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

FORM 10-K

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

For the fiscal year ended December 31, 2023

or

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

For the transaction period from _____ to _____

Commission File No. 001-41231

TC BIOPHARM (HOLDINGS) PLC
(Exact Name of Registrant as Specified in Its Charter)

Scotland	**N/A**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Maxim 1, 2 Parklands Way Holytown, Motherwell, ML1 4WR Scotland, United Kingdom	**N/A**
Address of Principal Executive Offices	Zip Code

+44 (0) 141 433 7557
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
American Depositary Shares, each representing one Ordinary Share, nominal value £0.0001 per share	TCBP	The Nasdaq Stock Market LLC
Warrants, each warrant representing the right to purchase one American Depositary Share	TCBPW	The Nasdaq Stock Market LLC

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

N/A
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐No ☒

Indicate by check mark whether the registrant: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large Accelerated Filer ☐
Non-accelerated Filer ☒
Accelerated Filer ☐
Smaller Reporting Company ☒
Emerging Growth Company ☒

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12(b)-2 of the Exchange Act). Yes ☐ No☒

The aggregate market value of the voting and non-voting ordinary shares held by non-affiliates of the registrant, based upon $10.84, the closing price of the registrant's American Depositary Shares on the Nasdaq Capital Market on June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $3.1 million.

As of March 29, 2024, 63,902,641 shares of the registrant's ordinary shares, £0.0001 par value per share representing 2,426,504 American Depository shares, were outstanding.

TC BIOPHARM (HOLDINGS) PLC
2023 ANNUAL REPORT ON FORM 10-K
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Unless we state otherwise or the context otherwise requires, the terms "TC Biopharm,", "TCB", "we," "us," "our" and the "Company" refer to TC Biopharm (Holdings) plc.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "intends", "plans", "anticipates", "believes", "estimates", "predicts", "potential", "continue" or the negative of these terms or other comparable terminology.

Forward-looking statements are neither historical facts nor assurances of future performance, and are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following:

- the ultimate impact of the coronavirus (COVID-19) pandemic, or any other health epidemic, on our business, results of operations, cash flows, financial condition and liquidity, and the global economy as a whole;
- the sufficiency of our existing cash and cash equivalents to meet our working capital and capital expenditure needs over the next 12 months and our need to raise additional capital;
- our ability to generate revenue from products;
- our limited operating history;
- our ability to maintain proper and effective internal financial controls;
- our ability to continue to operate as a going concern;
- changes in laws, government regulations and policies and interpretations thereof;
- our ability to obtain and maintain protection for our intellectual property;
- our ability to attract and retain qualified employees and key personnel;

- our ability to manage our rapid growth and organizational change effectively;
- the possibility of security vulnerabilities, cyberattacks and network disruptions, including breaches of data security and privacy leaks, data loss, and business interruptions;
- our compliance with data privacy laws and regulations;
- our ability to develop and maintain our brand cost-effectively; and
- the other factors set forth in Part I, Item 1A, "Risk Factors" of this Form 10-K.

These forward-looking statements speak only as of the date of this Form 10-K and are subject to business and economic risks. We do not undertake any obligation to update or revise the forward-looking statements to reflect events that occur or circumstances that exist after the date on which such statements were made, except to the extent required by law.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel immunotherapy products based on our proprietary allogeneic gamma delta T (GD-T) cell platform. Harnessing the innate ability of GD-Ts has enabled us to develop a range of clinical-stage cell therapies designed to combat cancer and viral infection.

In-house clinical studies have demonstrated that our unmodified allogeneic GD-T products are (i) well tolerated and (ii) show preliminary evidence of disease modification in patients with the late-stage blood cancer, known as acute myeloid leukemia – AML. Based on clinical data generated by us believe that unmodified GD-Ts have the potential to treat all blood cancers.

TCB now is embarking on phase 2b-into-pivotal (phase 3) clinical studies with a view to launching its first oncology product for the treatment of AML. Clinical results generated thus far have enabled us to obtain FDA orphan drug status for treatment of AML.

In addition to unmodified allogenic GD-Ts for treatment of blood cancers, we are also developing an innovative range of genetically-modified CAR-T products for treatment of solid cancers. We believe that solid cancers are more difficult to treat than blood cancers and may require the addition of a CAR "chimeric antigen receptor" (i) to help therapeutic cells to "navigate" into diseased cancerous tissue and (ii) to retain therapeutic cells in-situ at the lesion for maximal efficacy (increased persistence).

In order to manufacture our portfolio of allogeneic products, we select the highest quality GD-T cells from healthy donors, activate the cells and grow them in large numbers at our in-house GMP-compliant manufacturing facility before administration to a patient in order to target and then destroy malignant or virally-infected tissues. We believe that we have introduced a step-change to our manufacturing platform by implementing a freeze-thaw process that will allow product to be shipped from cleanroom to patient without any shelf-life issue. Resulting products, we believe, will be more cost-effective and straightforward to ship form cleanroom to clinic.

History and Development of the Company

We are a public company with limited liability incorporated on October 25, 2021, pursuant to the laws of Scotland, under the name TC BioPharm (Holdings) plc. We were incorporated with nominal share capital for the purpose of becoming the ultimate holding company of TC BioPharm Limited, the company in which our principal clinical, research and development operations have been and are currently undertaken, and for the purpose of consummating the corporate reorganization described herein. TC BioPharm (Holdings) plc will not conduct any operations except those as the listed entity, as explained below.

