possible that we may not successfully commercialize KIMMTRAK in the United States or expand as planned to other jurisdictions, which could have a material adverse effect on our financial condition.

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;
- our ability to successfully commercialize KIMMTRAK in the U.S. and to obtain approval for the product outside the U.S.
- 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 product and royalty 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.

Internal Control Over Financial Reporting

In the summer and fall of 2020, we conducted an internal investigation as a result of receiving a whistle blower complaint alleging employee misconduct and other improper activities related to a kick-back 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.

However, we cannot assure you that these measures will be sufficient to prevent future material weaknesses or significant deficiencies in our internal control over financial reporting from occurring. See "Item 3.D Risk Factors—We previously identified a material weakness in our internal control over financial reporting and may identify 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."

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, we are entitled to rely on certain exemptions as an "emerging growth company," we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering, or December 2026, or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Recently Issued and Adopted Accounting Pronouncements

For information on the standards applied for the first time as of January 1, 2021 and 2020, please refer to our consolidated financial statements as of December 31, 2021 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, 2019, 2020, and 2021, 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.

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 and to faithfully depict the level of progress for each project; however, assumptions concerning estimated tasks and timelines can change and it is possible that other factors may arise which cause estimates in future periods to significantly differ to both current and previous estimates.

Deferred revenue, relating to performance obligations satisfied over time, is £30.9 million as at December 31, 2021. If the assessed life of the project was underestimated by six months, equating to approximately 10% of the weighted average life of projects under collaboration, the deferred revenue would have been £5.3 million higher (and the cumulative revenue recognized correspondingly lower).

Valuation of share options

We operate equity-settled, share-based payment 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 plans is calculated using the Black Scholes valuation model for awards following our 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 valuations models used require the input of subjective assumptions, including judgements about the expected life of share-based awards and share price volatility, which are used to determine the fair value of our ordinary shares. The assumptions represent our best estimates at the time of grant, but such estimates involve inherent uncertainties and the application of our 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.

Prior to our IPO, there was no public market for the ordinary shares, and the estimated fair value of the ordinary shares was determined as of the date of each grant considering the most recently available third-party valuations of the Group's ordinary shares, and the assessment of additional objective and subjective factors that we believed were relevant. The ordinary share valuations were prepared using a probability weighting expected return and a current value method. The probability weighted expected return method estimated the fair value of the common stock based on an analysis of future values for the enterprise assuming various future outcomes. Share value was based on the probability-weighted present value of the expected future investment returns, considering each of the possible outcomes available to the enterprise, as well as the rights of each share class. Although we do not expect the estimated fair value of the ordinary shares to generate material differences within a reasonable range of sensitivities, judgement was involved in selecting the inputs into the valuations and the movement in the determined fair value had an impact on the share-based payment charge recognized in the statement of loss.

Further judgments, including periodic estimates of options expected to vest and estimates relating to option modifications, also significantly impact the share-based compensation charge associated with granted options.

Following our IPO and the award of a total of 4.7 million options under our Equity Incentive Plan, the share-based payment expense has materially increased. We recognized a total charge of £35.9 million in the year ended December 31, 2021, compared to a charge of £8.2 million in the year ended December 31, 2020.

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, 2021.

Name	Age	Position(s)
Executive Officers:		
Bahija Jallal, Ph.D.	60	Chief Executive Officer and Director
Brian Di Donato	55	Chief Financial Officer and Head of Strategy
David Berman, M.D., Ph.D.	51	Head of Research and Development
Tina St Leger	53	Chief Human Resources Officer
Non-Executive Directors:		
Professor Sir John Bell	69	Chairman of the Board of Directors
Travis Coy	41	Director
Roy S. Herbst, M.D., Ph.D	58	Director
Robert Perez	57	Director
Kristine Peterson	62	Director
Professor Sir Peter Ratcliffe	67	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 boards of directors of Anthem, Inc. and Guardant Health, 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 immediate 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 Senior Vice President and 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 Managing Director and 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 Bachelor of Science 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 (Medical Oncology), Professor of Pharmacology, Chief of Medical Oncology and Associate Cancer Center Director for Translational Research 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., where he held various positions of increasing responsibility, including most recently as its President and Chief Executive Officer from 2003 until its sale to Merck & Co. in 2015. Mr. Perez currently serves on the board of directors of Vir Biotechnology, 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.

Diversity of the Board of Directors

The table below provides certain information regarding the diversity of our board of directors as of the date of this Annual Report.

Board Diversity Matrix (As of December 31, 2021)

Country of Principal Executive Offices	United Kingdom			
Foreign Private Issuer	Yes			
Disclosure Prohibited under Home Country Law	No			
Total Number of Directors	7			
	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	2	5	-	-
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction			1	
LGBTQ+			-	
Did Not Disclose Demographic Background			1	

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, 2021, 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 £2.0 million (2020: £1.5 million). In 2021, our highest paid director was Dr Bahija Jallal, our Chief Executive Officer, received compensation of £0.7 million (2020: £1.0 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, 2021 payable to members of our board of directors and our executive officers of £0.8 million (\$1.0 million), of which £0.4 million (\$0.5 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 £29,423 (\$39,721) during the year ended December 31, 2021, which amount is included in the foregoing aggregate compensation figure.

For the year ended December 31, 2021, 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 1.35.

Name	Salary and Fees \$	Benefits \$	Pension (401(k)) \$	Total Fixed Remuneration \$	Annual Bonus \$	Total Remuneration \$	Share-Based Awards Number ⁽¹⁾
<i>Executive Director</i>							
Bahija Jallal, Ph.D.	700,000	30,914	14,500	745,414	525,000 ⁽²⁾	1,270,414	2,076,080
<i>Non-Executive Directors</i>							
Professor Sir John Bell	70,559	—	—	70,559	—	70,559	33,985
Travis Coy ⁽³⁾	—	—	—	—	—	—	—
Roy Herbst, M.D., Ph.D.	46,890	—	—	46,890	—	46,890	10,620
Robert Perez ⁽³⁾	—	—	—	—	—	—	—
Kristine Peterson	44,658	—	—	44,658	—	44,658	13,778
Professor Sir Peter Ratcliffe	60,370	—	—	60,370	—	60,370	—
<i>Other Executive Officers</i>	905,000	59,088	25,221	989,309	518,100	1,507,409	875,507
Total compensation	1,827,477	90,002	39,721	1,957,200	1,043,100	3,000,300	3,009,970

Notes to the compensation table:

- Represents number of options granted during the year ended December 31, 2021. Further information regarding these awards including date of grant, exercise price and expiration date is disclosed in the table below. See Note 19 to our audited financial statements included elsewhere in this Annual Report for a discussion of the assumptions made by us in determining the share-based payment expense calculated in accordance with IFRS 2.
- Represents a performance-based cash bonus awarded to Dr. Jallal in connection with the achievement of 2021 annual performance milestones (paid in 2022) 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 2021 was set 75%. For 2021, the Board determined to award Dr. Jallal an annual bonus of \$525,000 (reflecting an achievement level of 100%), as reflected in the “Annual Bonus” column of the table above.

- 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, 2021.

Name	Ordinary Share Underlying Option Award	Exercise Price (\$)	Grant Date	Expiration Date
<i>Executive Director</i>				
Bahija Jallal, Ph.D. ⁽²⁾⁽³⁾	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
<i>Non-Executive Directors</i>				
Professor Sir John Bell ⁽⁴⁾	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. ⁽⁴⁾	10,620	26.00	February 4, 2021	February 4, 2031
Kristine Peterson ⁽⁴⁾	13,778	26.00	February 4, 2021	February 4, 2031
	11,520	17.46	November 16, 2020	November 16, 2030
Professor Sir Peter Ratcliffe ⁽⁴⁾	—	—	—	—
<i>Other Executive Officers</i>				
	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:

- 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.
- Options granted to Dr. Jallal on 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.
- 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.
- All option awards granted to our non-executive directors vest over a four-year period from the date of grant, with 25% of the award vesting on the first anniversary of the vesting commencement date and the remaining shares vesting in quarterly installments thereafter, subject to the director's continued service through each vesting date.
- 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, 2021.

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 seven 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 Mr. Coy, Dr. Herbst, Mr. Perez, Ms. Peterson, Professor Sir John Bell and Professor Sir Peter Ratcliffe, representing six of our seven 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, whose terms will expire at our first annual general meeting which will be held in May 2022;
- Class II consists of Robert Perez and Kristine Peterson, whose terms will expire at our second annual general meeting held in 2023; and
- Class III consists of John Bell and Bahija Jallal, whose terms will expire at our third annual general meeting held in 2024.

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. We intend to enter into new appointment letters with our non-executive directors prior to the closing of this offering, and a new appointment letter with our non-executive chairman, Professor Sir John Bell. 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.

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, Mr. Perez, Professor Sir Peter Ratcliffe and Dr. Roy S Herbst, 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, Professor Sir Peter Ratcliffe and Dr. Roy S Herbst and assists the board of directors in determining executive officer compensation. Ms. Peterson serves as chairman 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 Mr. Perez, Professor Sir John Bell 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, 2021, we had 324 full-time employees, 126 (39%) of whom hold Ph.D. or M.D. degrees. Of these employees, 247 are engaged in research and development activities and 77 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,		
	2019	2020	2021
Function:			
Administrative	67	55	77
Research and development	392	236	247
Total	459	291	324
Geography:			
United Kingdom	409	242	264
European Union	3	2	2
United States	47	47	58
Total	459	291	324

As a result of the corporate restructuring, which was completed in the second quarter of 2020, our overall headcount was reduced by 78.

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

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.”

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 December 31, 2021 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 December 31, 2021. Percentage ownership calculations are based on 43,862,850 ordinary shares outstanding (including ordinary shares in the form of ADSs) as of December 31, 2021, of which 831,627 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 (%)
<i>5% or Greater Shareholders:</i>		
Entities affiliated with General Atlantic ⁽¹⁾	4,922,575	11.2%
Entities affiliated with Baker Brothers ⁽²⁾	3,352,357	7.6%
Eli Lilly S.A. ⁽³⁾	2,548,145	5.8%
Entities affiliated with Rock Springs Capital ⁽⁴⁾	2,471,555	5.6%
Malin Life Sciences Holdings Limited ⁽⁵⁾	2,389,979	5.4%
Ian Laing ⁽⁶⁾	2,358,650	5.4%
<i>Executive Officers and Directors:</i>		
Bahija Jallal, Ph.D. ⁽⁷⁾	1,571,156	3.5%
Brian Di Donato ⁽⁸⁾	233,451	*
David Berman, M.D., Ph.D. ⁽⁹⁾	792,991	1.8%
Tina St. Leger	—	—
Professor Sir John Bell ⁽¹⁰⁾	49,748	*
Travis Coy	—	—
Roy Herbst ⁽¹¹⁾	2,655	*
Robert Perez	—	—
Kristine Peterson ⁽¹²⁾	14,965	*
Professor Sir Peter Ratcliffe	—	—
All current directors and executive officers as a group ⁽¹³⁾	2,664,966	5.7%

* Represents beneficial ownership of less than one percent.

- (1) Consists of 4,922,575 ADSs 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.
- (2) The information shown is based, in part, upon disclosures filed on a Schedule 13D on May 20, 2021 filed jointly by Baker Bros. Advisors LP (the “Adviser”), Baker Bros. Advisors (GP) LLC (the “Adviser GP”), Felix J. Baker and Julian C. Baker (collectively, the “Reporting Persons”). The number reported consists of 2,520,730 ADSs and 831,627 ordinary shares issuable upon conversion of 831,627 non-voting ordinary shares directly held by the funds. 3,104,143 ADSs are held by Baker Brothers Life Sciences, L.P. and 248,214 ADSs are held by 667,L.P.The address of Baker Bros. Advisors LP is 860 Washington Street, 3rd Floor, New York, NY 10014, United States.
- (3) Consists of 2,548,145 ADSs held by Eli Lilly S.A. Eli Lilly S.A.’s address is 16, Chemin des Coquelicots, 12 Geneva, Switzerland.
- (4) Consists of 2,455,155 ADSs held by Rock Springs Capital Management LP (“RSCM”), Rock Springs Capital LLC (“RSC”), and Rock Springs Capital Management LP (“Master Fund”)The address of Rock Springs Capital Management LP and Rock Springs Capital LLC is 650 South Exeter, Suite 1070, Baltimore, MD 21202.
- (5) Consists of 2,389,979 ADSs held by Malin Life Sciences Holdings Limited. Malin Life Sciences Holdings Limited’s address is The Lennox Building, 50 Richmond Street South, Dublin D02 FK02, Ireland.
- (6) Consists of 2,358,650 ADSs held by Ian Michael Laing and Caroline Elizabeth Laing.
- (7) Consists of 1,571,156 ordinary shares underlying options that are exercisable within 60 days of December 31, 2021 held by Dr. Jallal.
- (8) Consists of (a) 19,230 ADSs held by Mr. Di Donato and (b) 214,221 ordinary shares underlying options that are exercisable within 60 days of December 31, 2021 held by Mr Di Donato.
- (9) Consists of 792,991 ordinary shares underlying options that are exercisable within 60 days of December 31, 2021 held by Dr. Berman.
- (10) Consists of (a) 13,452 ADSs and (b) options to purchase 36,296 ordinary shares that are or will be immediately exercisable within 60 days of December 31, 2021 held by Professor Sir John Bell.

- (11) Consists of 2,655 ordinary shares underlying options that are or will be immediately exercisable within 60 days of December 31, 2021 held by Dr. Herbst.
- (12) Consists of 14,965 ordinary shares underlying options that are exercisable within 60 days of December 31, 2021 held by Ms. Peterson.
- (13) Consists of (a) 32,682 ADSs and (b) options to purchase 2,632,284 ordinary shares that are or will be immediately exercisable within 60 days of December 31, 2021.

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 June 30, 2021, 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 30% of our outstanding ordinary shares (including ordinary shares underlying ADSs) were held in the United States by 32 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.

Participation in Initial Public Offering

In our initial public offering, certain of our existing principal shareholders and their affiliates purchased an aggregate of 3,989,102 ADSs. Each of those purchases was made through the underwriters at the initial public offering price. The following table sets forth the aggregate number of ADSs that these principal shareholders and their affiliates purchased in our initial public offering:

Purchaser	Number of ADSs
Entities affiliated with General Atlantic	950,000
Entities affiliated with Baker Brothers	1,689,102
Entities affiliated with Fidelity	1,350,000

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.”

Registration Rights Agreement

We have entered into a registration rights agreement with certain of our existing shareholders pursuant to which we have granted them customary registration rights for the resale of the common shares held by certain of our existing shareholders.

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 interference or opposition proceedings. There is currently one patent opposition proceeding ongoing at the European Patent Office relating to a non-core aspect of our ImmTAX platform technology and which challenges the validity of European patent no. EP3116901. At a Hearing, which took place on February 17, 2022, the opposition division decided to maintain the patent as granted. The opponent may appeal 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 our development of our product candidates. 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 one or more of these actions, 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.

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 31, 2021. 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 should 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 7.5% to the extent that the excess amount falls within the basic rate tax band, 32.5% to the extent that the excess amount falls within the higher rate tax band and 38.1% to the extent that the excess amount falls within the additional rate tax band. It has been announced that the current tax rates of 7.5%, 32.5% and 38.1%, respectively, referred to above will respectively be increased to 8.75%, 33.75% and 39.35%, respectively, with effect from April 6, 2022.

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

A document which acts to transfer ordinary shares will normally give rise to a charge to stamp duty at the rate of 0.5% (rounded up to the next £5.00) of the amount or value of the consideration payable for the transfer. However, where there is a transfer to a connected company market value deeming rules may apply in certain circumstances. Stamp duty is normally paid by the purchaser. An unconditional agreement to transfer ordinary shares will also give rise to a charge to SDRT at the rate of 0.5% on any consideration given in money or moneys worth. However, where there is a transfer to a connected company market value deeming rules may apply in certain circumstances. The purchaser of the shares is liable for the SDRT. Notwithstanding this, the charge to SDRT will be cancelled or, if already paid, repaid (generally with interest), where a transfer instrument is executed in pursuance of the agreement that gave rise to SDRT and the instrument is 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 being stamped.

The issue or transfer (or 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 stamp and/or SDRT 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 (a “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 97A Election having been made by DTC. However, no stamp duty or SDRT is generally payable where there is an issue or transfer of ordinary shares to a clearance service or depositary receipt system which is an integral part of raising new capital.

Any stamp duty or SDRT payable on an issue or transfer of ordinary shares to a depositary receipt system or clearance service (which has not made a 97A Election) 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 our ADSs, except that stamp duty or SDRT may apply where shares are issued or transferred to the depositary receipt issuer (see above).

Transfers of ADSs

No stamp duty or SDRT should be payable on the transfer of, or agreement to transfer, ADSs as an ADS should be outside the scope of both taxes.

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 an 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 Loan Agreement with Oxford Finance, a derivative liability, 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 are 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.

We are currently not subject to interest rate risks related to any liabilities shown in the statement of financial position, outside of the Loan Agreement.

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 our operating activities in the United States and outsourced supplier agreements denominated in currencies other than pound sterling.

Our cash and cash equivalents were £237.8 million and £129.7 million as of December 31, 2021 and 2020, respectively. As of December 31, 2021, 98% of our cash and cash equivalents were held in United Kingdom, of which 44% were denominated in pounds sterling, 54% were denominated in U.S. dollars and 2% were denominated in euros. The significant remainder of our cash and cash equivalents (2%) are held in the United States and denominated in U.S. dollars. A hypothetical 10% change in exchange rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

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, 2021, by £2.6 million and as at December 31, 2020, 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, 2021, by £2.6 million and as at December 31, 2020, 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 collaboration partners which are significantly 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 form 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 under the terms of the deposit agreement:

Service	Fee
Issuance of ADSs (<i>e.g.</i> , 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 (<i>e.g.</i> , 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 (<i>e.g.</i> , 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 (<i>e.g.</i> , 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, 2021. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2021, 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, 2021, 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, 2021, was effective.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of the Company’s registered public accounting firm since we are an emerging growth company.

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 15T. Controls and Procedures.

Not applicable.

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, 2021 and 2020.

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, 2021 and 2020.

	Year Ended December 31,	
	2021	2020
	£ '000	£ '000
Audit fees	650	470
Audit-related fees	125	237
Total	775	707

Audit fees. Audit fees consisted of fees for the audit of our annual financial statements and other professional services provided in connection with the statutory and regulatory filings or engagements, including fees for the review of our interim financial information.

Audit-related fees. Audit-related fees included fees for assurance reporting on our current and historical financial information included in our SEC registration statements in connection with our initial public offering, including services that generally only the independent accountant can reasonably provide such as comfort letters.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee reviews and pre-approves the scope and the cost of audit services related to us and permissible non-audit services performed by the independent auditors. 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.

Not applicable.

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
2.2	Deposit Agreement.	20-F	001-39992	2.2	03/25/21
2.3	Form of American Depositary Receipt (included in Exhibit 2.2).	20-F	001-39992	2.3	03/25/21
2.4	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†	Collaboration and License Agreement, dated as of June 29, 2013, between the Registrant and GlaxoSmithKline Intellectual Property Development Ltd.	F-1	333-252166	10.6	01/15/21
4.4†	Development and License Agreement, dated as of July 11, 2014, between the Registrant and Eli Lilly and Company, as amended on December 21, 2016, September 20, 2017 and December 19, 2018.	F-1	333-252166	10.7	01/15/21
4.5†	License Agreement, dated as of September 27, 2016, between the Registrant and Genentech, Inc.	F-1	333-252166	10.8	01/15/21
4.6†	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
4.7†	Convertible Loan Note Purchase Agreement, dated as of September 13, 2017, between the Registrant and the Bill & Melinda Gates Foundation.	F-1	333-252166	10.10	01/15/21
4.8	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

4.9†	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
4.10	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
4.11	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
4.12	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
4.13†	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
4.15	Loan and Security Agreement, dated as of November 6, 2020, among the Registrant, Oxford Finance Luxembourg S.a r.l., and the lenders listed on Schedule 1.1 thereof.	F-1	333-252166	10.17	01/15/21
4.16#	Employment Agreement between the Registrant and Bahija Jallal, Ph.D., dated January 29, 2021.	F-1/A	333-252166	10.18	02/01/21
4.17	Deed of Termination of Convertible Loan Note Purchase Agreement, dated as of February 3, 2021, between the Registrant and the Bill & Melinda Gates Foundation.	F-1/A	333-252166	10.19	02/03/21
4.18	Form of Deed of Indemnity between the Registrant and each of its directors.	F-1	333-252166	10.1	01/15/21
4.19#	Form of Deed of Indemnity between the Registrant and each of its executive officers.	F-1	333-252166	10.2	01/15/21
4.20#	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
4.21*	Notice of Termination Letter from GlaxoSmithKline Intellectual Property Development Ltd. to the Registrant with respect to NY-ESO, dated February 8, 2021.				
4.22*	First Amendment to Loan and Security Agreement, dated January 22, 2021, among the Registrant, Oxford Finance Luxembourg S.à r.l., and the lenders listed on Schedule 1.1 thereof.				
4.23*	Second Amendment to Loan and Security Agreement, dated September 10, 2021, among the Registrant, Oxford Finance Luxembourg S.à r.l., and the lenders listed on Schedule 1.1 thereof.				
4.24*†	Notice of Termination Letter from GlaxoSmithKline Intellectual Property Development Ltd. to the Registrant with respect to the Collaboration and License Agreement, dated October 8, 2021.				
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.