TC BioPharm Limited was incorporated on July 1, 2013, as a private company with limited liability pursuant to the laws of Scotland and conducts our principal clinical. research and development operations. TC BioPharm Limited has two wholly owned subsidiaries:

- TC BioPharm BV, The Netherlands – incorporated March 2019
- TC BioPharm (North America) Inc. – incorporated June 2021

These two subsidiaries have had limited operating activity since their incorporation. It is anticipated that TC BioPharm (North America) Inc. will develop operations and a management presence in the United States, with a view to expanding our product offerings into that jurisdiction in the future.

The corporate reorganization took place in several steps as follows:

- On December 17, 2021, all shareholders in TC BioPharm Limited and holders of convertible loan notes in TC BioPharm Limited exchanged their shares and convertible loan notes for the same number and classes of newly issued shares and/or convertible loan notes in TC BioPharm (Holdings) Limited and, as a result, TC BioPharm Limited became a wholly owned subsidiary of TC BioPharm (Holdings) Limited.

- On December 17, 2021, TC BioPharm (Holdings) Limited carried out a 10 for 1 forward split of all classes of its share capital.

- On December 30, 2021, holders of various options to subscribe for shares in TC BioPharm Limited exchanged their options for equivalent options in TC BioPharm (Holdings) Limited.

- On January 10, 2022, TC BioPharm (Holdings) Limited re-registered under the laws of Scotland as a public limited company, with a change of name to TC BioPharm (Holdings) plc.

- Immediately prior to the completion of the initial public offering, the different classes and nominal values of issued share capital of TC BioPharm (Holdings) plc were reorganized into a single class of ordinary shares with the same nominal value. The ADSs represent a portion of these ordinary shares.

- On February 10, 2022, TC BioPharm (Holdings) plc completed an initial public offering on the Nasdaq Capital Market. Our ADSs and warrants are traded under the symbols TCBP and TCBPW respectively. Our ordinary shares are not listed. Our registered office in the United Kingdom is located at Maxim 1, 2 Parklands Way, Holytown, Motherwell, ML1 4WR, Scotland, United Kingdom, and the telephone of our registered office is +44 (0) 141 433 7557.

On November 18, 2022 the Company undertook a reverse share split such that fifty issued ordinary shares were exchanged for one new ordinary share. As a result of the share split, all references in these consolidated financial statements and accompanying notes to units of ordinary shares or per share amounts are reflective of the reverse share split for all periods presented. In addition, the exercise prices and the numbers of ordinary shares issuable upon the exercise of any outstanding options to purchase

ordinary shares were proportionally adjusted pursuant to the respective anti-dilution terms of the share-based payment plans.

On December 15, 2023 the Company changed its ratio of ADSs to one ADS representing one ordinary share to one ADS representing 20 ordinary shares. As a result of the ratio change, all references to ADSs in these consolidated financial statements and accompanying notes to units of ADSs or per ADS amounts are reflective of the ratio change for all periods presented. In addition, the exercise prices and the numbers of ADSs issuable upon the exercise of any outstanding options to purchase ADSs were proportionally adjusted pursuant to the respective anti-dilution terms of the share-based payment plans.

Our agent for service of process in the United States is TC BioPharm (North America) Inc., c/o Business Filings, Inc., 108 West 13th Street, Wilmington, Delaware 19801 and the telephone number is (800) 981-7183.

Our capital expenditures for the years ended December 31, 2023 and 2022 were £0.1 million and £0.2 million, respectively. These capital expenditures primarily consisted of property, plant and equipment, computer equipment and office equipment 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.tcbiopharm.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.

Business Strategy

We have taken a step-wise approach to clinical development and commercialization. To achieve this, we have made the clinical transition from autologous GD-Ts to allogeneic GD-Ts to CAR-modified allogeneic GD-Ts. Our commercialization strategy is to introduce products firstly in blood cancers (AML initially) and then solid tumor indications.

Our strategic objective is to build a global therapeutic business with an extensive portfolio of GD-T cell-based products with the potential to significantly improve the outcomes of patients with cancer and infectious disease. In order to achieve our objective, we are focused on delivering success in the following areas:

Progress unmodified GD-T2s into Phase 2/3 clinical trials for the treatment of blood cancers

Having generated meaningful clinical data showing our product is well-tolerated in late-stage AML patients with no remaining treatment options, we commenced phase 2b-into pivotal (phase 3) clinical studies under the trial name ‘ACHIEVE’, with OmnImmune® during 2022 in AML patients who have failed to respond adequately to induction therapy. The aim is to provide a form of salvage therapy which will either stabilize the patient, thereby preventing disease progression, or delay the requirement for human stem cell transplant. Our initial trial centers are in the UK and we are currently dosing patients in this trial. Working on the premise that other blood cancers should respond to GD-Ts in a similar manner to AML, TCB plans to conduct clinical studies for OmnImmune® in other hematological malignancies in future.

OmnImmune® clinical program

Our OmnImmune® clinical program is an example of our stepwise approach to clinical development. The initial phase 1b/2a trials were undertaken using fresh cell-based product under the program number TCB002. For ease of reference, when discussing that specific trial, we refer the program as OmnImmune® (TCB002). The phase 2b-into pivotal (phase 3) clinical studies are using a frozen cell-based product under the program number TCB008-001. When discussing that specific trial, we refer the program as OmnImmune® (TCB008-001).

Unmodified GD-T2s for use in the treatment of infectious disease

Gamma-delta T cells are dysfunctional in patients with many severe viral diseases and TCB anticipates that its unmodified gamma delta T cell therapy platform will be used in due course to treat viral infections as well as cancers under the name ImmuniStim®. For example, during 2022 TCB developed a clinical trial protocol to treat patients with COVID 19. Because of the progress of the disease and absence of appropriate trial patients this trial is not currently being progressed, although we expect to continue our infectious disease program in future.

Progress CAR-modified GD-Ts into Phase 1 clinical trials for treatment of solid tumors

TCB aims to treat solid cancers using its patented co-stimulatory GD-T and is currently undergoing pre-clinical work to determine the most appropriate CAR construct and target indication.

Grow our business operations to support the increasing number of clinical-phase products in development

We believe that our existing cell and gene manufacturing facility in the UK has the capacity to support our committed clinical development plans. We plan to continue to build upon this to support expansion of our product pipelines to new assets and to grow our clinical team. We also will work closely with vendors to embrace emerging technologies in our manufacturing operations that are appropriate and optimized for our products to continually improve the quality and efficiency of our manufacturing systems. We believe that maintaining in-house control of these activities is critical to effective and efficient progression and we will continue to seek to build integrated business functions where possible.

Apply our discovery engine to target further diseases and add additional functionality to our products

As a platform technology, our co-stimulatory CAR-T GD-T cell system has a wealth of potential options to build added functionality into our cell-based platform. We plan to continue to innovate and partner in the field to augment our drug products and introduce next generation attributes. We also plan to continue to innovate our manufacturing and supply chains to efficiently scale our processes and simplify the interface with patients and healthcare professionals, whilst continually seeking to reduce manufacturing costs to improve patient access.

Expand our intellectual property portfolio and acquire additional technologies to augment our strong IP position

We intend to continue building on our technology platform, comprised of intellectual property, proprietary methods and know-how in the field of GD-T cells. These assets form the foundation for our ability, not only to strengthen our product pipeline, but also to successfully defend and expand our position as a leader in the field of GD-T based immune-oncology.

Our Pipeline

What are gamma delta T cells?

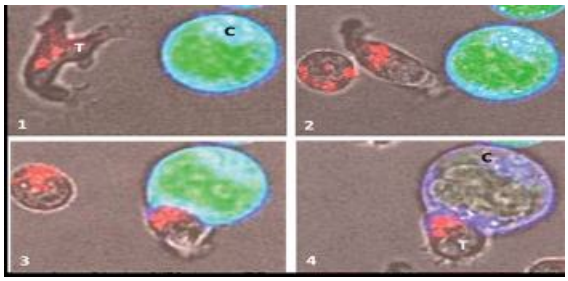
The immune system plays an important role in targeting and destroying cancer cells. One component has evolved to scan the body for diseased cells and eradicate them. In humans, GD-Ts arise as a number of different subtypes, defined by the sequence of the gamma and delta chains of the T-cell receptor (TCR) on the cell surface. The gammadelta2 (GD-T2) subtype typically is the most abundant of these cells in healthy humans, and its TCR- of anti-cancer immunity is GD-T cells – a type of white blood cell

that express a variety of innate receptors, which mediated signaling has been fully characterized by researchers.

Virally-infected or cancerous cells become stressed and accumulate cell surface phosphoantigens (isopentenyl pyrophosphate – IPP's) which are recognized by GD-T2 cells. Our proprietary technology platform includes the manufacturing of unmodified and genetically modified (CAR-T) GD-T cells as therapeutic candidates for use in clinical trials and commercialization. Almost all aspects of the value-chain from product manufacture, quality systems, clinical and regulatory are operated in-house by TC BioPharm. We believe this is one of our core competitive advantages, which we believe will contribute materially to our ability to overcome the challenging nature of developing new products.

Human lymphocytes comprise two groups of cells, B cells that generate antibodies for humoral immunity, and T cells that are responsible for cellular immune responses. In healthy individuals, GD-T cells generally represent between 1% and 10% of peripheral blood T lymphocytes and present one of the first lines of defense against a wide range of bacterial and viral pathogens, as well as surveillance for cancerous cells. GD-T cells have the ability to regulate the initial immune response in several ways, including recruitment of other immune cells such as neutrophils, dendritic cells and macrophages through production of various chemokines (Kirby *et al*., 2007). Depletion of GD-T cells leads to impaired host defense to lung infections, for example (Moore *et al*., 2000; Lockhart *et al*., 2006). The predominant subset of GD-T cells in the blood is the GD-T2, which mediates a variety of immune responses by direct cytolysis of cancer cells and infected cells, development of memory phenotypes and modulation of other immune cells. The gammadelta1 (GD-T1) is a functionally distinct subset of GD-T cells, which are a predominantly tissue resident population. GD-T1s are less well characterized, but their cytotoxic function also has been described in different liquid and solid tumors (Siegers & Lamb, 2014).

Both subsets of GD-T cells are thought to play a role in autoimmune disorders such as celiac disease, rheumatoid arthritis, autoimmune polyglandular syndrome and sarcoidosis where such lymphocytes are seen to accumulate in high numbers.



GD-T cell killing a cancer cell.

(1) A human GD-T (labelled 'T') identifies and scans (2) the surface of a cancer cell (labelled 'C'). On contact with the cancer cell (3) the GD-T releases perforin granules (stained red) into the cancer cell, rupturing its membrane (4) destroying the cancer cell (adapted from – Enc Life Sci, Jul-2007).

How can GD-Ts be used to treat disease?

Cellular immunotherapy is a form of treatment that harnesses the cells of the immune system to combat disease and is one of the most actively pursued areas of research by biotechnology and pharmaceutical companies today. Interest in immunotherapy is largely driven by recent compelling efficacy data in cancers and by the potential to achieve a cure or functional cure for some patients. While the field of immunotherapy in cancer, in general, has achieved proof of concept and yielded significant durable responses in multiple tumor types, there remain major tumor types such as colon, breast, and prostate cancers as well as patient groups within responsive tumors, that do not respond to current immunotherapy treatments. One theory to explain this non-responsiveness is that certain tumors require direct immune stimulation. T cell-based technologies seek to deliver activated T cells towards malignancies to initiate an immune response. The primary challenges in the field have been to couple an acceptable efficacy and safety profile to successfully target solid tumors.