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 3, 2022

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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 statements of financial position of Immunocore Holdings plc and subsidiaries (the Company) as of December 31, 2021 and 2020, the related consolidated statements of loss and other comprehensive income, changes in equity, and cash flows for each of the years in the three year period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the (consolidated) financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2009.

Reading, United Kingdom
March 3, 2022

Immunocore Holdings Plc
Annual report and consolidated financial statements
December 31, 2021

Consolidated Statements of Loss and Other Comprehensive Income for the years ended December 31,

	Notes	2021 £'000	2020 £'000	2019 £'000
Revenue	2	26,520	30,114	25,669
Total revenue		26,520	30,114	25,669
Net other operating (loss) / income	5	(57)	4,242	185
Research and development costs		(73,226)	(74,809)	(99,991)
Administrative expenses		(88,399)	(45,740)	(44,183)
Operating loss		(135,162)	(86,193)	(118,320)
Finance income	6	47	2,208	1,510
Finance costs	7	(5,813)	(3,375)	(9,379)
Non-operating expense		(5,766)	(1,167)	(7,869)
Loss before taxation		(140,928)	(87,360)	(126,189)
Income tax credit	8	9,405	13,267	22,258
Loss for the year		(131,523)	(74,093)	(103,931)
Other comprehensive (expense) / income				
<i>Other comprehensive (expense) / income that are or may be reclassified to profit or loss in subsequent periods (net of tax):</i>				
Exchange differences on translation of foreign operations		(74)	195	(99)
Total other comprehensive (expense) / income for the year, net of tax		(74)	195	(99)
Total comprehensive loss for the year, net of tax		(131,597)	(73,898)	(104,030)
Basic and diluted loss per share - £	9	(3.10)	(2.79)	(4.66)

The accompanying notes form an integral part of these financial statements.

Immunocore Holdings Plc
Annual report and consolidated financial statements
December 31, 2021

Consolidated Statements of Financial Position as at December 31,

		2021	2020
	Notes	£'000	(Adjusted) £'000
Non-current assets			
Property, plant and equipment	11	8,944	13,754
Right of use assets	12	22,593	23,093
Investment in sub-lease	12	—	776
Other non-current financial assets	13	4,935	4,410
Deferred tax asset	8	2,575	2,230
Total non-current assets		39,047	44,263
Current assets			
Trade and other receivables	14	15,208	10,280
Tax receivable	8	9,632	12,935
Cash and cash equivalents		237,886	129,716
Total current assets		262,726	152,931
Total assets		301,773	197,194
Equity			
Share capital	15	88	64
Share premium	15	212,238	—
Foreign currency translation reserve	15	89	163
Other reserves	15	386,167	386,167
Share-based payment reserve	15, 19	54,357	18,821
Accumulated deficit		(481,392)	(349,869)
Total equity		171,547	55,346
Non-current liabilities			
Interest-bearing loans and borrowings	16	37,226	36,654
Deferred revenue	2	6,408	24,868
Lease liabilities	12	25,355	25,190
Provisions	17	57	138
Total non-current liabilities		69,046	86,850
Current liabilities			
Trade and other payables	18	35,436	25,728
Deferred revenue	2	24,450	27,118
Lease liabilities	12	1,255	2,043
Provisions	17	39	109
Total current liabilities		61,180	54,998
Total liabilities		130,226	141,848
Total equity and liabilities		301,773	197,194

Share capital, Share premium and Other reserves in the table above have been adjusted to give retrospective effect to the Group's corporate reorganization. Further details of the effects of this reorganization are provided in Note 15 to these consolidated financial statements. The effect of these reclassifications has had no impact on Total equity or the Accumulated deficit as previously stated as at December 31, 2020.

The accompanying notes form an integral part of these financial statements.

Immunocore Holdings Plc
Annual report and consolidated financial statements
December 31, 2021

Consolidated Statements of Changes in Equity for the years ending December 31, 2019, 2020 and 2021

	Note	Share capital - adjusted £'000	Share premium - adjusted £'000	Foreign currency translation reserve £'000	Share- based payment reserve £'000	Other reserves - adjusted £'000	Accumulated deficit £'000	Total equity £'000
At January 1, 2019 - adjusted	15	43	—	67	7,603	224,044	(175,175)	56,582
Loss for the year	15,19	—	—	—	—	—	(103,931)	(103,931)
Other comprehensive loss		—	—	(99)	—	—	—	(99)
Total comprehensive loss for the year		—	—	(99)	—	—	(103,931)	(104,030)
Issue of share capital	15	6	—	—	—	59,157	—	59,163
Equity-settled share-based payment transactions	15,19	—	—	—	3,056	—	—	3,056
At December 31, 2019	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		—	—	—	—	—	(510)	(510)
Derecognition of derivative liability		—	—	—	—	—	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 income		—	—	(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	15	—	952	—	—	—	—	952
Equity-settled share-based payment transactions	15,19	—	325	—	35,536	—	—	35,861
At December 31, 2021	15	88	212,238	89	54,357	386,167	(481,392)	171,547

Share capital, Share premium and Other reserves in the table above have been adjusted to give retrospective effect to the Group's corporate reorganization. Further details of the effects of this reorganization are provided in Note 15. The accompanying notes form an integral part of these financial statements.

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Consolidated Statements of Cash Flows for the years ended December 31,

	Notes	2021 £ '000	2020 £ '000	2019 £ '000
Cash flows from operating activities				
Loss for the year		(131,523)	(74,093)	(103,931)
Adjustments for:				
Depreciation of property, plant and equipment	11	5,511	6,446	6,549
Depreciation of right of use assets	12	1,501	2,530	2,454
Remeasurement of leases	3	(15)	(227)	—
Amortization of intangible assets		—	—	210
Write-off of intangible assets	3	—	—	306
Loss on disposal of property, plant and equipment	3	180	1,064	3
Profit on derecognition of leases	3	—	(3,700)	—
Net finance costs		5,766	1,167	7,869
Unrealized foreign exchange differences		586	(787)	(620)
Equity settled share-based payment expenses	19	35,861	8,162	3,056
Income tax credit	8	(9,405)	(13,267)	(22,258)
Working capital adjustments:				
(Increase) / decrease in trade and other receivables		(5,147)	(532)	1,828
Increase / (decrease) in trade and other payables		9,469	(3,774)	9,946
Movement in provisions and other charges		(150)	(41)	71
Decrease in deferred liabilities		(21,128)	(24,497)	(21,866)
Cash used in operations		(108,494)	(101,549)	(116,383)
Net taxation received	8	12,384	40,299	13,482
Net cash used in operating activities		(96,110)	(61,250)	(102,901)
Cash flows from investing activities				
Bank interest received on cash and cash equivalents		15	676	1,525
Proceeds from sale of property, plant and equipment		77	675	82
Purchase of property, plant and equipment	11	(1,008)	(3,074)	(4,078)
Purchase of intangible assets		—	—	(198)
Proceeds from investment in sub-leases		549	378	57
Leasehold incentive		—	2,488	—
Net cash flows (used in) from investing activities		(367)	1,143	(2,612)
Cash flows from financing activities				
Gross proceeds from issue of share capital	15	226,528	83,218	59,874
Costs from issue of share capital	15	(15,543)	(176)	(738)
Proceeds from exercise of share options	15	952	73	27
Non-current interest-bearing loan received		—	37,543	—
Interest paid on non-current interest-bearing loan		(4,147)	(291)	—
Repayment of lease liabilities	12	(3,159)	(4,426)	(4,036)
		204,631	115,941	55,127
Increase / (decrease) in net cash and cash equivalents		108,154	55,834	(50,386)
Net foreign exchange difference on cash held		16	(84)	(33)
Cash and cash equivalents at beginning of the year		129,716	73,966	124,385
Cash and cash equivalents at end of the year		237,886	129,716	73,966

The accompanying notes form an integral part of these financial statements.

Immunocore Holdings Plc
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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 and Immunocore Nominees Limited (collectively referred to as the “Group”).

On February 9, 2021, the Company completed its initial public offering (“IPO”) of 11,426,280 American Depositary Shares (“ADSs”) representing 11,426,280 ordinary shares with nominal value of £0.002 per ordinary share for aggregate gross proceeds of \$297,083,000. The Company’s ADSs began trading on the Nasdaq Global Select Market under the ticker symbol “IMCR” on February 5, 2021. In addition to the ADSs sold in the IPO, the Company completed the concurrent sale of an additional 576,923 ADSs at the initial offering price of \$26.00 per ADS, for gross proceeds of approximately \$15.0 million, in a private placement to the Bill & Melinda Gates Foundation (“Gates Foundation”).

The IPO and private placement to the Gates Foundation generated net proceeds of \$286,887,000 (£210,985,000) after underwriting discounts, commissions and directly attributable offering expenses.

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 has been 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 has been given retrospective effect in these financial statements and such financial statements represent the financial statements of Immunocore Holdings plc.

The principal activity of the Group is 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 its proprietary, flexible, off the-shelf ImmTAX platform, the Group is developing a deep pipeline in multiple therapeutic areas, including five clinical stage programs in oncology and infectious disease, advanced pre-clinical programs in autoimmune disease and multiple earlier pre-clinical programs. Following FDA approval of the Group’s lead product candidate, KIMMTRAK, in January 2022, the Group has commenced the sale and distribution of this immunotherapy in the United States.

Basis of preparation and statement of compliance

The consolidated Group financial statements as of December 31, 2021 and 2020 and for the years ended December 31, 2021, 2020 and 2019 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 3, 2022 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 material impact on the Group.

During the year ended December 31, 2020, Interest Rate Benchmark Reform – Phase 1, issued by the International Accounting Standards Board (“IASB”), became effective. Phase 1 contained amendments to IFRS 9, IAS 39, and IFRS 7 related to the impact of interest rate benchmark reform on hedging relationships. These amendments were not applicable to the Group, as the Group does not have any hedging arrangements. During the year ended December 31, 2021, the Group adopted the amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4, and IFRS 16 related to Interest Rate Benchmark Reform – Phase 2, issued by the IASB, which addresses issues that might affect financial reporting during the reform on an interest rate benchmark. The adoption has not had a material effect on the consolidated financial statements. The only financial instrument subject to interest rate reform is the Group’s loan and security agreement (“Loan Agreement”) with Oxford Finance Luxembourg S.A.R.L. (“Oxford Finance”), which has a carrying amount of £37,226,000 as of December 31, 2021 (£36,654,000 as of December 31, 2020). Currently, borrowings under the Loan Agreement bear 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%. LIBOR is the subject of recent national, international, and other regulatory guidance and proposals for reform. The current administrator of LIBOR will cease to publish the settings relevant to our agreements on June 30, 2023. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, has identified the Secured Overnight Financing Rate, or SOFR, a new index calculated by short-term repurchase agreements, backed by Treasury securities, as its preferred alternative rate for LIBOR. At this time, it is not possible to predict how markets will respond to SOFR or other alternative reference rates as the transition away from LIBOR is anticipated in coming years. There is currently no definitive information regarding the future utilization of LIBOR or of any particular replacement rate. While a transition away from LIBOR as a benchmark for establishing the applicable interest rate may adversely affect the Group’s outstanding variable-rate indebtedness, and, while the Group’s loan balance is material, the potential effect of this is not expected to materially affect the Group’s future interest payments. The Group is monitoring developments in alternative benchmarks in relation to the loan, and does not expect any material impact in making the transition to an alternative benchmark rate on the loan in future periods, should this be required.

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 £237,886,000 and net current assets of £201,546,000 as at December 31, 2021, with an operating loss for the year ended December 31, 2021 of £135,162,000. The negative operational cash flow was largely due to the continuing focus on the research, development, and clinical activities to advance the programs within the Group’s pipeline. During the year ended December 31, 2021, the Company completed its IPO and the concurrent private placement to the Gates Foundation and received aggregate net proceeds of \$286,887,000. Further, on January 26, 2022 the Group’s lead product candidate, KIMMTRAK received regulatory approval for marketing by the U.S. Food and Drug Administration. Tebentafusp is also undergoing review from the European Medicines Agency following acceptance of the Group’s Marketing Authorization Application in Europe in the year ended December 31, 2021. While the Group generated a negative operational cash flow overall, pre-product revenue of £3,010,000 was generated from sales of tebentafusp, the Group’s lead product candidate, under a compassionate use program in France.

In assessing the going concern assumptions, the Board has undertaken an assessment of the current business and strategy forecasts covering a two-year period, which includes the potential receipt of commercial revenue following regulatory approval of KIMMTRAK in the United States. In assessing the downside risks, the Board has also considered a number of severe but plausible scenarios incorporating the impact of a delay or failure in successfully commercializing KIMMTRAK in the U.S and in receiving regulatory approval for tebentafusp outside the U.S.. As part of considering the downside risks, the Board has considered the impact of the ongoing coronavirus 2019 (“COVID-19”) pandemic and have concluded that the pandemic may have a future impact on the Group’s business and implementation of its strategy and plans, but 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 Company is not aware of any specific event or circumstance that would require the Company 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 Company’s financial statements.

Having considered downside scenarios, the current cash position, and the assessment performed, the Board is confident that the Group will have sufficient funds to continue to meet its liabilities as they fall due until at least the third quarter of 2023 and therefore, have prepared the financial statements on a going concern basis. With the inclusion of expected revenue for KIMMTRAK in the United States and pre-product revenue in France, the Group estimates it will have sufficient funds to continue to meet its liabilities as they fall due into 2024. The Group has based this estimation of capital requirements on assumptions that may prove to be wrong, and it could utilize available capital resources sooner than currently expected. In addition, while the Group has received regulatory approval for KIMMTRAK in the United States, the Group’s efforts to successfully commercialize the product could materially differ to estimates, and it is possible that the Group may not successfully commercialize KIMMTRAK, which could have a materially adverse effect on its financial condition. As the Group continues to incur significant expenses in the pursuit of its business strategy, additional funding will be needed before further existing programs may be expected to reach commercialization, which would potentially lead to operational cash inflows. Until the Group can generate a higher level of revenue from product sales, 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.

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 and to faithfully depict the level of progress for each project; however, assumptions around estimated tasks and timelines can change and it is possible that other factors may arise which cause estimates in future periods to significantly differ to both current and previous estimates.

Deferred revenue, relating to performance obligations satisfied over time, is £30,858,000 as at December 31, 2021. If the assessed life of all projects was underestimated by six months, equating to approximately 10% of the weighted average life of projects under collaborations, deferred revenue would have been £5,300,000 higher (and the cumulative revenue recognized correspondingly lower).

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.

Prior to the Group's IPO, there was no public market for the ordinary shares, and the estimated fair value of the ordinary shares was determined as of the date of each grant considering the most recently available third-party valuations of the Group's ordinary shares, and the assessment of additional objective and subjective factors that the Group believed were relevant. The ordinary share valuations were prepared using a probability weighting expected return and a current value method. The probability weighted expected return method estimated the fair value of the common stock based on an analysis of future values for the enterprise assuming various future outcomes. Share value was based on the probability-weighted present value of the expected future investment returns, considering each of the possible outcomes available to the enterprise, as well as the rights of each share class. Although the Group does not expect its estimated fair value of the ordinary shares to generate material differences within a reasonable range of sensitivities, judgement was involved in selecting the inputs into the valuations and the movement in the determined fair value had an impact on the share-based payment charge recognized in the statement of loss.

Following the Group's IPO and the award of a total of 4,702,027 options under its Equity Incentive Plan in the year ended December 31, 2021, the share-based payment expense has materially increased. The Group recognized a total charge of £35,861,000 in the year ended December 31, 2021, compared to a charge of £8,162,000 in the year ended December 31, 2020.

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:

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 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.

Significant accounting policies

Basis of consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries as of December 31, 2021 and 2020 and for the years ended December 31, 2021, 2020 and 2019. 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 three geographic regions: the United Kingdom, the Republic of Ireland 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 currency 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 in the profit and loss account.

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.

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*". In doing so, the Group will consider 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 these collaboration agreements, depending on the terms, the Group may also receive commercialization milestones upon the first commercial sale of a product, the amount of which is based on the territory the sale occurs in, and royalties based on worldwide net sales. These amounts have not been included within the transaction price as of December 31, 2021, 2020 and 2019 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.

The Group recognizes deferred revenue when the amount of unconditional consideration is in excess of the value of satisfied, or part satisfied, performance obligations. Once a right to receive consideration is unconditional, that amount is presented as a receivable.

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.

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 'Critical accounting estimates and judgments' section.

Pre-product revenue

Pre-product revenue relates to the sale of tebentafusp under a compassionate use program in France. This program provides patients with access to tebentafusp prior to receipt of marketing approval. 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 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 Condensed 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. Manufacturing costs are recognized within Research and development costs and other third-party selling expenses are recognized within Administrative expenses. Costs associated with pre-product revenue up to December 31, 2021 are not material.

Pre-product revenue arrangements have standard payment terms and do not contain a significant financing component.

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, 2021, expected credit losses are not material.

Inventories

Pre-launch inventories are goods manufactured for commercial sale. They are presented as assets in the Condensed Consolidated Statement of Financial Position if there is a high probability of future economic benefits. Since tebentafusp was not approved for such sale by a regulatory body as of December 31, 2021, the Group carried a full provision against the carrying amount of inventory manufactured for commercial sale to ensure such inventories are included in the Condensed Consolidated Statement of Financial Position at the lower of cost and net realizable value.

As at December 31, 2021, both the cost and associated provision of pre-launch inventories was £877,000. Costs associated with these inventories are recognized in Research and development expenses in the Condensed Consolidated Statement of Loss and Comprehensive Income. The cost is measured using a weighted average cost method and includes raw materials, external manufacturing costs, and other direct costs incurred in bringing inventories to their location and condition prior to sale.

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 in our financial statements 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 'Critical accounting 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 asset is 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 on occasion enters into sub-lease arrangements which are 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 assess 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).

Cash and cash equivalents

Cash and cash equivalents comprise cash balances and with original maturities of three months or less.

Loans and borrowings

All loans and borrowings are classified as financial liabilities and are initially recorded at fair value less the value attributable to any separately accounted for embedded derivative. 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.

The Group has a long-term loan, drawn down under the Oxford Finance agreement entered into on November 6, 2020, which is classified as a non-current liability, as at December 31, 2021, and accounted for under the amortized cost method. The loan is subsequently measured at amortized cost, with the unwinding of the discount recorded in finance costs over the life of the loan.

The Group previously had a convertible loan, evidenced by loan notes, which was classified as a current liability and accounted for under the amortized cost method with the embedded derivative, the conversion features, accounted for separately. The convertible loan was initially recognized at fair value less the value attributable to the separated embedded derivative. The notes and embedded derivative were derecognised following the conversion of the loan into series B preferred shares in March 2020.

The fair value of the convertible loan was calculated based on the present value of the future principal and interest cash flows, discounted at the market rate at the statement of financial position date. The loan notes were subsequently measured at amortized cost, with the unwinding of the discount recorded in finance costs over the life of the loan. The initial difference between proceeds received, net of transaction costs, and fair value was recognized in finance income.

Derivatives

Derivatives are initially measured at fair value and are subsequently remeasured to fair value at each reporting date. Changes in fair value are recognized in finance income or finance costs as appropriate.

Equity conversion features within host instruments that meet the definition of a derivative and have economic and risk characteristics that are not closely related to the host are considered embedded derivatives and are separated from the host instrument and accounted for separately.

The Group had a recognized embedded derivative asset related to the conversion features within the \$40 million convertible loan it received from the Bill and Melinda Gates Foundation (the "Gates Foundation"). This derivative financial asset was initially recorded at fair value and re-measured to fair value at each reporting period, while the convertible loan is outstanding, with gains and losses arising from changes in the fair value recognized in finance income or finance costs as appropriate. The initial tranche of the Gates Foundation convertible loan in the amount of \$25 million was converted into equity as part of the Group's series B preferred share financing in March 2020 and the embedded derivative asset derecognized.