Adoptive T cell transfer typically involves administration of autologous, allogeneic, or genetically-modified T cells (see footer below) into a recipient host with the specific goal of boosting or transferring enhanced immunologic functionality. One of the most advanced cell-based approaches – chimeric antigen receptor modified T cells (CAR-T) – has gained momentum. In a recent study, patients with refractory B cell acute lymphoblastic leukemia were treated with autologous genetically-modified T cells, with almost 90% of patients showing a marked improvement (Pan *et al.,* 2017*)*. Although the treatment is showing promise for specific tumor types, the safety profile remains a concern, as serious adverse events have previously been reported following CAR-T therapy (Grigor *et al.,* 2017). As a consequence of safety issues related to this approach, regulatory approval may be more complex for this genetically modified T cell therapy which effectively has two 'starting materials' – (i) the cellular component, and (ii) a lentiviral vector. The therapeutic premise is well-established – T cells are transduced with a viral vector encoding a chimeric antigen receptor capable of recognizing cancer-specific antigens, for example, CD19 which is commonly expressed on several tumors such as myeloma and B cell lymphomas. Transduction is the process by which DNA is transferred from one cell to another by a virus; in this specific case DNA is introduced via a viral vector (a tool commonly used by molecular biologists to deliver genetic material).

Following transduction, the T cells are genetically primed to recognize and kill specific tumor cells expressing the target antigen. The process involves extracting a patient's T cells (or growing an allogeneic T cell bank), transfecting the cells with a gene for a chimeric-antigen-receptor (CAR), and re-infusing transfected T cells into the patients. The use of cancer-specific cell therapies has gained momentum as several companies demonstrated that genetically modified CAR-T cells are efficacious when directed against blood tumors. These breakthrough findings have moved cell-based immunotherapy into the forefront of clinical oncology with two drugs now in the market.

T lymphocytes have long been known to play an important role in cancer suppression and modulation of tumor growth and numerous experimental studies have demonstrated the anti-cancer potential of GD-T lymphocytes. Indeed, GD-T cells can recognize a number of specific tumor-associated molecules including non-peptidic antigens (IPP's – isopentenyl pyrophosphate) and immune surveillance stress signals (such as HSP60/70, MICA, MICB, and ULBP) present on the surface of transformed cells. The GD-T cell overexpresses IL-2 receptors and this cytokine is necessary to activate them (Kjeldsen-Kragh, 1993). On recognizing a tumor cell, GD-T cells exert their anti-cancer properties *via* release of both perforin and of granzyme, a serine protease which enters the target cell to trigger cell death (apoptosis). Our research efforts are focused entirely on targeting tumors in ways that may result in an improved therapeutic index and that have potential applications in solid tumors as well as hematological malignancies. In contrast to conventional AB CAR-T cells, our GD-T cell technology provides greater specificity in targeting tumors through recognition of IPP-expressing cells, whilst avoiding on-target, off-tumor effects on healthy tissue lacking in IPPs.

Liquid cancers

For cell therapies to be effective several parameters need to be addressed. These include (i) viability, (ii) homing to the tumor, (iii) persistence at the tumor, and (iv) target-specificity.

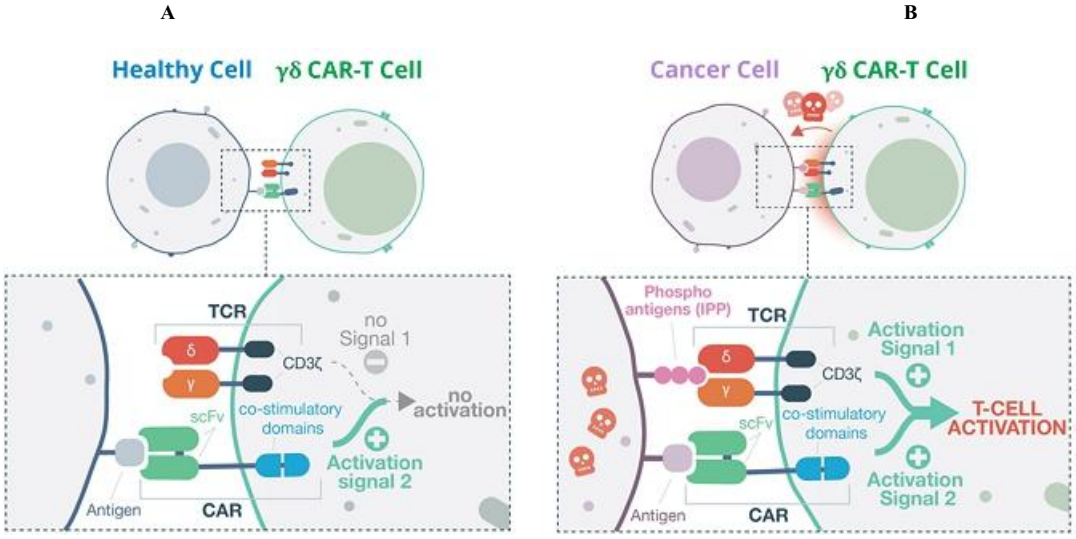
Use of unmodified GD-Ts to treat blood cancers addresses all the above factors. We believe that (i) we have demonstrated therapeutic cells remain viable when injected into the bloodstream of cancer patients; (ii) our research shows GD-Ts injected into the bloodstream remain in-situ; and (iii) they persist for up to 100 days after administration. Moreover, we believe we have demonstrated that certain late-stage blood cancer patients treated with multiple GD-T doses have shown significantly positive responses. These findings lead TCB to believe that all patients with similar blood cancers may respond to GD-T cell therapy in a positive manner.