The fair value of the embedded derivative asset was determined using the Back Solve model, discounted and probability weighted for the conversion features within the underlying convertible loan, which includes unobservable inputs supported by little or no market activity. The conversion features within the convertible loan were activated under different circumstances and the resulting fair value may have varied based on factors including the date of conversion or the event triggering conversion, such as an IPO or the Gates Foundation electing to convert its loan to the Group into equity, under specified circumstances. The option pricing model incorporated input assumptions reflecting the varied circumstances under which the conversion from debt to equity may occur. Significant unobservable inputs used in the fair value measurement of the embedded derivative asset were predominantly regarding the probability of each of the conversion features occurring. The probabilities were determined based on all relevant internal and external information available and were reviewed and reassessed at each reporting date. The Group de-recognized the embedded derivative asset when the convertible loan converted.

The Group also had a derivative liability that is marked to fair value at each reporting period. The derivative liability represented a foreign exchange call option over certain series B shares which was settled in full in March 2020.

The fair value of the derivative liability was determined using an option pricing model using a range of inputs both observable and unobservable in nature. The unobservable input was the expected final close date of the series B private finance round which was determined based on all relevant internal and external information available and was reviewed and reassessed at each reporting date. The resulting fair value of the derivative liability was not sensitive to changes in the expected close date.

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 & segmental reporting

Revenue recognized during 2021, 2020 & 2019 arose primarily from collaboration agreements with GlaxoSmithKline Intellectual Property Development Ltd ("GSK"), Eli Lilly and Company ("Eli Lilly") and Genentech, Inc. ("Genentech"). The revenue figures for GSK and Genentech in the table below each represented more than 10% of the Group's revenue in the year ended December 31, 2021.

	2021 £'000	2020 £'000	2019 £'000
<i>Collaboration revenue</i>			
GlaxoSmithKline	6,083	6,356	5,753
Eli Lilly	—	3,522	819
Genentech	17,427	20,236	19,097
<i>Total collaboration revenue</i>	23,510	30,114	25,669
Pre-product revenue	3,010	—	—
Total revenue	26,520	30,114	25,669

Revenue is presented by region in the table below based on the location of the customer.

United Kingdom	6,083	6,356	5,753
United States	17,427	23,758	19,916
Europe	3,010	—	—
Total revenue	26,520	30,114	25,669

For the year ended December 31, 2021, a total of £21,128,000 of revenue recognized was included in deferred revenue at January 1, 2021 (2020: £24,432,000 recognized included in deferred revenue at January 1, 2020).

Trade receivables were £6,047,000 as at December 31, 2021, compared to £2,051,000 as at December 31, 2020, reflecting an increase mainly due to pre-product revenue under a compassionate use program in France. As at December 31, 2021, there were no expected credit losses in relation to revenue receivables.

	2021 £'000	2020 £'000
Current deferred revenue	24,450	27,118
Non-current deferred revenue	6,408	24,868
	30,858	51,986

Deferred revenue is 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 £21,128,000 as a result of the revenue recognised under our collaboration agreements detailed above. The deferred revenue of £30,858,000 above, represents the amount of transaction price allocated to performance obligations that are unsatisfied or partially satisfied as at December 31, 2021, and is expected to be recognized as revenue within one to two years. Included in the current deferred revenue balance of £24,450,000 as at December 31, 2021 and (£27,118,000 as at December 31, 2020) is £7,361,000 of deferred revenue held whilst program focus is reviewed.

During the year ended December 31, 2020, the Group reviewed and revised the estimated completion of each of the programs under the collaboration agreements, arising from the availability of additional historical data as programs progress through research and development activities within the Group. The impact of this revision increased revenue recognized in the year ended December 31, 2020 by £705,000.

No revenue was recognized in 2021 relating to performance obligations satisfied in previous years (2020: £705,000; 2019: no revenue).

Genentech Collaboration

Under the Genentech agreement signed in November 2018, the Group received an aggregate non-refundable payment 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. After completion of the Phase 1 clinical trial, the Group has a limited time period in which to decide to either continue co-development (including co-funding) of the IMC-C103C program or withdraw from the co-funding commitment and convert the co-exclusive license to a full out-license to Genentech of the IMC-C103C program, in exchange for future milestone and royalty payments to the Group.

The total payments of \$100 million (£77.4 million) upfront payment was 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 may decide to withdraw from the co-funding commitments and convert the co-exclusive license to a full out-license to Genentech. This occurs after completion of the Phase I clinical trial and should the Group withdraw from the co-funding commitment, 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 in time. Research and development costs reimbursed under the 2018 Genentech Agreement 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.

During the year ended December 31, 2021, the Group recognized £17,428,000 revenue relating to the 2018 Genentech Agreement (2020: £20,236,000; 2019: £19,097,000). 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, 2021, £338,000 represented research and development cost reimbursements (2020: £2,785,000; 2019: £1,696,000), and £17,090,000 represented revenue that was included in the deferred revenue balance at January 1, 2021. As at December 31, 2021, £23,497,000 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 to two years.

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 targets as being exclusive to GSK under the GSK Agreement. 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.

Under the GSK Agreement, for the NY-ESO target, the Group was responsible for the development of the soluble TCR bispecific therapeutic candidate compounds over the period of time to estimated completion of the initial Phase 1 clinical trials. GSK had the option until a certain period following completion of such development work to obtain an exclusive worldwide license to NY-ESO. For the second collaboration target, GSK had an option to obtain an exclusive worldwide license for the therapeutic candidate compounds until a certain period following the identification of at least one development candidate or the earlier termination of the applicable development work.

The Group received non-refundable upfront payments upon execution of the agreement and nomination of the second collaboration target. Further non-refundable milestone payments have been received based on the achievement of specified development milestones. These development milestone payments were considered variable consideration and assessed at contract inception and each subsequent reporting period and not recognised in the transaction price until it was highly probable that the recognition of such revenue would not be reversed. In respect of the first target, development costs incurred over a specified amount were reimbursed to the Group.

As at December 31, 2021, 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, 2021 and 2020. These 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, 2021, the Group recognized £6,083,000 revenue relating to the GSK Agreement (2020: £6,356,000; 2019: £5,753,000). Of the total revenue recognized during the year, £2,044,000 represented research and development cost reimbursements (2020: £2,897,000; 2019: £2,159,000) and £4,039,000 represented revenue recognized that was included in the deferred revenue balance at 1 January 2021. Reimbursements arise where research and development costs in excess of a defined amount are incurred on one specified program.

In March 2021, following a portfolio review, GSK and the Group jointly elected not to initiate the efficacy determining expansion stage of the current phase I trial for GSK-01 targeting NY-ESO. As a result, GSK relinquished their option to acquire an exclusive license to this program and ownership of the program and the NY-ESO target remains with the Group. Later in 2021, GSK and the Group elected not to progress with the final program under the agreement and all revenue under the GSK agreement has therefore been recognized as at December 31, 2021.

Lilly Collaboration

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. Eli Lilly no longer has the ability to nominate any further targets under the initial agreement with Lilly. 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 is 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 has the right to opt in to gain exclusive co-development/co-promotion rights to the target program. Upon receipt of the proposed development plan and Phase 1 budget, the Group has a limited time period in which to elect to contribute either 25% or 50% costs to reach the next clinical phase or to opt-out of further development. Similar provisions are available at the start of Phase 2 clinical trials and registrational clinical trials. Should the Group opt-out of co-development on a collaboration target-by-collaboration target basis, Eli Lilly would obtain an exclusive worldwide license to develop and commercialize the compound at its sole expense.

The \$45 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 is recognized as the Group satisfies the combined performance obligations over the estimated period of time to when Eli Lilly can exercise the option to obtain exclusive co-development/co-promotion rights to the target and the Group can opt-out of the co-development of the target. Should this occur, the Group has no further contractual obligations relating to the associated performance obligation and accordingly the associated performance obligation is deemed satisfied and complete at this point in time.

During the year ended December 31, 2021, the Group recognized no revenue relating to the Lilly Agreement (2020: £3,522,000; 2019: £819,000), and, whilst the program focus is reviewed, a deferred revenue balance of £7,361,000 is held under current liabilities in respect of both the second and third programs, which represents the amount of transaction price allocated to performance obligations that are unsatisfied or partially satisfied as at December 31, 2021 under the collaboration. The Group expects to recognise this revenue within the next year.

During 2019, following termination of the first program under the collaboration, a balance of £3,132,000 was held as deferred revenue at December 31, 2019 whilst a change in program focus was considered. This was subsequently released in full during the year ended December 31, 2020.

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, 2021 is: £33,941,000 (2020: £35,774,000). The total located in other countries is £1,580,000 (2020: £1,073,000).

3. Operating loss is stated after charging (crediting)

The following items have been included in operating loss:

	2021	2020	2019
	£'000	£'000	£'000
Loss on disposal of property, plant and equipment	180	1,064	3
Profit on derecognition of leases	—	(3,700)	—
Remeasurement of leases	(15)	(227)	—
Loss on write-offs of intangible fixed assets	—	—	306
Depreciation of property, plant and equipment (Note 11)	5,511	6,446	6,549
Depreciation of right-of-use assets (Note 12)	1,501	2,530	2,454
Amortization of intangible assets	—	—	210
Short-term lease expense	—	296	486
Sub-lease income (Note 5)	(108)	(460)	(185)
Foreign exchange (gains)/losses	(277)	477	189

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 £358,000 for 2021 (2020: £227,000; 2019: £396,000).

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:

	2021	2020	2019
	No. of employees	No. of employees	No. of employees
Research	154	177	284
Development	88	96	108
Corporate	73	56	67
Total	315	329	459

The aggregate staff costs of these persons were as follows:

	2021	2020	2019
	£'000	£'000	£'000
Wages and salaries	27,337	29,038	31,920
Social security costs	2,258	2,131	2,767
Share-based payments (Note 19)	35,861	8,162	3,056
Contributions to defined contribution plans (Note 21)	1,001	1,035	1,213
	66,457	40,366	38,956

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. Net other operating (loss) / income

	2021 £'000	2020 £'000	2019 £'000
Profit on derecognition of leases	—	3,700	—
Loss on disposal of property, plant and equipment	(180)	(1,064)	—
Settlement agreement	—	810	—
Sub-lease income	108	460	185
Remeasurement of leases	15	227	—
Other	—	109	—
	(57)	4,242	185

During the year ended December 31, 2020, the Group terminated the lease term for two 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 has undertaken 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 comprises income from sub-lease arrangements on operating leases on certain leasehold properties.

6. Finance income

	2021 £'000	2020 £'000	2019 £'000
Interest on cash and cash equivalents and other receivables	21	668	1,386
Gain on entering into sub-leases on leasehold properties	—	215	115
Interest on investment in sub-lease	26	38	9
Gain from change in fair value of derivative liability	—	1,287	—
	47	2,208	1,510

The derivative liability represents a foreign exchange call option over certain series B shares which was settled in full in March 2020, resulting in a gain of £1,287,000 based on the fair value as at derecognition, and a credit to equity of £3,840,000.

7. Finance costs

	2021 £'000	2020 £'000	2019 £'000
Interest on lease liabilities (see Note 12)	1,732	2,401	2,947
Interest expenses on financial liabilities measured at amortized cost	4,081	708	849
Loss from change in fair value of embedded derivative asset	—	266	454
Loss from change in fair value of derivative liability	—	—	5,127
Other finance costs	—	—	2
	5,813	3,375	9,379

Interest expenses on financial liabilities measured at amortized cost in the year ended December 31, 2021 relate to the Oxford Finance debt agreement signed on November 6, 2020.

Included within interest expenses for the year ended December 31, 2020, are £159,000 related to the Bill & Melinda Gates Foundation (the “Gates Foundation”) convertible loan, which was converted into series B shares in March 2020 (see Note 15) and £549,000 arising on the \$50 million drawn down under the Oxford Finance debt agreement (see Note 16). Interest expenses for the year ended December 31, 2019 relate to the convertible loan received from the Gates Foundation.

The Group received a convertible loan in September 2017 from the Gates Foundation which contains conversion features which are accounted for as an embedded derivative and separated from the convertible loan. During the year ended December 31, 2020 the loss from the change in fair value of the embedded derivative asset represents the movement in fair value of this embedded derivative asset on derecognition arising from the conversion of the loan into series B shares and during the year ended December 31, 2019, this also represents the movement in fair value of this embedded derivative asset.

The derivative liability represents a foreign exchange call option over certain series B shares. The loss of £5,127,000 from the change in fair value of the derivative liability represents the movement in fair value of this derivative from inception, during 2019, to December 31, 2019.

8. Income tax

The major components of the income tax expenses for the years ended December 31, 2021, 2020 and 2019 are:

	2021 £'000	2020 £'000	2019 £'000
Profit or loss			
<i>Current tax:</i>			
R&D tax credit for the year	(9,322)	(12,432)	(21,767)
Tax related to share-based compensation plans	—	—	—
Foreign corporation tax on profits for the year	—	84	152
Adjustments in respect of prior years	370	(100)	43
Total current tax	(8,952)	(12,448)	(21,572)
<i>Deferred tax:</i>			
Current year	(484)	(790)	—
Effect of changes in tax rates	—	(1)	—
Movement in overseas unrecognized deferred tax asset	25	351	—
Originating and reversal of timing differences, including adjustments in respect of prior years	6	(379)	(686)
Total deferred tax	(453)	(819)	(686)
Total income tax credit	(9,405)	(13,267)	(22,258)
Reconciliation of tax expense and accounting profit for 2021, 2020 and 2019:			
	2021 £'000	2020 £'000	2019 £'000
Loss before tax	(140,928)	(87,360)	(126,189)
Tax credit using the UK Corporation tax rate of 19% (2019: 19% and 2018: 19%)	(26,776)	(16,598)	(23,976)
Effect of:			
Non-deductible expenses	12,836	9,120	13,148
Other permanent differences	—	—	(1)
Additional deduction for R&D expenditure	(12,354)	(16,286)	(29,365)
Surrender of tax losses for R&D tax credit refund	12,354	16,286	28,523
R&D expenditure credits	(10,210)	(13,424)	(22,602)
Movement in deferred tax not recognized	14,315	8,084	12,413
Adjustments to tax charge in respect of previous periods - deferred tax	18	(379)	(500)
Adjustments to tax charge in respect of previous periods	370	(100)	43
State taxes	—	7	—
Effects of overseas tax rates	42	24	—
Effects of tax rates in foreign jurisdictions	—	(1)	59
Total tax credit included in loss for the year	(9,405)	(13,267)	(22,258)

The components of income tax are as follows:

	2021 £'000	2020 £'000	2019 £'000
<i>Current tax:</i>			
United States:			
Federal	106	(16)	100
State	—	—	15
United Kingdom	(9,058)	(12,432)	(21,687)
Total current tax	(8,952)	(12,448)	(21,572)
<i>Deferred tax:</i>			
United States:			
Federal	(453)	(819)	(644)
State	—	—	(42)
United Kingdom	—	—	—
Total deferred tax	(453)	(819)	(686)
Total income tax credit	(9,405)	(13,267)	(22,258)

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 £2,575,000 has been recognized in 2021 (2020: £2,230,000) primarily representing unused tax credits 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 on tax losses of £58,093,000 (2020: 30,827,000) 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 £49,283,000 (2020: £33,852,000).

9. Basic and diluted loss per share

	2021	2020	2019
Loss for the year (£000's)	(131,523)	(74,093)	(103,931)
Basic and diluted weighted average number of shares	42,488,579	26,523,411	22,297,935
Basic and diluted loss per share (£) ⁽¹⁾	(3.10)	(2.79)	(4.66)

(1) The basic and diluted loss per share 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. Refer to Note 30 for further information.

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 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.

10. Intangible assets

Intangible assets comprise patent and trademarks and the purchase of intellectual property from the Company's predecessor on January 1, 2016. There were no movements on intangible assets for the years ended December 31, 2021 and 2020, and a nil net book value remains (original cost: £516,000)

11. Property, plant and equipment

	Leasehold properties and improvements £'000	Plant and equipment £'000	Assets under construction £'000	Total £'000
Cost:				
At January 1, 2020	12,240	26,326	2,571	41,137
Additions	564	775	1,735	3,074
Transfers	4,123	2	(4,125)	—
Effect of foreign currency translation	(27)	(2)	—	(29)
Disposals	(1,090)	(1,118)	(61)	(2,269)
At December 31, 2020	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
Depreciation and impairment:				
At January 1, 2020	5,642	17,193	—	22,835
Depreciation charge for the year	2,356	4,090	—	6,446
Effect of foreign currency translation	(7)	(67)	—	(74)
Disposals	(156)	(892)	—	(1,048)
At December 31, 2020	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
Carrying value:				
At December 31, 2021	5,461	3,467	16	8,944
At December 31, 2020	7,975	5,659	120	13,754
At January 1, 2020	6,598	9,133	2,571	18,302

At December 31, 2021 and 2020, none of the Group's property, plant and equipment was held under finance leases or similar hire purchase agreements.

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 102,000 square feet. In addition, the Group leases approximately 19,000 square feet of office space in the USA, and a small office in Ireland. The Group's United Kingdom leases expire between 2037 and 2040, 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 recognized in the profit and loss account on a straight-line basis over the term of the lease. These 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 are leasehold properties to which the Group is committed to assume the leases should the properties 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

	2021 £'000	2020 £'000
Balance at 1 January	23,093	36,578
Effect of adopting new accounting standards	—	(31)
Additions	31	453
Remeasurements	970	(2,269)
Derecognition	—	(9,108)
Depreciation charge for the year	(1,501)	(2,530)
	22,593	23,093

Following a review of the Group's lease commitments under leasehold agreements during the year ended December 31, 2020, the Group identified leasehold agreements in excess of the Group's future requirements. As a result of this review, the Group terminated the lease term for two leasehold properties, reducing right-of-use assets by £9,108,000.

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, 2021, the Group does not expect to make future payments as a result of these agreements.

Lease liabilities

Maturity analysis – contractual undiscounted cash flows

	2021 £'000	2020 £'000
Less than one year	2,929	3,560
One to five years	10,289	9,607
More than five years	30,126	32,600
Total undiscounted lease liabilities	43,344	45,767

Lease liabilities included in the Consolidated Statements of Financial Position

	2021 £'000	2020 £'000
Current	1,255	2,043
Non-current	25,355	25,190
Total lease liabilities	26,610	27,233

During the year ended December 31, 2020, the lease term for two leasehold properties was terminated and the lease liability for four leasehold properties were remeasured reducing the associated lease liability by £10,414,000 and £1,075,000 respectively. The Group also entered into a new lease for a leasehold property with an associated lease liability of £405,000 in the year ended December 31, 2020. The maturity of undiscounted lease commitments is set out in Note 22.

	2021 £'000	2020 £'000
<i>Amounts recognized in the Consolidated Statements of Loss</i>		
Interest on lease liabilities	1,732	2,401
Expenses relating to short-term leases	—	296
Expenses relating to leases of low-value assets	—	19
Interest on investment in sub-lease	26	(38)

Amounts recognized in the Consolidated Statement of Cash Flows

	2021 £'000	2020 £'000
Total cash outflow for leases	3,159	4,426

Leases in which the Group is a Lessor

Lease income

	2021 £'000	2020 £'000
Sub-lease income	108	460
Finance lease income on the net investment in the lease	26	38

Maturity analysis – undiscounted finance lease income

	2021 £'000	2020 £'000
Less than one year	—	720
One to two years	—	96
Two to three years	—	—
Three to four years	—	—
Four to five years	—	—
More than five years	—	—
Total undiscounted finance lease income	—	816
Unearned finance income	—	(40)
Net investment in the lease	—	776

During the year ended December 31, 2021 the Group received cash of £549,000 under its subleasing arrangements (2020: £378,000).

13. Other non-current financial assets

	2021 £'000	2020 £'000
Long-term security deposits	786	786
Prepayments	3,984	3,427
Other	165	197
	4,935	4,410

The long-term security deposits represent lease security deposits for buildings. Following the termination of a leasehold property during the year ended December 31, 2020, the Group was repaid the security deposit of £1,800,000 associated with that property.

Prepayments are those amounts paid in advance for clinical trials that will be repaid at the end of the associated clinical trials which is expected to occur in more than twelve months.