Solid cancers

We believe that it may be necessary to use CAR-T technology (i) to maximize therapeutic cell homing into the solid tumor site, and (ii) to increase GD-T cell persistence by 'tethering' the cell to antigens present on the cancer cell surface.

In order to overcome toxicities seen with conventional CAR-T approaches, we believe that we have developed a 'co-stimulatory' GD-T CAR which will only attack and kill cancerous cells whilst leaving healthy cells unharmed. This is important as many of the current conventional CAR-T therapies cannot distinguish target antigens expressed on healthy cells from those on cancerous cells, which results in various pathologies, including cytokine release syndrome, that in some cases had led to patient death. Such targeting of health cells with conventional CAR-T makes their use in solid cancers difficult, as too much healthy tissue is likely to be destroyed as 'collateral' damage in the treatment process.

The diagram below illustrates how TCB's approach works, using the innate receptors on the GD-T cell surface to act as a 'safety switch' – such receptors are generally not triggered by healthy cells, only by disease markers (IPP's) on the surface of cancerous or virally infected cells.



Co-stimulatory CAR-T: A) No GD-T cell activation in healthy cell. B) GD-T activation and cell-killing in cancer cell.

Autologous cells are derived from 'self', using patients own cells to treat their specific disease

Allogeneic cells are derived from donor material, giving rise to cell banks able to treat numerous patients

Genetically-modified cells are typically engineered with a 'chimeric' receptor to target specific cancer antigens

Commercialization of conventional CAR-T cell therapy has taken decades of high-quality research in academia and industry, and it has provided transformational results for a number of patients with B cell malignancies. However, as noted, there are numerous barriers to widespread adoption, including:

- Severe Toxicities. The significant risk of severe toxicities, especially cytokine release syndrome (CRS) and neurotoxicity occurring up to 3 weeks from treatment. These toxicities have resulted in the need for implementing specific clinical pathways to certify staff and facilities in the administration of the drugs and the management of the toxicities.

- On-target, off tumor toxicities. Conventional CAR-T products have no mechanism for discriminating between diseased and healthy cells. Activation is governed solely by the expression of the target antigen, which can lead to toxicity when the target antigen is expressed on healthy cells. In marketed products targeting CD19 (present in the vast majority of B cells), this can be tolerated as B-cell aplasia, albeit with the need for regular long-term immunoglobulin replacement therapy. However, in experimental CAR-T products targeting other antigens this has been shown to cause serious side-effects, up to and including fatality.

- Complex supply chains associated with autologous treatments. By definition, autologous treatments require the source cells to have been collected from the patient. It therefore requires a personalized supply chain with multiple touch points and the manufacturing process can only ever be performed on a single-patient batch size. This adds complexity to each treatment and has required the introduction of completely new processes and infrastructure in able to commercialize the products.

- Inherent variability of the drug product. Each patient has a different cell population and so the starting material of each manufacturing batch is always variable, leading to variable final product. This can be minimized during pre-screening, which eliminates some patients from treatment, but there are still significant challenges in manufacturing to provide consistent batches of drug products and in understanding which variables are critical to product quality.

- High list price of the products. The need for personalized manufacturing, new supply chain processes and management of acute and chronic toxicities have all contributed to the high prices associated with the first CAR-T products reaching the market. In the USA, Kymriah® has a list price of $475,000 for pediatric ALL, and Yescarta® lists at $373,000 for DLBCL patients. The associated treatment costs and ongoing management can increase this price significantly.

The combination of the co-stimulatory CAR, with GD-T cells, provides TCB with a proprietary platform which we believe addresses the problems with existing CAR-T products in the following ways:

- Using the natural T cell signaling of the GD-T cell will, we believe, result in less risk of hyperactivation and tonic signaling with an overall reduction in the risk of CRS and less exhaustion of the cells.

- The requirement on cell activation remains on the endogenous GD-T cell TCR signal, which detects stress signals associated with cancerous cells, so healthy cells are not targeted for destruction even if the target antigen is expressed and the CAR binds, thus off-tumor toxicity is avoided.

- Manufacturing in batches of high dose numbers, without the complex patient collection of personalized supply chain steps, we believe will result in a dramatic reduction in cost of goods. This will be reflected in a list price which is in line with current biologicals. With the reduced likelihood of associated toxicities, the treatment and management costs should also be significantly lower, and the products can be made available to many more patients as a result.

- The combination of a well-tolerated product and simplified supply chain (by virtue of our proprietary CryoTC freeze-thaw process), we believe, will make the therapy suitable for administration in local oncology centers without patients having to locate in centralized specialist centers of excellence, further reducing financial and logistic barriers to treatment.

- The tolerance of "off tumor" antigen binding without associated toxicity allows for a complete change in the current target identification paradigm. Instead of identifying targets that are exclusively expressed on tumor cells, we believe our co-stimulatory CAR-T approach confers an advantage to select targets that can be highly expressed on tumors and at low levels on healthy tissue. We select targets based on their relative therapeutic index increase in expression, their homogeneity in tumors and the antigen density. This allows us to target significantly more tumor associated antigens and to significantly expand the therapeutic index into higher doses or repeat administration.

- GD-T cells have multiple roles in humans, possessing both innate and adaptive functions. One role is a sentinel surveillance cell, and they are biologically primed to travel through tissue searching for sites of cellular stress. This ability to penetrate tissue makes them advantageous agents for treating solid tumors. We can add additional function to the GD-T cells by using one or more co-stimulatory CAR-T constructs to add targeting to appropriate antigen(s) and to provide armor or strategies to overcome environmental and immune suppression in the tumor microenvironment. Therefore, we believe that the platform offers a promising approach to target the full spectrum of cancer diseases.

Viral infections

GD-Ts are natural killers of virally infected cells, as well as cancerous cells. We believe that our unmodified GD-T therapy offers substantial potential as a first line of attack against future viral pandemics. During the COVID-19 pandemic, we took the opportunity to develop a trial protocol to treat patients with COVID-19, which was approved by the MHRA. We are currently not progressing this trial because of the absence of available patients given the progression of the disease; however we would consider conducting a phase 1b/2a trial if more severe/pathogenic variants emerge and we believe that there is considerable opportunity to deploy our GD-T therapy in the treatment of viral infections, including rapid response treatment of future epidemics and pandemics and selected acute viral infections. Whilst our current focus is to prioritize cancer treatment we will seek opportunities to develop viral treatments either on our own or in partnership in future Numerous peer-reviewed publications have demonstrated that GD-T cells innate killers of cells which have become virally infected. Using Epstein-Barr virus infected cells as an exemplar, TCB has conducted pre-clinical studies to demonstrate that our GMP-compliant manufacturing process results in GD-T with potent anti-viral cytotoxicity

Autologous versus allogeneic

Commercially available cell therapies typically are either autologous or allogeneic. Autologous products are taken from one donor (the patient) and used to treat that same donor (self-to-self), whilst allogeneic products are usually taken from a single donor (not a patient) and used as the starting material to treat a large number of different individuals (patients). GD-T lymphocytes are known to exert their biological effect in a non-MHC restricted manner. This means the potential for graft-versus-host mediated rejection is significantly reduced if allogeneic (non-self) cells are used as a treatment compared with many other immune cell therapies. As many patients with late-stage cancer or severe viral infections are also immunosuppressed, potential for host-mediated rejection of allogeneic cells is also reduced. When compared with autologous variants, commercial benefits of allogenic treatment include the following:

- significant reduction in cost of goods;
- product can be campaign manufactured and stockpiled frozen;
- increased capacity to treat more patients;
- logistics of shipping product are simplified;
- higher doses of (reproducible) product are possible; and
- product is immediately available for acute disorders

Our strategy for developing an allogeneic solution for CAR-T is to select a pathway which will allow us to bring our products to patients as quickly as possible. These concepts build upon decades of previous development in allogeneic cell therapies and have clear understanding of development requirements in terms of manufacturing, clinical and regulatory execution.

Although manufacture of allogeneic cell therapies allows product to be "pharmaceuticalized" by virtue of campaign manufacture and storage, the approach is however not without technical and logistic challenges. To manufacture allogeneic banks, donor cells need to be screened for numerous adventitious agents, including for example, HIV, hepatitis, CMV and syphilis. Additional tumorgenicity testing is required, and assays conducted to ensure the cell bank is free from karyotypic aberrations. In order to overcome any potential for rejection, TCB has developed allogeneic GD-T cell banks that are unlikely to elicit a graft-versus-host (GvH) or host-versus-graft (HvG) immune response.

Donors are screened and selected based on clinically-relevant history and then based on the proliferative capacity and phenotypic character of their GD-Ts, based on a small volume blood draw and in-house assays. In this way, only good quality GD-T cells are selected for repeat apheresis and banking. The banks are HLA-typed and become the starting material for all of the allogeneic CAR-T products. These banks are cryopreserved in our facilities and can later be thawed, genetically engineered with the CAR, activated and expanded into final product, before being frozen again as multiple individual doses of drug product.

Generation of Gamma Delta T cells from IPSC cells

Identification of appropriate donors whilst possible is challenging as only a limited number of batches can be created from a single donation. GD-T cells can be routinely expanded from peripheral blood over 14 days. This provides a short window of opportunity for cell modification/engineering.

Induced pluripotent stem cells (iPSCs) have the potential to overcome these issues because they are capable of unlimited proliferation and multidirectional differentiation. In 2013, several research groups from Japan reported the successful reprogramming of αβT-cells, followed by re-differentiation back to αβT cells (Vizcardo *et al.,* 2013; Nishimura *et al.,* 2013; Themeli *et al.,* 2013). While re-differentiated αβT cells-maintained antigen specificity, they were also characterized by higher proliferation ability than an original T-cell clone.

We hypothesized that GD-T derived iPSCs cells that carry the rearrangements at the TCRG and TCRD gene locus will be able to generate GD-T but not αβT cells.

Furthermore, iPSC cells will provide a vast opportunity for the gene-editing without any time constraints of terminally differentiated cells.

Reprogramming GD-T cells has proven to be a challenge, as these cells are not tolerant of cell sorting. Therefore, GD-T cells can be reprogrammed in a bulk culture with the rest of peripheral blood cells or at the end of 14 days expansion, when the purity of GD-T is highest. After several unsuccessful reprogramming attempts, we have optimized the conditions favoring GD-T cells reprogramming. In the last round of reprogramming >50 clones were created. After extensive analysis of DNA rearrangements in δ- and γ-locus of 5 pre-selected clones, it was confirmed that they are derived from GD-T cells with different TCR sequences.

IPSC technology is an attractive approach for the limitless source of GD-T cells are successful progress in reprogramming has been demonstrated. Further work is now required for the establishment of a GMP compatible T-cell differentiation protocol. Generation of GDT cells from iPSC cells presents TCB with a vast opportunity for scaling without any time constraints of terminally differentiated cells.