14. Trade and other receivables

	2021 £'000	2020 £'000
Trade receivables	6,047	2,051
Other receivables	1,470	1,722
Prepayments and accrued income	7,691	6,507
	15,208	10,280

Included within prepayments and accrued income are amounts paid in advance for clinical trials that are expected to be repaid within 12 months.

15. Capital and reserves

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 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 and have been 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 preferred, growth, ordinary, and deferred issued and outstanding at December 31, 2021 and also reflects the conversion of preferred and Growth Shares on 1-for-20 basis in the current and previous periods and the creation of deferred shares.

	Growth shares	Series A shares	Series B shares	Series C shares	Ordinary shares	Deferred shares
<i>Issued and fully paid share capital (0.2p per share, except deferred shares which are 0.01p per share)</i>						
At January 1, 2019 - adjusted	391	—	—	—	20,849,445	11,805,500
Repurchased and cancelled	—	—	—	—	—	(6,024,000)
New shares issued for cash	—	—	—	—	3,297,560	—
Exercise of share options	—	—	—	—	38,125	—
At December 31, 2019	391	—	—	—	24,185,130	5,781,500
Repurchased and cancelled	—	—	—	—	—	(2,932,499)
New shares issued for cash	—	—	—	—	6,540,050	2,944,500
New shares issued for non-cash consideration	—	—	—	—	1,042,560	—
Exercise of share options	—	—	—	—	15,145	—
At December 31, 2020	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

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 are 831,627 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.

	2021 £	2020 (Adjusted) £
Allotted, called up and fully paid		
Ordinary shares	87,726	63,566
Series A shares	—	—
Series B shares	—	—
Series C shares	—	—
Growth shares	—	—
Deferred shares	579	579
	88,305	64,145

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.

Share premium

	£'000
At January 1, 2019 – adjusted	—
At December 31, 2019	—
At December 31, 2020	—
New shares issued for cash	210,961
Exercise of share options	952
Equity-settled share-based payment transaction	325
At December 31, 2021	212,238

The £325,000 of share premium is attributable to ordinary shares issued for non-cash consideration arising from the redesignation of 1,926,000 Growth Shares in the ratio of one ordinary share, issued for non-cash consideration and three deferred shares.

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.

No dividends were paid or declared in the years ended December 31, 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 Oxford Finance Agreement detailed in Note 16, 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 interest-bearing loans and borrowings

	2021 £'000	2020 £'000
Long-term borrowings	37,226	36,654
	37,226	36,654

On November 6, 2020, the Group entered into a loan and security agreement with Oxford Finance 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. The second tranche of \$25 million is available to be drawn down following tebentafusp having received Biologics License Application approval prior to June 30, 2022. The third and final tranche of \$25 million can be drawn down at the sole discretion of Oxford Finance.

17. Provisions

	Total £'000
At January 1, 2020	288
Arising during the year	299
Utilized	(340)
At December 31, 2020	247
Arising during the year	84
Utilized	(235)
At December 31, 2021	96
Current	39
Non-current	57

The provision represents the contractual liability that will arise on termination of lease agreements on leasehold properties.

18. Trade and other payables

	2021 £'000	2020 £'000
Trade payables	7,499	5,783
Other taxation and social security	532	620
Pension Liability	23	2
Accruals	27,382	19,323
	35,436	25,728

Accruals include estimates for rebates and returns in respect of pre-product revenue relating to the sale of tebentafusp under a compassionate use program in France.

19. Share-based payments

The Group operates various employee share schemes that grant equity settled awards to certain 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 2021 was £35,861,000 (2020 – £8,162,000; 2019 – £3,056,000), all of which relate to equity settled awards.

Share Option Plan

Under the Share Option Plan, 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), the following changes were undertaken in respect to 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 an extent that these Growth Shares are 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 has been 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 \$40.93 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 has been 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, 2021, options over a total of 4,702,027 shares were awarded, respectively which will 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. The awards are not entitled to dividends prior to exercise.

The number and weighted average exercise prices of share options are as follows:

	Number of share options (#)	Weighted average exercise price (\$)
Number of shares issuable		
Outstanding at 1 January 2019 - adjusted	743,615	15.69
Awards granted	2,911,260	40.93
Awards exercised	(42,870)	0.74
Awards forfeited	(32,890)	28.15
Outstanding at 31 December 2019	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 31 December 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 replacing Growth Shares	312,500	38.72
Outstanding at December 31, 2021	9,198,460	22.31
Exercisable at December 31, 2021	2,663,600	18.13

The weighted average fair value of options granted in 2021 was \$16.48 (2020: \$9.11; 2019: \$3.26). The weighted average share price at the date of exercise of the options during the year was \$33.97 (2020: \$17.46; 2019: \$17.46).

The number and weighted average hurdle rate of growth shares are as follows:

Number of shares issuable	Number of growth shares	Weighted average hurdle rate \$
Outstanding at January 1, 2019	592,230	46.39
Awards forfeited	(301,200)	46.39
Awards replaced with options	—	—
Outstanding at December 31, 2019	291,030	46.39
Awards granted	171,300	30.13
Awards forfeited	(147,874)	46.39
Awards replaced with options	—	—
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	—	—
Exercisable at December 31, 2021	—	—

For share options outstanding at December 31, 2021, 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	439,220	3.2
17.46	3,915,749	8.7
26.00	4,433,612	9.3
32.98	16,545	4.1
36.79	161,500	9.8
39.02	4,000	9.5
40.93	114,045	7.4
41.74	51,944	9.3
46.39	61,845	9.1

Awards granted in the year ended December 31, 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, 2021, are as follows:

	February 2021	April 2021	July 2021	October 2021
Share price at grant date	\$ 26.00	\$ 41.74	\$ 39.02	\$ 36.79
Exercise price	\$ 26.00	\$ 41.74	\$ 39.02	\$ 36.79
Expected volatility	88%	89%	85%	84%
Expected life (years)	4 years	4 years	4 years	4 years
Risk free rate	(0.05)%	0.25%	0.26%	83.93%
Fair value	\$ 16.16	\$ 26.18	\$ 23.69	\$ 22.18

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 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 have been 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	\$ 9.37 - 9.36	\$ 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 trade and other 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 Oxford Finance, lease liabilities, trade and other payables and previously the convertible loan from the Gates Foundation and a derivative liability. The main purpose of these financial liabilities is to finance the Group's operations.

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, which is 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 assets and liabilities, including estimated interest payments in respect of the interest-bearing loans and borrowings:

	Carrying amount £'000	Contractual cash flows £'000	One year or less £'000
At December 31, 2021			
Financial assets			
Trade receivables	6,047	6,047	6,047
Non-current financial assets	951	951	—
Cash and cash equivalents	237,886	237,886	237,886
Total financial assets	244,884	244,884	243,933
Financial liabilities			
Trade payables and accruals	32,393	32,393	32,393
Interest-bearing loans and borrowings (Note 16)	37,226	37,226	—
Total financial liabilities	69,619	69,619	32,393
	Carrying amount £'000	Contractual cash flows £'000	One year or less £'000
At December 31, 2020			
Financial assets			
Trade receivables	1,797	1,797	1,797
Prepayments and accrued income	1,221	1,221	1,221
Long-term security deposit	3,573	3,573	—
Cash and cash equivalents	129,716	129,716	129,716
Total financial assets	136,307	136,307	132,734
Financial liabilities			
Trade payables	25,084	25,084	25,084
Interest-bearing loans and borrowings (Note 16)	36,654	51,421	3,354
Total financial liabilities	61,738	76,505	28,438

The maturity of contractual cashflows for the majority of financial assets and liabilities is one year or less in except for the following balances. Non-current financial assets include long-term security deposits are estimated to be received in more than one year, as at December 31, 2021.

The carrying amount of interest-bearing loans and borrowings has 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.

The contractual cash flows represent the cash contractually due to Oxford Finance in accordance with the agreement. The contractual maturity for the initial tranche of \$50 million drawn down under the agreement is interest-only payments through to November 2023 followed by equal monthly payments of principal and interest through to the maturity date in November 2025.

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 (primarily trade receivables), including 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, and based on these factors, expected credit losses as at December 31, 2021 are not significant and there have been no changes in expected loss allowances in the year ended December 31, 2021. The Group's material receivables are from large pharmaceutical companies and healthcare providers. Appropriate due diligence is performed on these organizations before agreements are entered into. There are no significant amounts which are past due at December 31, 2021 or December 31, 2020.

The Group held cash and cash equivalents of £237,886,000 at December 31, 2021 (2020: £129,716,000) which are held with multiple highly rated banks. The Group monitors the credit rating of those banks.

An impairment analysis is performed at each reporting date on an individual basis for major customers. In addition, minor receivables are grouped into homogenous groups and assessed for impairment collectively. The calculation considers actual incurred historical data and other available information about the customer or type of customer in order to generate an estimate of lifetime expected credit losses, which are recognized with the initial recognition of a trade receivable balance. 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.

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 is also exposed to interest rate risk as a variable rate of interest is 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 the Group's consolidated financial statements.

Financial assets subject to variable interest rates are as follows:

	2021 Carrying amount £'000	2020 Carrying amount £'000
Cash and cash equivalents	237,886	129,716
	237,886	129,716

An increase in Bank of England base rates by 0.5 percentage points would increase the net annual interest income as of December 31, 2021 by £1,189,000 (2020: £649,000). 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, 2021 by £1,189,000 (2020: £649,000).

Financial liabilities subject to variable interest rates are as follows:

	2021 Carrying amount £'000	2020 Carrying amount £'000
Interest-bearing loans and borrowings	37,226	36,654
	37,226	36,654

Interest-bearing loans and borrowings as at December 31, 2021 represent borrowings under the Oxford Finance agreement bear 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%. An increase in LIBOR by 0.5 percentage points would increase the finance cost as of December 31, 2021 by £185,000 (2020: £183,000). A decrease in LIBOR by 0.5 percentage points would hypothetically reduce the finance cost as of December 31, 2021 by £183,000 (2020: £183,000); however, the Oxford Finance Agreement has a minimum interest rate of 9.01%, and therefore the effect of a reduction in LIBOR is both hypothetical and immaterial.

Interest-bearing loans and borrowings as at December 31, 2020 represent the \$40 million convertible loan with the Gates Foundation in which the first tranche of \$25 million was received on September 13, 2017. This first tranche bore interest at an annual rate of 2% for the first year and subsequently interest free. This convertible loan was converted into series B shares in March 2020 (see Note 15).

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 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.

Financial assets and liabilities in foreign currencies are as follows:

	2021 Carrying amount £'000	2020 Carrying amount £'000
Financial assets at amortized cost:		
Deposits and non-current assets	—	4,036
Cash and cash equivalents	134,935	92,844
Trade and other receivables	3,628	—
	138,563	96,880
Financial liabilities at amortized cost:		
Trade payables	15,589	13,779
Accruals	16,174	—
Interest-bearing loans and borrowings (Note 16)	37,226	36,654
	68,989	50,433

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, 2021 by £2,598,000 (2020: £2,869,000 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, 2021 by £2,598,000 (2020: £2,869,000 increase).

Disclosure of financial assets and liabilities

Fair value of financial assets

	2021		2020	
	Carrying amount £'000	Fair value £'000	Carrying amount £'000	Fair value £'000
Financial assets at amortized cost:				
Trade receivables	6,047	6,047	1,797	1,797
Current deposits and accrued income	—	—	1,221	1,221
Non-current financial assets and other receivables	951	951	3,573	3,573
Cash and cash equivalents	237,886	237,886	129,716	129,716
Total financial assets at amortized cost	244,884	244,884	136,307	136,307

Fair value of financial liabilities

	2021		2020	
	Carrying amount £'000	Fair value £'000	Carrying amount £'000	Fair value £'000
Financial liabilities at amortized cost				
Trade payables and accruals	32,393	32,393	25,084	25,084
Interest-bearing loans and borrowings (Note 16)	37,226	37,226	36,654	36,654
Total financial liabilities	69,619	69,619	61,738	61,738

The carrying amount of all financial assets and financial liabilities, excluding the embedded derivative asset and the derivative liability, approximates their fair value because of the short maturities of these instruments.

Interest bearing loans and borrowings

On November 6, 2020, the Group entered into a loan and security agreement, or the Oxford Finance Agreement for the provision of up to \$100 million debt financing to fund the Group's working capital and other general corporate needs. The loan is subject to funding in three tranches, of which the first tranche of \$50 million was received on signing the Loan Agreement. The second tranche of \$25 million can be drawn down upon tebentafusp receiving Biologics License Application approval from the FDA prior to June 30, 2022 and the third and final tranche of \$25 million can be drawn down at the sole discretion of Oxford Finance.

Borrowings under the Oxford Finance Agreement bear 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%. Borrowings under the Loan Agreement are repayable in monthly interest-only payments through November 2023. The interest only period may be extended for an additional twelve months upon tebentafusp receiving BLA approval from the FDA. The ultimate interest-only period will be followed by equal monthly payments of principal and interest to the maturity date in November 2025. The Group's obligations under the Oxford Finance Agreement may be prepaid in part or part at any time; provided that the Group may prepay in full or in part a minimum of \$10 million of the Group's obligations together with accrued interest and a prepayment fee. The Group's obligations under the Oxford Finance Agreement are secured by substantially all the Group's current and future assets, including the Group's intellectual property.

The Oxford Finance Agreement contains 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 Oxford Finance Agreement includes customary events of default, including but not limited to the non-payment of principal or interest, violations of covenants and material adverse changes. Upon an event of default, the lender may, among other things, accelerate the loans and foreclose on the collateral.

Trade and other receivables, cash and cash equivalents and trade and other payables

For trade and other receivables, cash and cash equivalents and trade and other payables with a remaining life of less than one year, the nominal amount is deemed to reflect fair value.

Other non-current financial assets

Included within other non-current financial assets are long-term deposits representing lease security deposits for buildings, the balance at December 31, 2021 is £786,000 (2020: £786,000) and £145,000 for a legal settlement.

Changes in liabilities arising from financing activities

Movements relating to finance costs are set out in Note 7 and the changes in cash flows from financing activities related to the Group's liabilities are outlined in the Consolidated Statement of Cash Flows.

Interest costs and cash outflows on the Oxford Finance Agreement increased in the year ended December 31, 2021 following a full year of interest being incurred and paid on the loan. As a result, there was no material change on year in the loan liability of £37,226,000 and £36,654,000 as at December 31, 2021 and 2020 respectively. There was an increase in cash from financing activities relating to the loan in the year ended December 31, 2020, which reflects the initial draw-down of \$50 million under the agreement.

In the year ended December 31, 2020 the Foundation Loan was converted to Series B shares as set out in Note 15. A derivative liability associated with the Foundation Loan was also derecognized during the year ended December 31, 2020 as set out in Note 6.

Interest costs on lease liabilities are set out in Note 7 and Note 12, and lease payments, which are classified as outflows from financing activities, are presented in the Consolidated Statement of Cash Flows. In the year ended December 31, 2020 there was also a reduction in lease liabilities following the termination of the lease term for leasehold properties as set out in Note 12, and details of lease remeasurements are also set out in Note 12. There was no material change on year in the lease liability balances of £26,610,000 and £27,233,000 as at December 31, 2021 and 2020 respectively.

The effect of foreign exchange movements on our liabilities was not material in the years ended December 31, 2021 and 2020, and the potential impact of foreign exchange rates on our financial liabilities is illustrated further above in this note under 'Foreign Currency Risk'.

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, 2021 were £23,000 (2020: £2,000; 2019: £1,000). The total expense relating to these plans in the current period was £1,001,000 (2020: £1,035,000; 2019: £1,213,000).

22. Commitments and contingencies

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
As at December 31, 2021					
Lease liabilities – existing	2,947	5,407	4,959	30,447	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	30,447	46,065
	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
As at December 31, 2020					
Lease liabilities – existing	3,529	5,322	4,286	32,600	45,737
Lease liabilities – contingent	—	2,254	2,471	1,841	6,566
Manufacturing	2,824	500	—	—	3,324
Capital commitments	77	—	—	—	77
Total contractual obligations	6,430	8,076	6,757	34,441	55,704

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, 2021 and has classified the potential obligation as a contingent liability totaling £1,122,000 (2020: £6,566,000).

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'

	2021 £'000	2020 £'000	2019 £'000
Short-term employee benefits	2,222	3,421	6,502
Share-based payment	25,813	5,602	3,667
	28,035	9,023	10,169

Short-term employee benefits above include £29,423 of pension contributions for the year ended December 31, 2021.

24. Events after the reporting period

On January 26, 2022, the Group received approval from the FDA for its lead product candidate, KIMMTRAK (tebentafusp-tebn) for the treatment of metastatic uveal melanoma. The Group has subsequently commenced selling the product in the United States.



February 8th 2021

Immunocore Limited
92 Park Drive
Milton Park
Abingdon
Oxon
OX14 4RY
United Kingdom
Attn: Dr. Bahija Jallal, CEO

Dear Dr. Jallal:

Reference is made to that certain Collaboration and Licence Agreement between Immunocore Limited ("Immunocore") and GlaxoSmithKline Intellectual Property Development Limited ("GSK") dated June 29, 2013, as amended from time to time (the "Agreement"). Terms not defined in this letter have the meanings ascribed to them in the Agreement.

Following from discussions internally at GSK, GSK has decided to terminate the Agreement pursuant to Section 13.2(b), solely with respect to the Initial Target Program related to the Initial Target (NY-ESO-1) (the "NYESO Program"). Termination of the NYESO Program will be effective 90 Business Days from the date of this notice. We will be in touch shortly to discuss next steps and which of the provisions of Section 13.6 are applicable to the termination of the NYESO Program.

We are disappointed that the NYESO Program will not continue but remain excited about our remaining Collaboration Program. All terms and conditions of the Agreement not affected by this notice remain in full force and effect.

Sincerely,

GlaxoSmithKline Intellectual Property Development Limited

/s/ Claire Macleod

Claire Macleod – Authorized signatory for and behalf of Edinburgh Pharmaceutical Industries Limited

/s/ John Sadler

John Sadler – Authorized signatory for and behalf of Glaxo Group Limited

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT to Loan and Security Agreement (this “**Amendment**”) is entered into as of January 22, 2021 (the “**First Amendment Date**”), by and among OXFORD FINANCE LUXEMBOURG S.À R.L., a Luxembourg private limited liability company (société à responsabilité limitée) with registered office at 2 route d’Arlon, 8008 Strassen, Grand Duchy of Luxembourg and registered with the Luxembourg commercial register under number B243395, acting in respect of its Compartment 1 (“**Oxford**”), as collateral agent (in such capacity, “**Collateral Agent**”), the Lenders listed on Schedule 1.1 of the Loan Agreement (defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender (each a “**Lender**” and collectively, the “**Lenders**”), and IMMUNOCORE LIMITED, a private limited company incorporated under the laws of England and Wales and limited by shares under registration number 6456207 with offices located at 92 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY, UK (“**Parent**” and “**Borrower**”), IMMUNOCORE LLC, a Delaware limited liability company and wholly owned subsidiary of Parent with offices located at Six Tower Bridge, Suite 540, 181 Washington Street, Conshohocken, PA 19422 (“**Core Sub**”) and IMMUNOCORE COMMERCIAL LLC, a Delaware limited liability company and wholly owned subsidiary of Core Sub with offices located at Six Tower Bridge, Suite 540, 181 Washington Street, Conshohocken, PA 19422 (“**Commercial Sub**”) (Parent, Core Sub and Commercial Sub, each, an “**Existing Loan Party**” and collectively, the “**Existing Loan Parties**”) and IMMUNOCORE HOLDINGS LIMITED a private limited company incorporated under the laws of England and Wales and limited by shares under registration number 13119746 with offices located at 92 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY, UK (“**New Loan Party**”) (Core Sub, Commercial Sub and New Loan Party, each a “**Guarantor**” and collectively “**Guarantors**”) (New Loan Party and Existing Loan Parties, individually and collectively, jointly and severally, “**Loan Parties**”).

WHEREAS, Collateral Agent, Existing Loan Parties and Lenders party thereto from time to time have entered into that certain Loan and Security Agreement, dated as of November 6, 2020 (as amended, supplemented or otherwise modified from time to time, the “**Loan Agreement**”) pursuant to which the Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof;

WHEREAS, New Loan Party has entered into that certain share exchange agreement dated on or around the date of this Amendment between, amongst others, the members of the Borrower (as sellers) and the New Loan Party (as buyer), pursuant to which the members of the Borrower agreed to transfer, and the New Loan Party agreed to acquire, the entire issued share capital of Borrower, in the form attached hereto as Exhibit A and without any further amendments to the terms thereof, the “**Exchange Agreement**”) pursuant to which, among other things, Borrower/Parent shall become a wholly owned subsidiary of New Loan Party (the “**Exchange Transaction**”); and

WHEREAS, Loan Parties, Collateral Agent and Lenders desire to amend certain provisions of the Loan Agreement as provided herein and subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Loan Parties, Lenders and Collateral Agent hereby agree as follows:

1. **Definitions.** Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.
 2. **Joinder.**
 - a. **New Loan Party.** New Loan Party hereby is added as a “Loan Party” and a “Guarantor” under the Loan Agreement. All references in the Agreement to a “Loan Party” shall hereafter mean and include the Existing Loan Parties and New Loan Party, individually and collectively, jointly and severally; and New Loan Party shall hereafter have all rights, duties and obligations of a “Loan Party” thereunder. All references in the Agreement to a “Guarantor” shall respectively hereafter mean and include the Commercial Sub, Core Sub and New Loan Party, individually and collectively, jointly and severally; and New Loan Party shall hereafter have all rights, duties and obligations of a “Guarantor” thereunder.
-

- b. **Joinder to Loan Agreement.** New Loan Party hereby joins the Loan Agreement, and agrees to comply with and be bound by all of the terms, conditions and covenants of the Loan Agreement and the Loan Documents to which it is a party, as if it were originally named a “Loan Party” therein (effective as of the date of this Amendment).
- c. **Grant of Security Interest.** To secure the prompt payment and performance of all of the Obligations, New Loan Party hereby grants to Collateral Agent, for the ratable benefit of Lenders, a continuing lien upon and security interest in all of New Loan Party’s now existing or hereafter arising rights and interest in the Collateral, whether now owned or existing or hereafter created, acquired, or arising, and wherever located. New Loan Party further covenants and agrees that by its execution hereof it shall provide all such information, complete all such forms, and take all such actions, and enter into all such agreements, in form and substance reasonably satisfactory to Collateral Agent and each Lender that are reasonably deemed necessary by Collateral Agent or any Lender in order to grant a valid, perfected first priority security interest to Collateral Agent, for the ratable benefit of Lenders, in the Collateral. New Loan Party hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent’s security interests in the Collateral, without notice to the New Loan Party, with all appropriate jurisdictions to perfect or protect Collateral Agent’s interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of the Loan Agreement, by the New Loan Party, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code. Notwithstanding the foregoing, or anything to the contrary herein, no filing or registration of the Loan Agreement shall be made with Companies House in the United Kingdom. Without limiting the generality of the foregoing, New Loan Party hereby grants and pledges to Collateral Agent, for the ratable benefit of the Lenders, to secure the prompt payment and performance of all of the Obligations, a perfected security interest in all of the issued and outstanding shares of capital stock of Parent and shall deliver to Collateral Agent one or more original stock certificates, if certificated, representing such shares together with duly executed instruments of transfer or assignment in blank, all in form and substance satisfactory to Collateral Agent, within seven (7) Business Days of receipt by the relevant member of New Loan Party of the duly stamped STFs.
- d. **Representations and Warranties.** New Loan Party hereby represents and warrants to Collateral Agent and each Lender that all representations and warranties in the Loan Agreement and the Loan Documents to which New Loan Party is a party made on the part of Existing Loan Parties are true and correct on the date hereof (as updated by the Perfection Certificate delivered to Oxford on or around the date of this Amendment) with respect to Existing Loan Parties and New Loan Party, with the same force and effect as if New Loan Party were named as “Loan Party” in the Loan Agreement and the Loan Documents to which it is a party in addition to Existing Loan Parties.

3. Consent.

- a. Collateral Agent and Oxford, which constitute the Required Lenders, hereby consent to the Exchange Transaction on the date hereof, strictly in accordance with the terms of the Exchange Agreement and, to the extent that any waivers under the Loan Agreement or any other Loan Document, including, without limitations, Section 7.3 of the Loan Agreement, are required for Borrower to enter into the Exchange Agreement and consummate the Exchange Transaction, Collateral Agent and Required Lenders hereby provide such waivers.

4. Section 6.2(a)(i) of the Loan Agreement is hereby amended and restated in its entirety as follows:

(i) as soon as available, but no later than thirty (30) days after the last day of each month (other than January month-end reporting of each year, for which month only the following summary financial reporting shall be due each year: (A) the month-end unrestricted cash balance (inclusive of investments), (B) the cash burn for the month (net of cash received from collaboration revenue or financing activities), (C) any cash from collaboration and/or product revenue, and (D) any cash proceeds from financing activities), a company prepared consolidated balance sheet, income statement and cash flow statement covering the consolidated operations of Parent and its Subsidiaries for such month certified by a Responsible Officer, prepared in accordance with IFRS, and in a form reasonably acceptable to Collateral Agent, provided, however, that in the event that Parent or HoldCo becomes subject to the reporting requirements under a U.S. national stock exchange and Parent or HoldCo becomes subject to the reporting requirements under the Securities Exchange Act of 1934, then Parent or HoldCo, as applicable, shall no later than the due date of its filing of its quarterly report on Form 10-Q (or equivalent) under the Securities Exchange Act of 1934 (but in any event if not provided in accordance with the foregoing clause, no later than 90 days after the end of the applicable fiscal quarter, deliver a company prepared consolidated balance sheet, income statement and cash flow statement covering the consolidated operations of Parent and its Subsidiaries for the applicable fiscal quarter certified by a Responsible Officer, prepared in accordance with IFRS, with a Compliance Certificate, and in a form reasonably acceptable to Collateral Agent);

5. Section 6.2(a)(vi) of the Loan Agreement is hereby amended and restated as follows:

(vi) in the event that Parent or HoldCo becomes subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, within five (5) Business Days of filing, direct Collateral agent to the links to all reports on Form 10 K, 10 Q and 8 K filed with the Securities and Exchange Commission;

6. Section 6.2(a)(viii) of the Loan Agreement is hereby amended and restated as follows:

(viii) with the next due Compliance Certificate notice of any material amendments of or other material changes to the capitalization table of Parent (unless Parent or HoldCo is a reporting company), provided that for the avoidance of doubt, no reporting is required for changes solely due to stock option plan issuance and changes.

7. The Loan Agreement is hereby amended by adding the following Section 6.14 thereto:

6.14 IPO. No later than April 20, 2021, HoldCo must receive unrestricted net cash proceeds of not less than Seventy Five Million Dollars (\$75,000,000.00) from the sale and issuance of its equity securities (whether in a public market or otherwise) and/or in the form of upfront payments from the entrance into a collaboration agreement or similar business development agreement with an unaffiliated third party (which agreement must otherwise be permitted under the terms of this Agreement), and/or Subordinated Debt (or any combination of the foregoing).

8. Section 7.2 of the Loan Agreement is hereby amended and restated as follows:

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by such Loan Party as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Parent unless written notice thereof is provided to Collateral Agent within five (5) Business Days of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of any Loan Party who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of such Loan Party immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Parent's equity securities in a public offering, a private placement of public equity or to venture capital and or strategic investors so long as Parent identifies to Collateral Agent the venture capital investors prior to the closing of the transaction or with other than with respect to the Exchange Transaction and the Exchange Agreement). The Loan Parties shall not, without at least ten (10) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (i) contain less than Five Hundred Thousand Dollars (\$500,000.00) in assets or property of the Loan Parties or any of their Subsidiaries and (ii) are not a Loan Party's or their Subsidiaries' chief executive office); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization. For the avoidance of doubt, the transfer of the entire issued share capital of the Borrower to HoldCo pursuant to the Exchange Agreement and the related transactions under the Exchange Agreement and Exchange Transaction shall not cause or constitute a change of control or breach, as applicable, under this Section 7.2, Section 5.10, Section 7.3, or otherwise under this Agreement.

9. The Loan Agreement is hereby amended by deleting therefrom Sections 7.3(b) and 7.3(c).
10. The following Section 7.12 is hereby added to the Loan Agreement:
- 7.12 HoldCo Assets.** HoldCo holding (i) assets exceeding Five Hundred Thousand Dollars (\$500,000.00) in value, or (ii) any Intellectual Property, provided that HoldCo may hold (a) Shares of Parent, at all times, plus (b) from time to time HoldCo may hold or maintain total assets valued at up to Ten Million Dollars (\$10,000,000) (inclusive of the assets allowed for in (i)) for up to thirty (30) consecutive days.
11. Section 8.2(a) of the Loan Agreement is hereby amended and restated in its entirety as follows:
- (a)** A Loan Party or any of their Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.10 (Other Entities), 6.12 (Creation/Acquisition of Subsidiaries), 6.14 (IPO) or the Loan Party violates any covenant in Section 7; or
12. Section 8.12 of the Loan Agreement is hereby amended and restated in its entirety as follows:
- 8.12 Delisting.** After the initial public offering of any class of equity securities of HoldCo, the shares of such class of equity securities of HoldCo, are delisted for thirty (30) days from the primary stock exchange on which they are traded because of failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed no later than thirty (30) days after such delisting on any other nationally recognized stock exchange in the United States or United Kingdom having listing standards at least as restrictive as the aforementioned primary stock exchange;
13. Section 10 of the Loan Agreement is hereby amended by amending and restating the address for Borrower and Guarantors therein as follows:
- | | |
|--------------------------------------|--|
| If to Borrower and/or
Guarantors: | IMMUNOCORE HOLDINGS LIMITED
IMMUNOCORE LIMITED
IMMUNOCORE LLC
IMMUNOCORE COMMERCIAL LLC
92 Park Drive, Milton Park
Abingdon
Oxon
OX14 4RY
United Kingdom
Attn: Brian Di Donato, Chief Financial Officer
and Lily Hepworth, Chief Legal Counsel
Fax: +1 (610) 828-5918
Email: brian.didonato@immunocore and
lily.hepworth@immunocore.com |
|--------------------------------------|--|

IMMUNOCORE HOLDINGS LIMITED
IMMUNOCORE LLC
IMMUNOCORE COMMERCIAL LLC
Six Tower Bridge, Suite 540
181 Washington Street
Conshohocken, PA 19422
Attn: Brian Di Donato, Chief Financial Officer
and Lily Hepworth, Chief Legal Counsel
Fax: +1 (610) 828-5918
Email: brian.didonato@immunocore and
lily.hepworth@immunocore.com

14. Section 13.1 of the Loan Agreement is hereby amended by adding the following definitions thereto in alphabetical order:
- “**First Amendment Date**” is January 22, 2021.
- “**HMRC**” means HM Revenue & Customs.
- “**HoldCo Security Agreement**” is that certain Debenture, dated of the First Amendment Date, entered into by Collateral Agent and HoldCo, granting a security interest in the assets of HoldCo to secure the performance of the Obligations, as such agreement may be amended or amended and restated from time to time.
- “**STFs**” means the stock transfer forms executed pursuant to the Exchange Transaction (and for this references to such STFs being “duly stamped” shall include circumstances in which HMRC has confirmed in writing that it does not object to the registration by Borrower of the Exchange Transaction, either because relief from stamp duty has been granted by HMRC under section 77 of the Finance Act 1986 in respect of the STFs, or because stamp duty has been paid by New Loan Party in respect of the STFs, in each case under temporary measures put in place by HMRC in respect of COVID-19).
15. Section 13.1 of the Loan Agreement is hereby amended by amending and restating the following definitions therein as follows:
- “**HoldCo**” is IMMUNOCORE HOLDINGS LIMITED a private limited company incorporated under the laws of England and Wales and limited by shares under registration number 13119746 with offices located at 92 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY, UK.
- “**HoldcoTax Deduction**” means a deduction or withholding for or on account of Tax imposed by the jurisdiction in which the Holdco is resident in respect of payment made by the Holdco under a Loan Document, other than a deduction or withholding required by FATCA or a UK Tax Deduction.
- “**Loan Party**” is each of Parent, HoldCo, Core Sub and Commercial Sub, individually.
- “**Loan Parties**” are collectively Parent, HoldCo, Core Sub and Commercial Sub.
- “**Other Taxes**” means any and all present or future stamp, court or documentary, intangible, recording, or filing Taxes or any other similar Taxes arising from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are (i) Other Connection Taxes imposed with respect to an assignment, or (ii) imposed with respect to any assignment or transfer by Lender under Section 12.1 (Successors and assigns) of this Agreement.
- “**Success Fee Letter**” is that certain amended and restated success fee letter agreement entered into by and between Parent and Oxford on the First Amendment Date.

16. Parts (g) and (h) of the defined term “Permitted Indebtedness” in Section 13.1 of the Loan Agreement are hereby amended and restated in their entirety to read as follows:
- “(g) business credit card Indebtedness in an aggregate principal amount not in excess of Five Hundred Fifty Thousand Dollars (\$500,000.00) at any time outstanding;
- (h) reimbursement obligations under letters of credit related to existing leases, together with such obligations in respect of such other letters of credit as may be established in favor of the Loan Parties or their Subsidiaries, not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate at any time outstanding;”
17. Parts (i) and (j) of the defined term “Permitted Liens” in Section 13.1 of the Loan Agreement are hereby amended and restated in their entirety to read as follows:
- “(i) Liens on segregated bank accounts of Loan Parties and identified to Collateral Agent in writing securing Indebtedness described in clause (g) the definition of Permitted Indebtedness provided that such Liens may not secure obligations in excess of Five Hundred Thousand Dollars (\$500,000.00);
- (j) Liens on segregated bank accounts of Loan Parties (or other accounts with capture set-off rights in respect of credit card fees and applicable credit card exposure) and identified to Collateral Agent in in writing securing Indebtedness described in clause (h) the definition of Permitted Indebtedness provided that such Liens relating to the credit cards may not secure obligations in excess of Five Hundred Thousand Dollars (\$500,000.00);”
18. Section 13.1 of the Loan Agreement is hereby amended by deleting therefrom definitions of “HoldCo Loan Agreement,” “HoldCo Transaction,” and “SPAC.”
19. **Waiver and Extension.** With reference to that certain Post Closing Letter, dated as of November 6, 2020, and Exhibit A attached thereto, the Loan Parties, Collateral Agent and Lenders hereby agree as follows:
- a. The bailee waiver from DHL referenced in Section 5 on Exhibit A is hereby waived, and any Event of Default that shall have occurred with respect to non-delivery of such bailee waiver is hereby waived;
- b. The due date of the assignment separate from certificate, and share certificate (if not previously delivered to Collateral Agent) of Immunocore Ireland referenced in Section 2 of Exhibit A is hereby extended to February 18, 2021, and any Event of Default that shall have occurred with respect to non-delivery of such items is hereby waived;
20. **Limitation of Amendment and Waivers.**
- a. The amendments, waivers and consents set above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Loan Parties may now have or may have in the future under or in connection with any Loan Document, as amended hereby.
- b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect. For the avoidance of doubt, this Amendment shall be considered part of the Loan Documents.

21. To induce Collateral Agent and Lenders to enter into this Amendment, Loan Parties hereby represents and warrants to Collateral Agent and Lenders as follows:
- a. Holdco has no liabilities, Indebtedness or outstanding litigation immediately prior to the consummation of the Exchange Transaction and the HoldCo has no material liabilities, Indebtedness or outstanding litigation immediately prior to the consummation of the Exchange Transaction (this does not take away from any other representation or warranty previously made or being made herein by Borrower).
 - b. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;
 - c. Each of the Loan Parties has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;
 - d. The organizational documents of Loan Parties delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by the Loan Parties to the Collateral Agent, and including following and in connection with the Exchange Transactions, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;
 - e. The execution and delivery by Loan Parties of this Amendment and the performance by each of them of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;
 - f. The execution and delivery by Loan Parties of this Amendment and the performance by each Loan Party of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any law or regulation binding on or affecting Borrower, (ii) any contractual restriction with a Person binding on such Loan Party, (iii) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on such Loan Party, or (iv) the organizational documents of such Loan Party;
 - g. The execution and delivery by Loan Parties of this Amendment and the performance by each Loan Party of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on such Loan Party, except as already has been obtained or made; and
 - h. This Amendment has been duly executed and delivered by each of Loan Party and is the binding obligation of such Loan Party, enforceable against Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.
22. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

23. This Amendment shall be deemed effective as of the First Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto, (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited (or ACH'd) from the Designated Deposit Account in accordance with Section 2.3(d) of the Loan Agreement, (c) delivery by HoldCo to Collateral Agent of a separate Guaranty (in such form and substance as acceptable to Collateral Agent) entered into by HoldCo, (d) delivery by HoldCo to Collateral Agent of the HoldCo Security Agreement entered into by HoldCo and (e) delivery by Parent of fully executed Success Fee Letter to Oxford.
24. Borrower hereby covenants to the following:
- a. On the date hereof, deliver to Collateral Agent, evidence of consummation of the Exchange Transaction, subject to the post closing portions of such transactions.
 - b. On or before the due date set forth in Section 2(c) of this Amendment, deliver to Collateral Agent, original stock certificate(s) for all outstanding Shares of Parent along with assignment separate(s).
 - c. On or before February 22, 2021, deliver to Collateral Agent evidence satisfactory to Collateral Agent that the property insurance policies required by Section 6.5 of the Loan Agreement are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent.
25. Each Loan Party hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent ("**Releasees**"), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any act, omission or state of facts taken or existing on or prior to the date hereof, may have after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof through the date hereof. Without limiting the generality of the foregoing, such Loan Party waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest relative to the Loan Documents: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan Documents; (b) any provision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof.
26. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.
27. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

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IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

IMMUNOCORE LIMITED

By /s/ Bahija Jallal
Name: Bahija Jallal
Title: Director and Chief Executive Officer

GUARANTORS:

IMMUNOCORE LLC

By /s/ Bahija Jallal
Name: Bahija Jallal
Title: Chief Executive Officer

IMMUNOCORE COMMERCIAL LLC

By /s/ Bahija Jallal
Name: Bahija Jallal
Title: Chief Executive Officer

IMMUNOCORE HOLDINGS LIMITED

By /s/ Bahija Jallal
Name: Bahija Jallal
Title: Director and Chief Executive Officer

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LUXEMBOURG S.À R.L.

By _____
Name: _____
Title: _____

IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

IMMUNOCORE LIMITED

By _____
Name: _____
Title: _____

GUARANTORS:

IMMUNOCORE LLC

By _____
Name: _____
Title: _____

IMMUNOCORE COMMERCIAL LLC

By _____
Name: _____
Title: _____

IMMUNOCORE HOLDINGS LIMITED

By _____
Name: _____
Title: _____

COLLATERAL AGENT A.ND LENDER:

OXFORD FINANCE LUXEMBOURG S.A R.L.

By /s/ Laurent Belik _____
Name: Laurent Belik _____
Title: Manager _____

By /s/ Caroline Kinyua _____
Name: Caroline Kinyua _____
Title: Manager _____

EXHIBIT A

Exchange Agreement

Please see attached

(1) THE SELLERS

and

(2) THE BENEFICIAL OWNERS

and

(3) IMMUNOCORE LIMITED

and

(4) IMMUNOCORE HOLDINGS LIMITED

SHARE EXCHANGE AGREEMENT

relating to the interposition of a new holding company to hold the
entire issued share capital of Immunocore Limited

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THIS AGREEMENT is dated _____ 2021 and made

BETWEEN:

- (1) **THE PERSONS** whose names and addresses are set out in column (A) of the table in Part A of Schedule 1, save for those persons whose names are marked with an asterix next to their names in such table (each a “**Seller**” and together the “**Sellers**”);
- (2) **THE PERSONS** whose names and addresses are set out in column (A) of the table in Part B of Schedule 1 (each a “**Beneficial Owner**” and together the “**Beneficial Owners**”);
- (3) **IMMUNOCORE LIMITED**, a private limited company incorporated under the laws of England and Wales (company number: 06456207) whose registered office is at 92 Park Drive, Milton Park, Abingdon, Oxfordshire, United Kingdom OX14 4RY (the “**Company**”); and
- (4) **IMMUNOCORE HOLDINGS LIMITED**, a private limited company incorporated under the laws of England and Wales (company number: 13119746) whose registered office is at 92 Park Drive, Milton Park, Abingdon, Oxfordshire, United Kingdom OX14 4RY (the “**Buyer**”).