Fresh versus frozen product

Commercial and clinical development of cellular therapy products will invariably require cryopreservation and frozen storage of cellular starting materials, intermediates and/or final product.

Optimizing cryopreservation is important to obtaining maximum yield and a consistent end-product. Suboptimal cryopreservation can lead not only to batch-to-batch variation, lowered cellular functionality and reduced cell yield, but also to the potential selection of subpopulations with genetic or epigenetic characteristics divergent from the original cell line.

Regulatory requirements also impact on cryopreservation, requiring a robust and reproducible approach to freezing, storage and thawing of the product. This requires attention to all aspects of the application of low temperatures; from the choice of freezing container and cryoprotectant, the cooling rate employed and its mode of delivery, correct handling of the frozen material during storage and transportation, to eventual thawing of the product by the end-user. Each of these elements influences all of the others to a greater or lesser extent and have been taken into consideration as TCB moves from fresh to cryopreserved cell-based product.

In a submission to UK regulators, we provided batch manufacture and supporting data, and TCB was granted approval to commence treatment of cancer patients using frozen allogeneic product. This represents a significant milestone for TCB, as we pioneer use of cryopreserved-donated cells to treat cancer. Obvious benefits include increased product reproducibility, ability to ship product globally on request and significant economy of scale (through batch manufacture and storage).

Clinical studies – unmodified GD-Ts in blood cancer

Management of acute myeloid leukemia (AML) is based on intensive chemotherapy and/or stem cell transplant, but these therapies lead to high relapse rates amongst treated patients. Particularly for the relapsed/refractory AML population or those who are not eligible for alloHSCT or intensive chemotherapy, the therapy options are limited, and patients are often placed in experimental protocol therapies or palliative care. As a result, there is a need for additional therapies, particularly for these cohorts.

GD-T cells have emerged as a promising therapy due to their ability to specifically target cancer cells. Nonclinical studies performed in AML cell lines suggest that GD-T cells specifically target AML tumor cells and lead to cell lysis in vitro (Kirk *et al.,* 1993). Additionally, in xenotransplantation animal models, GD-T cells obtained from healthy volunteers specifically target AML cells and result in increased survival and diminished tumor burden in NOD mice (Gertner-Dardenne *et al.*, 2012). Similarly, in vitro experiments conducted by TCB further support such findings whilst providing evidence that OmnImmune® (TCB002) specifically targets stress induced cells and effectively kills AML cells lines.

In the clinic, allogeneic treatment in AML patients in the phase 1b/2a trial OmnImmune® (TCB002) has shown our product is well-tolerated with some preliminary evidence of anticancer activity. Firstly, there were no signs of graft vs. host disease (GvHD) following therapy and secondly, CR (complete response) and MLFS (morphologic leukemia free state) were observed. Earlier results with autologous product demonstrated good tolerability. For the allogeneic product, OmnImmune® (TCB002), additional procedures were included to prevent GvHD (e.g. AB T cell depletion). Literature reports were also supportive of the use of OmnImmune® (TCB002) in cancer patients. The phase 1b/2a trial tested OmnImmune® (TCB002) in active relapsed or refractory AML who were not eligible for or did not consent to high dose salvage chemotherapy and/or allogeneic hematopoietic stem cell transplantation (alloHSCT). The trial was conducted to identify a tolerable dose and better understand the safety of this therapy in the chosen indication as well as generate preliminary information on potential clinical benefit. The primary, secondary and exploratory endpoints were as follows:

Primary endpoints:

- Assessment of adverse events (Aes) graded by Common Terminology Criteria for Adverse Events (CTCAE) v5.0, vital signs and evaluation of laboratory parameters
- Incidence of dose-limiting toxicities (DLTs) during the first 28 days after γδ T cell administration.
- Establish Maximum Tolerated Dose (MTD) of OmnImmune®

Secondary endpoints:

- Complete Remission (CR) rate
- Overall survival (OS)
- Quality of life determined by EORTC QLQ-C30 questionnaire

Exploratory endpoints:

- Changes in γδ T cell count and phenotype before and after OmnImmune® infusion

No formal statistical analysis was planned. The incidence of DLTs were to be summarized descriptively by γδ T cells dose for evaluable patients. The recommended dose would be determined as the greatest with an incidence of DLTs no greater than 1/3. All other data including efficacy results were summarized descriptively by γδ T cells dose.

The trial enrolled 8 patients and healthy donors aged >18 years.

Clinical outcome

Seven patients were treated with OmnImmune® (TCB002). The eighth patient could not be dosed because the study was terminated as a result of the COVID-19 pandemic, which prevented the importation of investigational product from Scotland to the Czech Republic. No safety concerns were raised during Safety Review Committee (SRC) meetings. No treatment related Serious Adverse Reactions (SARs) were reported in any of the patients who were enrolled in the trial. No grade 3≥ OmnImmune®

(TCB002) treatment related toxicities were noted in any of the treated patients. No dose-limiting toxicities were observed and no emergency safety measures have occurred for any subjects receiving OmnImmune® (TCB002). Two patients at 28 days post-treatment achieved a CR (one patient) or MLFS (one patient); another patient was classified as attaining stable disease with > 50% reduction in bone marrow blast count; one additional patient exhibited reduction in blast levels at 14 days; and one patient had disease progression (see table below). One patient (PRA1-5003) died 21 days after TCB002 due to bilateral pneumonia, determined unrelated to study medication. One patient (PRA1-5010) was withdrawn because of the COVD-19 pandemic before bone marrow aspiration on day 28 post-treatment. These preliminary indications of anticancer activity were not expected given the refractory profile of the enrolled patients.