WHEREAS:

- (A) (i) The Sellers; and (ii) the persons whose names and addresses are set out in column (B) of the table in Part B of Schedule 1 (each a “**Nominee Shareholder**” and together the “**Nominee Shareholders**”) are the legal owners of the entire issued share capital of the Company comprising 2,679,764 Ordinary Shares, 1,699,576 Series A Shares, 1,148,703 Series B Shares, 823,719 Series C Shares, 43,490 G1 Shares and 19,260 G2 Shares (together, the “**Sale Shares**”).
- (B) Each of the Nominee Shareholders holds the legal title to the Sale Shares set out against such Nominee Shareholder’s name in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1 on behalf of the Beneficial Owner set out next to such Nominee Shareholder’s name in column (A) of the table in Part B of Schedule 1.
- (C) The Buyer wishes to acquire from the Sellers and, as regards the Sale Shares referred to in recital (B), the Beneficial Owners and the Nominee Shareholders the Sale Shares on the terms of this Agreement in consideration of the issue by the Buyer of such proportions and classes of its shares to the Sellers and the Nominee Shareholders so that the issued share capital of the Buyer following Completion is (ignoring the subscriber share which will be held (in addition) by the initial shareholder of the Buyer) identical to the issued share capital of the Company immediately prior to Completion and is held by the Sellers and the Nominee Shareholders in the same proportions, save that the number of shares in the capital of the Buyer is proportionately higher (the “**Share Exchange**”). The parties agree that the Share Exchange constitutes a Holding Company Reorganisation within the meaning of the Company Articles.

- (D) Immediately prior to the allotment and issue of the Consideration Shares by the Buyer pursuant to this Agreement, the entire issued share capital of the Buyer comprises one ordinary share of £0.0001 in the capital of the Buyer (such share being fully paid up and held by Sir John Irving Bell (as the initial shareholder of the Buyer)).
- (E) The Share Exchange is intended to qualify as an exchange under section 351 of the U.S. Internal Revenue Code of 1986, as amended (the “**Code**”) and may also qualify as a “reorganization” under section 368(a) of the Code. The parties intend for this Agreement to constitute a “plan of reorganization” under the provisions of section 368(a) of the Code and U.S. Treasury Regulations 1.368-2(g) and 1.368-3, if applicable.

NOW IT IS HEREBY AGREED as follows:

1. Interpretation

1.1 In this Agreement where the context admits:

“**Board**” means the board of directors of the Company as constituted from time to time;

“**Code**” has the meaning given in recital (E);

“**Companies Act**” means the Companies Act 2006 of the United Kingdom as in force from time to time;

“**Company Articles**” means the articles of association of the Company adopted on 21 December 2020, as amended, replaced or supplemented from time to time;

“**Completion**” means the date upon which completion of the sale and purchase of the Sale Shares by the Buyer shall take place in accordance with the terms of this Agreement;

“**Consideration Shares**” means the Ordinary Consideration Shares, Series A Consideration Shares, the Series B Consideration Shares, the Series C Consideration Shares, the G1 Consideration Shares and the G2 Consideration Shares, each having the rights set out in the New Articles;

“**Encumbrance**” means any claim, charge, pledge, mortgage, lien, assignment, option, equity, power of sale, hypothecation, retention of title, right of pre-emption, right of first refusal or other third party right or security interest of any kind (including any created by law) or an agreement, arrangement or obligation to create any of the foregoing;

“**G1 Consideration Shares**” means the G1 shares of £0.0001 each in the capital of the Buyer having the rights set out in the New Articles;

“G1 Shares” means the G1 shares of £0.0001 each in the capital of the Company having the rights set out in the Company Articles;

“G2 Consideration Shares” means the G2 shares of £0.0001 each in the capital of the Buyer having the rights set out in the New Articles;

“G2 Shares” means the G2 shares of £0.0001 each in the capital of the Company having the rights set out in the Company Articles;

“Insolvency Proceedings” means any formal insolvency proceedings, whether in or out of court, including proceedings or steps leading to any form of bankruptcy, liquidation, administration, receivership, arrangement or scheme with creditors, moratorium, stay or limitation of creditors’ rights, interim or provisional supervision by a court or court appointee, winding-up or striking-off, or any distress, execution or other process levied;

“Investor Director” has the same meaning as set out in the New Articles;

“IPO” has the same meaning as set out in the New Articles;

“Law” or **“Laws”** includes all applicable legislation, statutes, directives, regulations, judgments, decisions, decrees, orders, instruments, by-laws, and other legislative measures or decisions having the force of law, treaties, conventions and other agreements between states, or between states and the European Union or other supranational bodies, rules of common law, customary law and equity and all civil or other codes and all other laws of, or having effect in, any jurisdiction from time to time and whether before or after the date of this Agreement;

“New Articles” means the new articles of association of the Buyer adopted on _____ 2021;

“New Shareholders’ Agreement” means the shareholders’ agreement relating to the Buyer (in substantially the same form as the Shareholders’ Agreement) to be entered into between the Buyer and certain of the Sellers immediately following Completion;

“Nominee Shareholder(s)” has the meaning set out in recital (A);

“Ordinary Consideration Shares” means the ordinary shares of £0.0001 each in the capital of the Buyer having the rights set out in the New Articles;

“Ordinary Shares” means the ordinary shares of £0.0001 each in the capital of the Company having the rights set out in the Company Articles;

“Permitted Transferees” has the same meaning as set out in the New Articles;

“Prospective Qualifying IPO” means an IPO that the board of directors of the Buyer in good faith believes will constitute a Qualifying IPO;

“**Qualifying IPO**” has the same meaning as set out in the New Articles;

“**Sale Shares**” has the meaning given in recital (A);

“**Series A Consideration Shares**” means the series A convertible preference shares of £0.0001 each in the capital of the Buyer having the rights set out in the New Articles;

“**Series A Shares**” means the series A convertible preference shares of £0.0001 each in the capital of the Company having the rights set out in the Company Articles;

“**Series B Consideration Shares**” means the series B convertible preference shares of £0.0001 each in the capital of the Buyer having the rights set out in the New Articles;

“**Series B Shares**” means the series B convertible preference shares of £0.0001 each in the capital of the Company having the rights set out in the Company Articles;

“**Series C Consideration Shares**” means the series C convertible preference shares of £0.0001 each in the capital of the Buyer having the rights set out in the New Articles;

“**Series C Shares**” means the series C convertible preference shares of £0.0001 each in the capital of the Company having the rights set out in the Company Articles;

“**Share Exchange**” has the meaning given in recital (C); and

“**Shareholders’ Agreement**” means the shareholders’ agreement relating to the Company between the Company and certain of the Sellers dated 21 December 2020, as amended from time to time.

- 1.2 References to clauses and schedules are references to clauses of, and Schedules to, this Agreement and references to this Agreement include the Schedules.
- 1.3 The headings and sub-headings are inserted for convenience only and shall not affect the construction of this Agreement.
- 1.4 Unless the context does not so admit, references to the singular include a reference to the plural and references to the masculine include a reference to the feminine and the neuter.
- 1.5 In this Agreement, the interpretation of general words shall not be restricted by words indicating a particular class or particular examples and “**including**” means “**including without limitation**”.
- 2. **Waiver of pre-emption rights**
 - 2.1 Each Seller, in his, her or its capacity as holder of the Sale Shares set out beside such Seller’s name in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1, hereby waives all rights of pre-emption whether conferred upon such Seller by the Companies Act, the Company Articles, the Shareholders’ Agreement or otherwise in respect of the sale and transfer of the Sale Shares held by such Seller subject to the terms of, and as set forth in, this Agreement.

2.2 Each Beneficial Owner hereby waives and agrees to procure, and acknowledges and confirms that such Beneficial Owner has procured, the waiver by its Nominee Shareholder (as holder of the Sale Shares set out beside such Nominee Shareholder's name in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1) of all rights of pre-emption whether conferred upon such Nominee Shareholder by the Companies Act, the Company Articles, the Shareholders' Agreement or otherwise in respect of the sale and transfer of the Sale Shares held by such Nominee Shareholder subject to the terms of, and as set forth in, this Agreement.

3. Share Exchange

3.1 Terms of Sale

Subject to the terms of this Agreement, each Seller and each Beneficial Owner, in respect of himself, herself or itself only, shall sell and transfer (or procure the transfer) to the Buyer with full title guarantee, free from all Encumbrances (save for those which arise pursuant to the Company Articles and/or the Shareholders' Agreement) and together with all rights now or hereafter attaching thereto, the Sale Shares held by such Seller or such Beneficial Owner's Nominee Shareholder, being those Sale Shares set out beside such Seller's name and such Beneficial Owner's Nominee Shareholder's name in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1, and the Buyer shall purchase such Sale Shares with all rights attaching to them.

3.2 No sale of part only

None of the parties shall be obliged to complete the sale and purchase of any of the Sale Shares unless the sale and purchase of all of the Sale Shares is completed simultaneously.

4. Consideration

4.1 Consideration Shares

The total consideration for the Sale Shares due from the Buyer for the sale and transfer of the Sale Shares shall be the allotment and issue of the Consideration Shares, fully paid, to the Sellers and the Nominee Shareholders with each Seller and each Nominee Shareholder being allotted and issued the number and class of such Consideration Shares that are set out beside their respective names in column (H) of the table in Part A of Schedule 1, such that for every one Sale Share held by each Seller and each Nominee Shareholder, such Seller and such Nominee Shareholder shall receive 100 Consideration Shares of the same class as the Sale Share held by such Seller and such Nominee Shareholder immediately prior to Completion.

4.2 Rights

The Consideration Shares shall carry the rights and be subject to the restrictions set out in the New Articles including (where applicable) the right to receive all dividends, distributions or any return of capital declared, made or paid after the date of this Agreement.

4.3 Registration

The Consideration Shares referred to in clause 4.1 shall not be registered in the name of any person other than the Seller or the Nominee Shareholder to whom such shares are allotted and issued and the right to such allotment and issue of Consideration Shares shall not be capable of renunciation in any way.

5. Completion

5.1 Completion

Completion shall take place immediately following the execution of this Agreement, or such other date as may be agreed between the Buyer and the Sellers that constitute a “Preferred Majority” (as defined in the Company Articles). For the avoidance of doubt, Completion shall occur simultaneously in respect of all Sale Shares and shall not occur unless the entire issued share capital of the Company is simultaneously transferred to the Buyer.

5.2 Sellers’ and Beneficial Owners’ Obligations at Completion

On Completion:

- (A) each Seller shall deliver to the Buyer stock transfer form(s) in respect of the Sale Shares registered in the name of such Seller duly executed by such Seller in favour of the Buyer together with the share certificates for such Sale Shares or duly executed indemnities in respect of such share certificates;
- (B) each Beneficial Owner shall procure the delivery by its relevant Nominee Shareholder to the Buyer of the stock transfer form(s) in respect of the Sale Shares registered in the name of such Nominee Shareholder duly executed by such Nominee Shareholder in favour of the Buyer together with the share certificates for such Sale Shares or duly executed indemnities in respect of such share certificates; and
- (C) each Seller and Beneficial Owner who is a party to the Shareholders’ Agreement shall deliver to the Buyer the New Shareholders’ Agreement, duly executed by such Seller and Beneficial Owner.

5.3 Buyer's Obligations at Completion and post Completion

(A) On Completion, the Buyer shall:

- (1) allot and issue to the Sellers and the Nominee Shareholders, free from all Encumbrances and fully paid, the number of Consideration Shares set out beside their respective names in column (H) of the table in Part A of Schedule 1;
- (2) procure that the names of the Sellers and the Nominee Shareholders are entered in the register of members of the Buyer in respect of the Consideration Shares allotted to them pursuant to clause 3 (and the register of applications and allotments and the register of persons with significant control of the Buyer be updated accordingly);
- (3) execute and deliver to the Sellers and the Nominee Shareholders share certificate(s) in respect of the number and classes of Consideration Shares allotted to them as set out beside their respective names in column (H) of the table in Part A of Schedule 1; and
- (4) deliver to all signatories thereto the New Shareholders' Agreement, duly executed by the Buyer.

(B) Within 30 days of Completion, the Buyer shall file Companies House form SH01 (return of allotment of shares) in respect of the allotment of the Consideration Shares pursuant to this Agreement.

5.4 Company's Obligations at Completion

On or as soon as practicable after Completion, the Board shall approve directors' resolutions of the Company, as part of which there shall be passed a resolution to (subject to due stamping or adjudication that such transfers are not liable to stamp duty) approve the registration of the transfers of the Sale Shares to the Buyer and that the name of the Buyer be entered in the register of members of the Company in respect of the Sale Shares transferred to it from the Sellers and the Nominee Shareholders pursuant to clause 3 (and the register of transfers and the register of persons with significant control of the Company be updated accordingly).

5.5 Further Assurance

At any time after the date hereof, each party shall, at the request and cost of the other party, execute such documents and do such acts and things as the requesting party may reasonably require for the purpose of: (i) vesting the Sale Shares in the Buyer and giving to the Buyer the full benefit of all the provisions of this Agreement; and (ii) vesting the Consideration Shares in the Sellers and the Nominee Shareholders and giving the Sellers, the Nominee Shareholders and the Beneficial Owners the full benefit and provisions of this Agreement, provided that the procurement or execution of such request does not result in: (a) a material adverse and disproportionate effect on any non-requesting party; nor (b) any non-requesting party being in violation of applicable laws or regulations.

6. Warranties

6.1 Seller and Beneficial Owner Warranties

(A) Each Seller hereby severally warrants to and for the benefit of the Buyer as follows:

- (1) **Capacity.** Such Seller has full power and authority to enter into and perform this Agreement, and may execute and deliver this Agreement and perform such Seller's obligations hereunder without requiring or obtaining the consent of any third party and this Agreement constitutes (or will when executed constitute) valid and binding obligations of such Seller in accordance with its terms.
- (2) **Title.** Such Seller is the registered owner of the number of Sale Shares set out against such Seller's name in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1 and has the right to transfer the entire legal and beneficial title to such Sale Shares free from any Encumbrances (save for those which arise pursuant to the Company Articles and/or the Shareholders' Agreement).

(B) Each Beneficial Owner hereby severally warrants to and for the benefit of the Buyer as follows:

- (1) **Capacity.** Such Beneficial Owner has full power and authority to enter into and perform this Agreement, and may execute and deliver this Agreement and perform such Beneficial Owner's obligations hereunder without requiring or obtaining the consent of any third party and this Agreement constitutes (or will when executed constitute) valid and binding obligations of such Beneficial Owner in accordance with its terms.
- (2) **Title.** Such Beneficial Owner's Nominee Shareholder is the registered owner of the number of Sale Shares set out against such Nominee Shareholder's name in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1 and has the right to transfer the Sale Shares (and the Beneficial Owner has directed its Nominee Shareholder to transfer such Sale Shares to the Buyer (including the entire legal title)) free from any Encumbrances (save for those which arise pursuant to the Company Articles and/or the Shareholders' Agreement).
- (3) **Beneficial ownership.** Such Beneficial Owner is the holder of the entire beneficial title to the number of Sale Shares set out against such Beneficial Owner's Nominee Shareholder's name in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1 and such Beneficial Owner has the right to transfer (or procure the transfer) of the entire legal and beneficial title to such Sale Shares to the Buyer free from any Encumbrances (save for those which arise pursuant to the Company Articles and/or the Shareholders' Agreement).

- (C) The warranties given by each Seller or Beneficial Owner in clause 6.1(A) and/or clause 6.1(B) are given in respect of that Seller or Beneficial Owner only and no other person and each Seller and Beneficial Owner acknowledges and accepts that the Buyer is entering into this Agreement in reliance upon such warranties, each of which is given on the basis that it will remain true and accurate at all times up to and including Completion.

6.2 Company Warranties

The Company hereby warrants to and for the benefit of each Seller and each Beneficial Owner on a several basis as follows:

- (A) The Company has full power and authority to enter into and perform this Agreement and all agreements to be entered into by it pursuant to this Agreement.
- (B) The Company has been duly incorporated and is validly existing under the laws of England and Wales.
- (C) This Agreement constitutes (or will when executed constitute) binding and enforceable obligations on the Company in accordance with its terms.
- (D) The entering into and performance by the Company of its obligations under this Agreement:
- (1) will not result in a breach of any provision of the constitution of the Company;
 - (2) will not result in a breach of, or constitute a default under, any agreement under which the Company enjoys rights or by which it is bound;
 - (3) will not breach or constitute a default under any existing statutes or regulations having the force of law in England applicable to companies generally; and
 - (4) will not result in a breach of any order, judgment or decree of any court or governmental, administrative or regulatory body or agency to which the Company is party or by which it is bound; and
 - (5) does not require the consent of any third party that has not already been obtained as of the date hereof.

6.3 Buyer Warranties

The Buyer hereby warrants to and for the benefit of each Seller and each Beneficial Owner on a several basis as follows:

(A) Capacity

- (1) The Buyer has full power and authority to enter into and perform this Agreement and all agreements to be entered into by it pursuant to this Agreement.
- (2) The Buyer has been duly incorporated and is validly existing under the laws of England and Wales.
- (3) This Agreement constitutes (or will when executed constitute) binding and enforceable obligations on the Buyer in accordance with its terms.
- (4) The entering into and performance by the Buyer of its obligations under this Agreement:
 - (a) will not result in a breach of any provision of the constitution of the Buyer;
 - (b) will not result in a breach of, or constitute a default under, any agreement under which the Buyer enjoys rights or by which it is bound;
 - (c) will not breach or constitute a default under any existing statutes or regulations having the force of law in England applicable to companies generally;
 - (d) will not result in a breach of any order, judgment or decree of any court or governmental, administrative or regulatory body or agency to which the Buyer is party or by which it is bound; and
 - (e) does not require the consent of any third party.

(B) Share Capital

- (1) Immediately prior to the allotment and issue of the Consideration Shares by the Buyer, the entire issued share capital of the Buyer comprises one ordinary share of £0.0001 in the capital of the Buyer.
- (2) No person has the right or has claimed to have a right (whether exercisable now or at a future date and whether contingent or not) to subscribe for, convert any security into or otherwise acquire any shares, debentures or other securities of the Buyer, including pursuant to an option or warrant.
- (3) The Consideration Shares to be allotted and issued pursuant to the terms of this Agreement, when so allotted and issued in accordance with the terms and for the consideration set forth in this Agreement, will be validly allotted and issued, fully paid and free of any Encumbrances (other than restrictions on transfer under the New Articles or set out in the New Shareholders' Agreement). The Consideration Shares to be issued pursuant to the terms of this Agreement will be issued in compliance with all applicable laws.

(C) Subsidiaries

Other than pursuant to this Agreement, the Buyer has no interest in nor is it under a subsisting obligation to acquire any interest in any shares, debentures or other securities of any other body corporate.

(D) Insolvency

- (1) Insolvency Proceedings have not commenced in relation to the Buyer or (if applicable) any part of its assets or undertaking.
- (2) There are no circumstances which entitle or may entitle any person to commence any Insolvency Proceedings in relation to the Buyer or (if applicable) any part of its assets or undertaking.

6.4 Warranties to be independent

Each of the warranties in clauses 6.1 to 6.3 above shall be separate and independent and, save as expressly provided, shall not be limited by reference to any other warranty or anything in this Agreement.

7. United States tax matters

- 7.1 None of the Sellers or Beneficial Owners have any current plan or intention, contractual obligation, legally binding commitment, or similar obligation to transfer any Consideration Shares received in the Share Exchange. None of the Sellers or Beneficial Owners (by procuring their respective Nominee Shareholders to do so) shall transfer any of Consideration Shares received in the Share Exchange if such transfer would adversely affect the treatment of the Share Exchange as an exchange described in section 351 of the Code or as a reorganisation within the meaning of section 368(a) of the Code, it being agreed that this clause 7.1 shall not prohibit any transfer that is otherwise permitted under this Agreement unless such transfer, following Completion, is pursuant to a plan entered into or an intention that existed on or prior to Completion.

- 7.2 The Share Exchange is intended to qualify as an exchange under section 351 of the Code and may also qualify as a “reorganization” under section 368(a) of the Code. The parties intend for this Agreement to constitute a “plan of reorganization” under the provisions of section 368(a) of the Code and U.S. Treasury Regulations 1.368-2(g) and 1.368-3, if applicable. Solely for United States tax purposes, the Buyer, the Sellers and the Beneficial Owners shall treat, and shall not take any United States tax reporting position inconsistent with the treatment of, the Share Exchange as a transaction pursuant to which no gain or loss is recognised under section 351 of the Code or as a reorganisation within the meaning of section 368(a) of the Code for U.S. tax purposes, unless otherwise required by Law. The Buyer, the Sellers and the Beneficial Owners shall, and shall cause their affiliates to (if required for United States tax purposes), prepare all United States tax filings, including any applicable statements required by Treasury Regulations §1.351-3(a), §1.351-3(b), §1.368-3(a), and/or §1.368-3(b) as applicable (together, the “**U.S. Tax Statements**”) and, in a manner consistent with the treatment of the Share Exchange as a transaction pursuant to which no gain or loss is recognised under section 351 of the Code or as a reorganization within the meaning of section 368(a) of the Code unless otherwise required by applicable Law. Nothing herein shall require a Seller, a Beneficial Owner or its or their direct or indirect members to enter into a gain recognition agreement under section 367(a) of the Code or the Treasury Regulations thereunder. The Buyer, the Sellers and the Beneficial Owners (in each case, if applicable) shall report the Share Exchange as an exchange under section 351 of the Code unless otherwise notified in writing by the Buyer or unless otherwise required by law.
- 7.3 The Buyer, the Sellers and the Beneficial Owners and their affiliates shall reasonably cooperate with each other, including the sharing of relevant information, filings, and working papers (such as those related to the calculation of tax basis) necessary to complete the U.S. Tax Statements in a timely manner.
- 7.4 No consideration other than stock will be issued by the Buyer as part of the Share Exchange.
- 7.5 Each party to the Share Exchange will pay their respective expenses, if any, incurred in connection with the Share Exchange.
- 7.6 The Buyer will remain in existence following the Share Exchange.

8. Provisions relating to this Agreement

8.1 Whole agreement and variations

- (A) This Agreement, together with any documents referred to in it, constitutes the whole agreement between the parties relating to its subject matter and supersedes and extinguishes any prior drafts, agreements, representations, warranties, assurances, undertakings and arrangements of any nature, whether in writing or oral, relating to such subject matter, except to the extent that the same are repeated in this Agreement or the documents referred to in it. Nothing in this clause 8.1(A) shall exclude any liability of any party to this Agreement for fraud or fraudulent misrepresentation.
- (B) No variation of this Agreement shall be effective unless made in writing and signed by each of the parties.

8.2 Agreement survives Completion

The provisions of this Agreement, in so far as the same are capable of being performed after but have been performed at Completion, shall remain in full force and effect notwithstanding Completion.

8.3 Rights and other matters

- (A) The rights, powers, privileges and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers, privileges or remedies provided by law or otherwise.
- (B) No failure to exercise nor any delay in exercising any right, power, privilege or remedy under this Agreement shall in any way impair or affect the exercise thereof or operate as a waiver thereof in whole or in part.
- (C) No single or partial exercise of any right, power, privilege or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right, power, privilege or remedy.

8.4 Invalidity

If any provision of this Agreement shall be held to be illegal, void, invalid or unenforceable under the Laws of any jurisdiction, it shall be deleted and the legality, validity and enforceability of the remainder of this Agreement in that jurisdiction shall not be affected, and the legality, validity and enforceability of the whole of this Agreement in any other jurisdiction shall not be affected.

8.5 Counterparts

This Agreement may be executed in any number of counterparts, each of which shall constitute an original and all of the counterparts shall together constitute one and the same agreement. The exchange of a fully executed version of this Agreement (in counterparts or otherwise) by electronic transmission including DocuSign in PDF format shall be sufficient to bind the parties to the terms and conditions of this Agreement and no exchange of originals is necessary.

9. Notices

9.1 Language

Any notice (which term shall include any other communication required to be given under this Agreement or in connection with the matters contemplated by it) shall, except where otherwise specifically provided, be in writing in the English language.

9.2 Service

- (A) Any communication and/or information to be given to a party in connection with this Agreement shall be in writing in English and shall either be:

(1) delivered by hand or sent by pre-paid first-class post or a reputable international courier using overnight service (as applicable) at its registered office or: (i) in the case of a Seller, to the address of such Seller specified in the table in Part A of Schedule 1; or (ii) in the case of a Beneficial Owner, to the address of such Beneficial Owner's Nominee Shareholder specified in column (B) of the table in Part B of Schedule 1; or

(2) sent by email to the email addresses as may be notified by the parties from time to time,

(or in each such case to such other address as the recipient may notify to the other parties for such purpose).

(B) A communication sent according to clause 9.2 shall be deemed to have been received:

(1) if delivered by hand, at the time of delivery at the proper address;

(2) if sent by pre-paid first-class post or a reputable international courier using overnight service, on the business day after posting; or

(3) if sent by email, at the time of completion of transmission by the sender, unless the sender receives a notification that the email has not been successfully delivered,

except that if a communication is received between 5:30pm on a business day and 9:30am on the next business day, it shall be deemed to have been received at 9:30am on the second of such business days.

9.3 This clause 9 does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other method of dispute resolution which shall be governed by the applicable law, rule or regulation.

9.4 Change of address

Any party to this Agreement may notify the other parties of any change to its address by giving written notice of the same to the other parties, provided that such notification shall only be effective on the date specified in such notice or five business days after the notice is given, whichever is later.

9.5 Electronic and website communications

Each of the Sellers and each of the Beneficial Owners (on behalf of their respective Nominee Shareholder) hereby agrees for the purposes of the Companies Act that the Buyer may send or supply documents and information to them as a member of the Buyer: (i) via the website www.immunocore.com; and/or (ii) in electronic form to any electronic address (including any email address) that has previously been provided to the Company for this purpose or otherwise used by the Company in communications with them.

10. Law and jurisdiction

10.1 English Law

This Agreement and any dispute or claims relating to it or its subject matter or formation (including non-contractual disputes or claims) is governed by, and shall be construed in accordance with, English Law.

10.2 Jurisdiction

In relation to any legal action or proceedings to enforce this Agreement or arising out of or in connection with this Agreement (“**Proceedings**”), each of the parties irrevocably submits to the exclusive jurisdiction of the English courts and waives any objection to Proceedings in such courts on the grounds of venue or on the grounds that the Proceedings have been brought in an inappropriate forum.

10.3 Contracts (Rights of Third Parties) Act 1999

No person who is not a party to this Agreement shall have any right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.

11. Agency

11.1 Each Seller and each Beneficial Owner undertakes to the Buyer and to the Company (on a several basis) that such Seller or Beneficial Owner shall, and agrees to procure that any of his, her or its Permitted Transferees or Nominee Shareholder shall, from the date of this Agreement until the date on which the Buyer is entered in the register of members of the Company as holder of the relevant Sale Shares:

- (A) exercise all voting rights (including class rights) attaching to such Seller’s Sale Shares or such Nominee Shareholder’s Sale Shares (whether in writing or at a meeting of the shareholders of the Company or a class of any shareholders of the Company) to signify agreement on behalf of that Seller or that Nominee Shareholder to any resolution and/or class consent to be passed by the shareholders of the Company under Part 13 of the Companies Act or otherwise; and
- (B) approve, execute or sign and deliver all deeds, documents, resolutions (whether ordinary or special), consents, certificates, instruments, forms and/or agreements,

in each case as may be required under the Companies Act, this Agreement, the Company Articles or otherwise, which that Seller or Nominee Shareholder may be entitled to receive or do by reason of being or having been the registered holder of such Seller’s Sale Shares or such Nominee Shareholder’s Sale Shares, in such manner and on such terms as the Buyer in its absolute discretion thinks fit and to the exclusion of that Seller or any other person.

- 11.2 Without prejudice to the generality of clause 11.1, each Seller shall take such actions as required by clause 11.1 in connection with:
- (A) any re-organisation of the issued or unissued share capital of the Company (including, but not limited to, any conversion, re-designation, sub-division or consolidation of the issued share capital of the Company);
 - (B) any reduction of capital of the Company (by way of any reduction in the nominal value, or number, of any of the shares of the Company and/or any reduction of any undistributable reserves); and/or
 - (C) the adoption of new articles of association of the Company and any change of name of the Company,
- including voting in favour of any written resolution and/or class consent proposed by the Board in connection with such matters, provided that nothing in clause 11.1 nor this clause 11.2 shall require any Seller or Nominee Shareholder to take any unlawful action or step.
- 11.3 Each Seller and each Beneficial Owner undertakes to the Buyer (on a several basis) that such Seller or Beneficial Owner shall, and agrees to procure that any of his, her or its Permitted Transferees or Nominee Shareholder shall, at the request of the board of directors of the Buyer (following a majority vote including an affirmative vote from an Investor Director):
- (A) exercise all voting rights (including class rights) attaching to such Seller's Consideration Shares or such Nominee Shareholder's Consideration Shares (whether in writing or at a meeting or the shareholders of the Buyer or a class of any shareholders of the Buyer); and
 - (B) approve, execute or sign and deliver all deeds, documents, resolutions (whether ordinary or special), consents, certificates, instruments, forms and/or agreements,
- in each case as may be required under the Companies Act, the New Shareholders' Agreement, the New Articles or otherwise in order to give effect to, or which are considered by the board of directors of the Buyer to be desirable in connection with, a Qualifying IPO and/or a Prospective Qualifying IPO (provided that any such consent or approval of or vote for a Prospective Qualifying IPO will relate to the steps the board of directors of the Buyer believes to be desirable in preparation for a Qualifying IPO, but shall not allow the Buyer actually to implement an IPO that is not a Qualifying IPO).
- 11.4 Without prejudice to the generality of clause 11.3, each Seller and each Beneficial Owner shall take such actions as required by clause 11.3 in connection with:
- (A) the execution of the New Shareholders' Agreement;
 - (B) any reduction of capital of the Buyer (by way of any reduction in the nominal value of any of the shares of the Buyer and/or any reduction of any undistributable reserves);

- (C) the re-registration of the Buyer as a public limited company in accordance with the procedure set out in sections 90 – 96 (inclusive) of the Companies Act and the associated change of name of the Buyer and adoption of new articles of association of the Buyer appropriate for a public limited company (or equivalent in any jurisdiction);
 - (D) consenting to a general meeting of the Buyer being held on short notice in accordance with section 307(4) of the Companies Act and providing a proxy in favour of any director of the Buyer to vote such Seller’s Consideration Shares or a Nominee Shareholder’s Consideration Shares in favour of any resolution and/or class consent proposed at such general meeting in connection with a Prospective Qualifying IPO; and
 - (E) the authorisation of the board of directors of the Buyer to issue new shares in the Buyer pursuant to section 551 of the Companies Act and disapply any rights of pre-emption of the shareholders of the Buyer whether under section 561 of the Companies Act or set out in the New Articles.
- 11.5 If any Seller or Beneficial Owner fails to comply with the provisions of clauses 11.1 to 11.4, the Buyer shall be constituted as the agent of each defaulting Seller or defaulting Beneficial Owner (or its Nominee Shareholder, as applicable) for taking such actions as are necessary to enforce the provisions of clauses 11.1, 11.2, 11.3 and/or 11.4 and any director of the Buyer shall be empowered to execute and deliver on behalf of such defaulting Seller or defaulting Beneficial Owner (or its Nominee Shareholder, as applicable) any document that such director considers reasonably necessary in connection with any of the matters set out in clauses 11.1, 11.2, 11.3 and/or 11.4.

12. Nominee arrangements

The Beneficial Owners are parties to this Agreement in their capacity as beneficial holders of the Sale Shares set out beside the names of their respective Nominee Shareholders in columns (B), (C), (D), (E), (F) and/or (G) of the table in Part A of Schedule 1, and, by signing below, hereby direct and instruct their respective Nominee Shareholders to transfer the entire interest in the relevant Sale Shares to the Buyer.

This Agreement has been entered into on the date stated at the beginning of it.

SCHEDULE 1**Part A**

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
667, L.P. of 860 Washington Street, 3rd Floor, New York, NY 10014, United States	366	3,931	0	20,538	0	0	36,600 Ordinary Consideration Shares 393,100 Series A Consideration Shares 2,053,800 Series C Consideration Shares
Attridge, Penelope of Angeston Court, Fop Street, Uley, Dursley, GL11 5AL	661	0	0	0	0	0	66,100 Ordinary Consideration Shares
Avego Bioscience IMCR, LLC of c/o Avego Management, LLC, 1055B Powers Place, 2nd Floor, Alpharetta, GA 30009, United States	0	0	0	46,677	0	0	4,667,700 Series C Consideration Shares
Baker Brothers Life Sciences, L.P. of 860 Washington Street, 3rd Floor, New York, NY 10014, United States	4,599	49,181	0	254,036	0	0	459,900 Ordinary Consideration Shares 4,918,100 Series A Consideration Shares 25,403,600 Series C

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
							Consideration Shares
* The Bank of New York (Nominees) Limited of One Piccadilly Gardens, Manchester, M1 1RN	6,296	67,323	0	0	0	0	629,600 Ordinary Consideration Shares 6,732,300 Series A Consideration Shares
* BBHISL Nominees Ltd, Acct 122514 of c/o HSBC Bank Plc, 8 Canada Square, London, E14 5HQ, United Kingdom	6,857	73,318	0	0	0	0	685,700 Ordinary Consideration Shares 7,331,800 Series A Consideration Shares
* BBHISL Nominees Ltd, Acct 130646 of c/o HSBC Bank Plc, 8 Canada Square, London, E14 5HQ, United Kingdom	1,892	20,244	0	0	0	0	189,200 Ordinary Consideration Shares 2,024,400 Series A Consideration Shares
* BBHISL Nominees Ltd, Acct 131418 of c/o HSBC Bank Plc, 8 Canada Square, London, E14 5HQ, United Kingdom	5	75	0	0	0	0	500 Ordinary Consideration Shares 7,500 Series A Consideration Shares
Bell, John Irving of Riverholme, Thames Street, Wallingford, OX10 0HD, United	1,152	0	0	0	0	0	115,200 Ordinary Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
Kingdom							
Betton, Andrew of 21 Old Farm Avenue, London, N14 5QR	776	0	0	0	0	0	77,600 Ordinary Consideration Shares
Bill & Melinda Gates Foundation of PO Box 23350, Seattle MD, United States	6,948	0	203,697	0	0	0	694,800 Ordinary Consideration Shares 20,369,700 Series B Consideration Shares
BlackRock Health Sciences Trust II of 100 Bellevue Parkway, Wilmington, Delaware 19809	0	0	0	64,380	0	0	6,438,000 Series C Consideration Shares
BlackRock Health Sciences Master Unit Trust of 190 Elgin Avenue, George Town, Grand Cayman, KY1- 9005 Cayman Islands	0	0	0	1,517	0	0	151,700 Series C Consideration Shares
Blackwell, Christina Jane of Flat 3, 14 Cheyne Gardens, London SW3 5QT	74,673	800	0	0	0	0	7,467,300 Ordinary Consideration Shares 80,000 Series A Consideration Shares
Blackwell, Nigel Stirling of The Ham, Ickleton Road, Wantage, Oxfordshire,	164,428	1,350	2	0	0	0	16,442,800 Ordinary

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
OX12 9JA, United Kingdom							Consideration Shares 135,000 Series A Consideration Shares 200 Series B Consideration Shares
Blackwell, Nigel and Roots, Nigel, the Trustees of The Ham Trust of The Ham, Ickleton Road, Wantage, Oxfordshire, OX12 9JA, United Kingdom	6,329	0	0	0	0	0	632,900 Ordinary Consideration Shares
Blackwell, Nigel, Roots, Nigel and Maitland, Jane, the Trustees of the Nigel Blackwell Family Trust of The Ham, Ickleton Road, Wantage, Oxfordshire, OX12 9JA, United Kingdom	170,730	1,062	0	0	0	0	17,073,000 Ordinary Consideration Shares 106,200 Series A Consideration Shares
Canuto, Corin of 23 High Street, Potterne, Wiltshire, SN10 5NA, United Kingdom	815	0	0	0	0	0	81,500 Ordinary Consideration Shares
CCB International Overseas Limited of 12/F, CCB Tower, 3 Connaught Road Central, Central, Hong Kong	2,179	0	63,905	0	0	0	217,900 Ordinary Consideration Shares 6,390,500 Series B Consideration

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
							Shares
The Chancellor, Masters and Scholars of the University of Oxford of c/o Oxford University Innovation, Buxton Court, 3 West Way, Oxford OX2 0JB, United Kingdom	29,886	404	0	0	0	0	2,988,600 Ordinary Consideration Shares 40,400 Series A Consideration Shares
* Chase Nominees Limited A/C Fidlend of PO Box 7732, 1 Chaseside, Bournemouth, BH1 9XA, United Kingdom	1,053	11,275	0	0	0	0	105,300 Ordinary Consideration Shares 1,127,500 Series A Consideration Shares
Cross, Nicholas John of Lashford House, Dry Sandford, Abingdon, Oxfordshire, OX13 6JP, United Kingdom	467,458	6,462	2	0	0	0	46,745,800 Ordinary Consideration Shares 646,200 Series A Consideration Shares 200 Series B Consideration Shares
The Dean and Chapter of the Cathedral Church of Christ in Oxford of the Foundation of King Henry the Eighth of The Treasury, St Aldates, Oxford, OX1 1DP	2,419	41	0	0	0	0	241,900 Ordinary Consideration Shares 4,100 Series A Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
Duffy, Anthony of 20 Burnbury Road, London, SW12 0EJ	1,034	0	0	0	0	0	103,400 Ordinary Consideration Shares
Eli Lilly SA of Chemin des Coquelicots 16, 1214, Vernier, Switzerland	39,703	398,338	71,588	0	0	0	3,970,300 Ordinary Consideration Shares 39,833,800 Series A Consideration Shares 7,158,800 Series B Consideration Shares
Financial Consultants (Jersey) Limited a/c 91 of Centenary House, La Grande Route de St Pierre, St Peter, JE3 7AY, Jersey	35,186	416	0	0	0	0	3,518,600 Ordinary Consideration Shares 41,600 Series A Consideration Shares
Four Pines Master Fund LP of 650 South Exeter Street, Suite 1070, Baltimore MD 21202, United States	0	0	0	27,457	0	0	2,745,700 Series C Consideration Shares
GA IMC Holding, L.P. of Clarendon House, 2 Church Street, Hamilton, HM 11, Bermuda	18,963	0	555,893	219,659	0	0	1,896,300 Ordinary Consideration Shares 55,589,300 Series B Consideration Shares 21,965,900 Series C

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
							Consideration Shares
Gee, Jonathan of 3 Hornbeam Close, Podington, Wellingborough, NN29 7HZ	1,322	0	0	0	0	0	132,200 Ordinary Consideration Shares
GT Healthcare Fund 1 LP of c/o Walkers Corporate Limited, Cayman Corporate Centre, 27 Hospital Road, George Town, Grand Cayman KY1- 9008, Cayman Islands	116,599	0	0	0	0	0	11,659,900 Ordinary Consideration Shares
HC IC Holdings LLC of 1177 Avenue of the Americas, 40th floor, New York, NY 10036, United States	0	0	0	8,237	0	0	823,700 Series C Consideration Shares
Hietanen, Satu of 297a Green Lanes, London N4 2ES	287	0	0	0	0	0	28,700 Ordinary Consideration Shares
Holmes, Andrew of 51 Doneraile Street, London, SW6 6EW	130	300	0	0	0	0	13,000 Ordinary Consideration Shares 30,000 Series A Consideration Shares
Immunocore Nominees Limited of 92 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY, United	22,300	0	0	0	43,490	19,260	2,230,000 Ordinary Consideration Shares 4,349,000 G1 Consideration

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
Kingdom							Shares 1,926,000 G2 Consideration Shares
Jakobsen, Bent Karsten of Flat 7, Lincombe Lodge, Fox Lane, Boars Hill, Oxford OX1 5DN, United Kingdom	39,973	0	0	0	0	0	3,997,300 Ordinary Consideration Shares
JDRF T1D Fund, LLC of 200 Vesey Street, 28th Floor, New York, NY 10281, United States	1,090	0	31,953	0	0	0	109,000 Ordinary Consideration Shares 3,195,300 Series B Consideration Shares
Moore Kingston Smith Trust Corporation Limited and Tilly Vivien Lesley Chown as Trustees of the William Thomas Chown Discretionary Will Trust of Devonshire House, 60 Goswell Road, London EC1M 7AD, United Kingdom	24,676	0	0	0	0	0	2,467,600 Ordinary Consideration Shares
Knowles, Jonathan Kenneth Charles of Paradiesstrasse 73, CH4102, Binningen, Baselland, Switzerland	49,775	664	832	0	0	0	4,977,500 Ordinary Consideration Shares 66,400 Series A Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
							83,200 Series B Consideration Shares
Laing, Caroline Elizabeth of 4 Charlbury Road, Oxford, OX2 6UT, United Kingdom	88,628	1,228	0	0	0	0	8,862,800 Ordinary Consideration Shares 122,800 Series A Consideration Shares
Laing, Ian Michael of 4 Charlbury Road, Oxford, OX2 6UT, United Kingdom	377,792	5,234	2	0	0	0	37,779,200 Ordinary Consideration Shares 523,400 Series A Consideration Shares 200 Series B Consideration Shares
Lammer, Peter of Newton House, Faringdon, SN7 8PY, United Kingdom	96,589	0	8,595	0	0	0	9,658,900 Ordinary Consideration Shares 859,500 Series B Consideration Shares
Levi, Sergio of 29 Milliner House, Hortensia Road, London SW10 0QB	374	0	0	0	0	0	37,400 Ordinary Consideration Shares
Lincoln College Oxford of Turl Street,	2,419	41	0	0	0	0	241,900 Ordinary Consideration

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
Oxford, OX1 3DR							Shares 4,100 Series A Consideration Shares
* Mag & Co. FBO Fidelity Series Growth Company Fund of 140 Broadway, New York NY 10005, United States	1,730	18,504	0	0	0	0	173,000 Ordinary Consideration Shares 1,850,400 Series A Consideration Shares
Malin Life Sciences Holdings Limited of 2 Harbour Square, Crofton Road, Dun Laoghaire, County Dublin, A96 D6R0 Ireland	46,991	424,894	0	0	0	0	4,699,100 Ordinary Consideration Shares 42,489,400 Series A Consideration Shares
Master and Scholars of Balliol College in the University of Oxford of Broad Street, Oxford, OX1 3BJ	2,419	41	0	0	0	0	241,900 Ordinary Consideration Shares 4,100 Series A Consideration Shares
MediGene AG of Lochhamer Strasse 11, 82152, Planegg/Martinsried, Germany	32,407	0	0	0	0	0	3,240,700 Ordinary Consideration Shares
Mellon, James of Viking House, Nelson	3,571	0	0	0	0	0	357,100 Ordinary Consideration

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
Street, Douglas, Isle Of Man, IM1 2AH							Shares
Merton Acquisition HoldCo LLC of 4 Park Plaza, Suite 550, Irvine CA 92614, USA	47,093	239,003	0	0	0	0	4,709,300 Ordinary Consideration Shares 23,900,300 Series A Consideration Shares
Molloy, Peter Eamon of 193 Great Knollys Street, Reading, Berkshire, RG1 7HA	405	0	0	0	0	0	40,500 Ordinary Consideration Shares
N5 Investments AS of Parkveien 55, Oslo, 0256, Norway	1,613	0	0	0	0	0	161,300 Ordinary Consideration Shares
Neomed Innovation V L.P. of 13 Castle Street, St. Helier, Jersey JE4 5UT, Channel Islands	24,807	0	0	0	0	0	2,480,700 Ordinary Consideration Shares
* Nortrust Nominees Limited a/c WIZ02 of 50 Bank Street, London, E14 5NT, United Kingdom	27,303	291,814	0	0	0	0	2,730,300 Ordinary Consideration Shares 29,181,400 Series A Consideration Shares
Nuframe Limited of Centenary House, La Grande Route de St Pierre, St Peter,	35,185	416	0	0	0	0	3,518,500 Ordinary Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
JE3 7AY, Jersey							41,600 Series A Consideration Shares
Pointer, David James of 38 Pearce Avenue, Poole, BH14 8EH, United Kingdom	100,431	1,391	0	0	0	0	10,043,100 Ordinary Consideration Shares 139,100 Series A Consideration Shares
The President Fellows and Scholars of the College of the Holy and Undivided Trinity in the University of Oxford of Broad Street, Oxford, OX1 3BH	1,210	21	0	0	0	0	121,000 Ordinary Consideration Shares 2,100 Series A Consideration Shares
President and Scholars of the College of Corpus Christi in the University of Oxford of Merton Street, Oxford, OX1 4JF	1,210	21	0	0	0	0	121,000 Ordinary Consideration Shares 2,100 Series A Consideration Shares
President and Scholars of the College of Saint Mary Magdalen in the University of Oxford of High Street, Oxford, OX1 4AU	1,935	33	0	0	0	0	193,500 Ordinary Consideration Shares 3,300 Series A Consideration Shares
The Principal and Fellows of the College of the Lady Margaret in the	1,210	21	0	0	0	0	121,000 Ordinary Consideration

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
University of Oxford of Lady Margaret Hall, Norham Gardens, Oxford OX2 6QA							Shares 2,100 Series A Consideration Shares
The Principal and Fellows of Somerville College in the University of Oxford of Woodstock Road, Oxford, OX2 6HD	1,210	21	0	0	0	0	121,000 Ordinary Consideration Shares 2,100 Series A Consideration Shares
Robinson, George Edward Silvanus of 20 Campden Hill Square, London, W8 7JY, United Kingdom	424,255	6,447	2	0	0	0	42,425,500 Ordinary Consideration Shares 644,700 Series A Consideration Shares 200 Series B Consideration Shares
Rock Springs Capital Master Fund LP of 650 South Exeter Street, Suite 1070, Baltimore MD 21202, United States	2,724	0	79,881	104,338	0	0	272,400 Ordinary Consideration Shares 7,988,100 Series B Consideration Shares 10,433,800 Series C Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
RTW Innovation Master Fund, Ltd of c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014	0	0	0	14,744	0	0	1,474,400 Series C Consideration Shares
RTW Master Fund, Ltd of c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014	4,967	53,112	0	45,530	0	0	496,700 Ordinary Consideration Shares 5,311,200 Series A Consideration Shares 4,553,000 Series C Consideration Shares
RTW Venture Fund Limited of c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014	1,580	0	46,324	16,606	0	0	158,000 Ordinary Consideration Shares 4,632,400 Series B Consideration Shares 1,660,600 Series C Consideration Shares
Spark Venture Management Limited of 62 Dean Street, London, W1D 4QF	725	12	0	0	0	0	72,500 Ordinary Consideration Shares 1,200 Series A Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
Spooner, John of Glebe Farm, Great Rissington, Cheltenham, GL54 2LH	115	0	0	0	0	0	11,500 Ordinary Consideration Shares
* State Street Nominees Limited a/c 24F3 of Quartermile 3, 10 Nightingale Way, Edinburgh EH3 9EG, United Kingdom	1,603	17,149	0	0	0	0	160,300 Ordinary Consideration Shares 1,714,900 Series A Consideration Shares
* State Street Nominees Limited a/c 24JA of Quartermile 3, 10 Nightingale Way, Edinburgh EH3 9EG, United Kingdom	375	4,035	0	0	0	0	37,500 Ordinary Consideration Shares 403,500 Series A Consideration Shares
* State Street Nominees Limited a/c IM86 of Quartermile 3, 10 Nightingale Way, Edinburgh EH3 9EG, United Kingdom	48	524	0	0	0	0	4,800 Ordinary Consideration Shares 52,400 Series A Consideration Shares
St Catherine's College in the University of Oxford of Manor Road, Oxford, OX1 3UJ	13,516	166	0	0	0	0	1,351,600 Ordinary Consideration Shares 16,600 Series A Consideration Shares
Teichman, Thomas of 4 Ralston Street,	776	0	0	0	0	0	77,600 Ordinary Consideration

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
London, SW3 4DS							Shares
Terra Magnum LLC of 4701 Sangmore Road, Suite 100N-1018, Bethesda MD 20816, United States	136	0	3,995	0	0	0	13,600 Ordinary Consideration Shares 399,500 Series B Consideration Shares
Tran, Nghi of 8 Elm Close, Amersham, HP6 5DD	287	0	0	0	0	0	28,700 Ordinary Consideration Shares
Treves, Angela Veronica of 4 Alwyne Place, London, N1 2NL, United Kingdom	15,381	206	0	0	0	0	1,538,100 Ordinary Consideration Shares 20,600 Series A Consideration Shares
The Warden and Fellows of All Souls College of High Street, Oxford, OX1 4AL	967	16	0	0	0	0	96,700 Ordinary Consideration Shares 1,600 Series A Consideration Shares
The Warden and Fellows of St Antony's College of 62 Woodstock Rd, Oxford, OX2 6JF	1,210	21	0	0	0	0	121,000 Ordinary Consideration Shares 2,100 Series A Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
The Warden and Scholars of the House or College of Scholars of Merton in the University of Oxford of Merton Street, Oxford, OX1 4JD	1,210	21	0	0	0	0	121,000 Ordinary Consideration Shares 2,100 Series A Consideration Shares
Wanganui Pty Limited of c/o Intralink Wealth Management, Level 14, 470 Collins Street, Melbourne VIC, 3000, Australia	10,073	0	2,151	0	0	0	1,007,300 Ordinary Consideration Shares 215,100 Series B Consideration Shares
WuXi PharmaTech Healthcare Fund I L.P. of 288 Fute Zhong Road, Waigaoqiao Free Trade Zone, Shanghai, 200131, China	2,724	0	79,881	0	0	0	272,400 Ordinary Consideration Shares 7,988,100 Series B Consideration Shares
TOTAL	2,679,764 Ordinary Shares	1,699,576 Series A Shares	1,148,703 Series B Shares	823,719 Series C Shares	43,490 G1 Shares	19,260 G2 Shares	267,976,400 Ordinary Consideration Shares 169,957,600 Series A Consideration Shares 114,870,300 Series B Consideration Shares 82,371,900 Series C Consideration Shares

(A) Name and address of Seller	(B) Ordinary Shares	(C) Series A Shares	(D) Series B Shares	(E) Series C Shares	(F) G1 Shares	(G) G2 Shares	(H) Number and class of Consideration Shares to be issued by the Buyer
							4,349,000 G1 Consideration Shares 1,926,000 G2 Consideration Shares

PART B

(A) Beneficial Owner	(B) Name and address of Nominee Shareholders
Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund	The Bank of New York (Nominees) Limited of One Piccadilly Gardens, Manchester, M1 1RN
Fidelity Select Portfolios: Biotechnology Portfolio	BBHISL Nominees Ltd, Acct 122514 of c/o HSBC Bank Plc, 8 Canada Square, London, E14 5HQ, United Kingdom
Fidelity Growth Company Commingled Pool	BBHISL Nominees Ltd, Acct 130646 of c/o HSBC Bank Plc, 8 Canada Square, London, E14 5HQ, United Kingdom
Fidelity Blue Chip Growth Commingled Pool	BBHISL Nominees Ltd, Acct 131418 of c/o HSBC Bank Plc, 8 Canada Square, London, E14 5HQ, United Kingdom
Fidelity Securities Fund: Fidelity Blue Chip Growth Fund	Chase Nominees Limited A/C Fidlend of PO Box 7732, 1 Chaseside, Bournemouth, BH1 9XA, United Kingdom
Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund	Mag & Co. FBO Fidelity Series Growth Company Fund of 140 Broadway, New York NY 10005, United States
Schroder UK Public Private Trust Plc	Nortrust Nominees Limited a/c WIZ02 of 50 Bank Street, London, E14 5NT, United Kingdom
Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund	State Street Nominees Limited a/c 24F3 of Quartermile 3, 10 Nightingale Way, Edinburgh EH3 9EG, United Kingdom
Fidelity Securities Fund: Fidelity Series Blue Chip Growth Fund	State Street Nominees Limited a/c 24JA of Quartermile 3, 10 Nightingale Way,

(A) Beneficial Owner	(B) Name and address of Nominee Shareholders
	Edinburgh EH3 9EG, United Kingdom
Fiam Target Date Blue Chip Growth Commingled Pool	State Street Nominees Limited a/c IM86 of Quartermile 3, 10 Nightingale Way, Edinburgh EH3 9EG, United Kingdom

EXECUTED for and on behalf of)

IMMUNOCORE HOLDINGS LIMITED)

acting by a director:)

EXECUTED for and on behalf of)

IMMUNOCORE LIMITED)

acting by a director:)

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS SECOND AMENDMENT to Loan and Security Agreement (this "**Amendment**") is entered into as of September 10, 2021 (the "**Second Amendment Date**"), by and among OXFORD FINANCE LUXEMBOURG S.À R.L., a Luxembourg private limited liability company (société à responsabilité limitée) with registered office at 2 route d'Arlon, 8008 Strassen, Grand Duchy of Luxembourg and registered with the Luxembourg commercial register under number B243395, acting in respect of its Compartment 1 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 of the Loan Agreement (defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and IMMUNOCO RE LIMITED, a private limited company incorporated under the laws of England and Wales and limited by shares under registration number 6456207 with offices located at 92 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY, UK ("**Parent**" and "**Borrower**"), MUNOCORE LLC, a Delaware limited liability company and wholly owned subsidiary of Parent with offices located at Six Tower Bridge, Suite 540, 181 Washington Street Conshohocken, PA 19422 ("**Core Sub**"), IMMUNOCORE COMMERCIAL LLC, a Delaware limited liability company and wholly owned subsidiary of Core Sub with offices located at Six Tower Bridge, Suite 540, 181 Washington Street, Conshohocken, PA 19422 ("**Commercial Sub**") and IMMUNOCORE HOLDINGS PLC a public limited company incorporated under the laws of England and Wales and limited by shares under registration number 13119746 with offices located at 92 Park Drive, Milton Park, Abingdon, Oxfordshire., OX 14 4RY, UK ("**Holdings**") (Core Sub, Commercial Sub and Holdings, each a "**Guarantor**" and collectively "**Guarantors**") (Borrower and each of Guarantors, individually and collectively, jointly and severally, "**Loan Parties**").

WHEREAS, Collateral Agent, Loan Parties and Lenders party thereto from time to time have entered into that certain Loan and Security Agreement, dated as of November 6, 2020 (as amended, supplemented or otherwise modified from time to time, the "**Loan Agreement**") pursuant to which the Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

WHEREAS, Loan Parties, Collateral Agent and Lenders desire to amend certain provisions of the Loan Agreement as provided herein and subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Loan Parties, Lenders and Collateral Agent hereby agree as follows:

- I. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.
2. Section 6.10 of the Loan Agreement is hereby amended and restated as follows:

6.10 Non-Borrower Entities. The aggregate value of assets held by Immunocore Ireland shall not at any time exceed the lesser of (i) Ten Million Dollars (\$10,000,000.00) or (ii) 10% of Loan Parties' total consolidated assets at such time, and the aggregate assets held by Immunocore Nominees shall not at any given time exceed One Million Dollars (\$1,000,000.00). Immunocore LLC may not hold assets with an aggregate value in excess of Ten Million Dollars (\$10,000,000.00) and Immunocore Commercial LLC may not hold assets with an aggregate value in excess of Twenty Five Million Dollars (\$25,000,000.00). Furthermore, none of Immunocore Ireland, Immunocore Nominees, Immunocore LLC, or Immunocore Commercial LLC shall maintain any Intellectual Property.

3. Parts (k) of the defined term "Permitted Investments" in Section 13.1 of the Loan Agreement are hereby amended and restated in their entirety to read as follows:

"(k) (i) Investments by any Borrower in any other in co-borrowers or other Loan Parties that are direct Foreign Subsidiaries of Borrower, (ii) Investments by Subsidiaries in Borrower, (iii) Investments by Borrower or the Loan Parties in Immunocore Ireland in an aggregate annual amount not to exceed \$10,000,000, (iv) Investments by Borrower or the Loan Parties in Immunocore Nominees in an aggregate annual amount not to exceed \$10,000,000, (v) Investments by Borrower or the Loan Parties in Immunocore LLC and Immunocore Commercial LLC in any given year in an amount sufficient to fund their respective operations in accordance with the then applicable Board approved Annual Projections, and (vi) Investments by any Guarantor that is a parent entity of Borrower or any other Loan Party (a "**Parent Guarantor**"), in Borrower."

4. **Limitation of Amendments.**

- a. The amendments set above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Loan Parties may now have or may have in the future under or in connection with any Loan Document, as amended hereby.
- b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect. For the avoidance of doubt, this Amendment shall be considered part of the Loan Documents.

5. To induce Collateral Agent and Lenders to enter into this Amendment, Loan Parties hereby represents and warrants to Collateral Agent and Lenders as follows:

- a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;
 - b. Each of the Loan Parties has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;
 - c. The organizational documents of Loan Parties delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by the Loan Parties to the Collateral Agent, and including following and in connection with the Exchange Transactions, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;
 - d. The execution and delivery by Loan Parties of this Amendment and the performance by each of them of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;
 - e. The execution and delivery by Loan Parties of this Amendment and the performance by each Loan Party of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any law or regulation binding on or affecting Borrower, (ii) any contractual restriction with a Person binding on such Loan Party, (iii) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on such Loan Party, or (iv) the organizational documents of such Loan Party;
 - f. The execution and delivery by Loan Parties of this Amendment and the performance by each Loan Party of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on such Loan Party, except as already has been obtained or made; and
-

- g. This Amendment has been duly executed and delivered by each of Loan Party and is the binding obligation of such Loan Party, enforceable against Loan Party in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.
6. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.
7. This Amendment shall be deemed effective as of the Second Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto and (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited (or ACH'd) from the Designated Deposit Account in accordance with Section 2.3(d) of the Loan Agreement.
8. Each Loan Party hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent ("**Releasees**"), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any act, omission or state of facts taken or existing on or prior to the date hereof, may have after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof through the date hereof. Without limiting the generality of the foregoing, such Loan Party waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest relative to the Loan Documents: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan Documents; (b) any provision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof.
9. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.
10. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

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IN WITNESS WHEREOF, the parties hereto have caused this Second Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

IMMUNOCORE LIMITED

By /s/ Brian Di Donato
Name:Brian Di Donato
Title: CEO

GUARANTORS:

IMMUNOCORE LLC

By /s/ Bahija Jallal
Name:Bahija Jallal
Title: Dr

IMMUNOCORE COMMERCIAL LLC

By /s/ Bahija Jallal
Name:Bahija Jallal
Title: Dr

IMMUNOCORE HOLDINGS PLC

By /s/ Bahija Jallal
Name:Bahija Jallal
Title: Dr

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LUXEMBOURG S.A R.L.,
acting in respect of its Compartment 1

By _____
Name: _____
Title: _____

IN WITNESS WHEREOF, the parties hereto have caused this Second Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

IMMUNOCORE LIMITED

By _____
Name: _____
Title: _____

GUARANTORS;

IMMUNOCORE LLC

By _____
Name: _____
Title: _____

IMMUNOCORE COMMERCIAL LLC

By _____
Name: _____
Title: _____

IMMUNOCORE HOLDINGS PLC

By _____
Name: _____
Title: _____

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LUXEMBOURG S.A R.L.,
acting in respect of its Compartment 1

By	/s/ Laurent BÉLIK	/s/ Mélanie FLORSCH
Name:	Laurent BÉLIK	Mélanie FLORSCH
Title:	Manager	Manager

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT IMMUNOCORE TREATS AS PRIVATE OR CONFIDENTIAL.



October 8, 2021

Immunocore Limited
92 Park Drive
Milton Park
Abingdon
Oxon
OX14 4RY
United Kingdom

Attn: Dr. Bahija Jallal, CEO

Dear Dr. Jallal:

Reference is made to that certain Collaboration and Licence Agreement between Immunocore Limited ("Immunocore") and GlaxoSmithKline Intellectual Property Development Limited ("GSK") dated June 29, 2013, as amended from time to time (the "Agreement"). Terms not defined in this letter have the meanings ascribed to them in the Agreement.

Following from discussions internally at GSK, GSK has decided to terminate the Agreement in its entirety pursuant to Section 13.2(a). Termination of the Agreement will be effective 90 Business Days from the date of this notice. We will be in touch shortly to discuss next steps and which of the provisions of Section 13.6, if any, are applicable to the remaining Collaboration Program directed to [***].

GlaxoSmithKline Intellectual Property Development Limited

Sincerely,

/s/ John Sadler

Mr J Sadler
Authorised Signatory
For and on behalf of
Glaxo Group Limited
Corporate Director

/s/ Claire MacLeod

Mrs C MacLeod
Authorised Signatory
For and on behalf of
Edinburgh Pharmaceutical Industries Limited
Corporate Director

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT IMMUNOCORE TREATS AS PRIVATE OR CONFIDENTIAL.

**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)) 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 3, 2022

By: /s/ Bahija Jallal, Ph.D.

Bahija Jallal, Ph.D.

Chief Executive Officer

(Principal Executive Officer)

**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)) 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 3, 2022

By: /s/ Brian Di Donato

Brian Di Donato
Chief Financial Officer
(Principal Financial Officer)

**Certification by the Principal Executive Officer and Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report on Form 20-F of Immunocore Holdings plc (the “*Company*”) for the fiscal year ended December 31, 2021 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 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 3, 2022

/s/ Bahija Jallal, Ph.D.

Chief Executive Officer
(Principal Executive Officer)

/s/ Brian Di Donato

Chief Financial Officer
(Principal Financial Officer)

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statement (No. 333-255182) on Form S-8 of our report dated March 3, 2022, with respect to the consolidated financial statements of Immunocore Holdings plc.

/s/ KPMG LLP

London, United Kingdom

March 3, 2022