The EORTC QLQ-C30 questionnaire resulted in scoring from six of the seven patients dosed with OmnImmune® (TCB002) for varying periods of time depending on their study duration. At 7 days post dosing, the average QoL score from six patients had decreased from 55.7 to 47.2 out of a possible maximum of 100. This negative impact on QoL reflects the well characterized side effects of preconditioning therapy with cyclophosphamide and fludarabine given between 6 and 2 days prior to OmnImmune® (TCB002) administration. The score remained lower in the four patients assessed at 28 days at a level of 50.0. In the two patients (one CR and one MLFS) who were assessed at the end of the study (week 24), both had recovered to an improved QoL score, each of 67.0.

	PRA1-5002	PRA1-5006	PRA1-5007*	PRA1-5008	PRA1-5009
Initial Dose	$1x10^6$ cells/kg (total dose 6.1×10^7)	$1x10^6$ cells/kg (total dose 7.0×10^7)	$1x10^7$ cells/kg (total dose 7×10^8)	$1x10^7$ cells/kg (total dose 6.5×10^8)	$1x10^7$ cells/kg (total dose 8.5×10^8)
Preliminary Data	**Blast cell reduction:** 62.5% on treatment 28% 14 days post-treat	**Blast cell reduction:** 51% on treatment 8% 14 days post-treat	**Blast cell reduction:** 9% on treatment 4.5% 14 days post-treat	**Blast cell reduction:** 28% on treatment** 7% 14 days post-treat**	**Blast cell reduction:** 66% on treatment 38% 14 days post-treat
	10% on D28 (COMPLETE RESPONSE)* **	**2.6% on D28 (COMPLETE RESPONSE)*** **	**3.6% on D28 (COMPLETE RESPONSE)**	**MET 1° ENDPOINT (WITHDRAWN SEPSIS)**	**Study on hold (COVID-19)**

* PRA1-5007 was 4th line of treatment, relapsed refractory with low-blast count AML (LBC-AML).
Counts shown in bone marrow - peripheral blood blast count was 2.5% on treatment, 0% at day 14 and D28.
Patient PRA1-5007 achieved complete remission by D28.
** Peripheral blood (not bone marrow).
*** CRi, bone marrow response

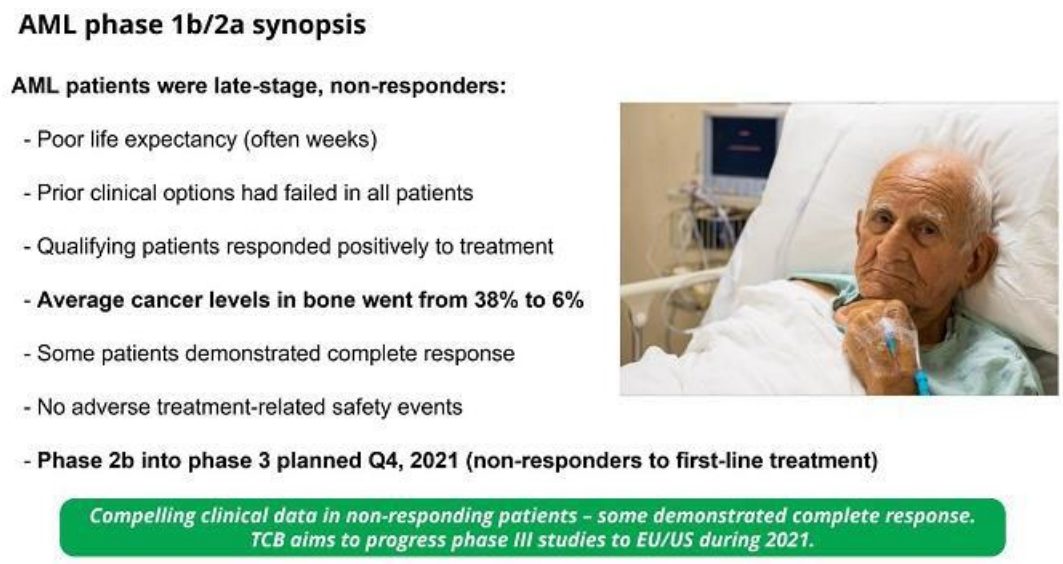
FDA Orphan Drug Designation

About 60 million people living in the European Union (EU) and USA suffer from a rare disease. The European Medicines Agency (EMA) and FDA play a central role in facilitating the development and authorization of medicines for rare diseases, which are termed 'orphan medicines' in the medical world. Developing medicines intended for small numbers of patients has little commercial incentive under normal market conditions. Therefore, the EU and USA offer a range of incentives to encourage the development of designated orphan medicines.

The general therapeutic strategy for the treatment of AML has not changed substantially over the past 30 years. Excluding APL (which should be treated with trans-retinoic acid), AML management is based primarily on induction, incorporating an anthracycline and cytarabine, and consolidation therapy, and/or allogeneic Hematopoietic Stem Cell Transplantation (alloHSCT). Induction/consolidation therapy leads to high CRs rates in those who are eligible for treatment and present a favorable risk profile.

Several novel agents are in various stages of development for the treatment of AML. Novel approaches include antibody-based immunotherapy and adoptive cell therapy that aim to improve anti-leukemia T cell function, such as the therapies developed by TCB (OmnImmune®).

OmnImmune® (TCB002) was initially studied in patients with active relapsed or refractory AML who are not eligible or do not consent to high dose salvage chemotherapy and/or alloHSCT. In July 2019, OmnImmune® (TCB002) was granted 'orphan medicine' status from the FDA for Acute Myeloid Leukemia (AML). TCB intends to conduct a further clinical phase 2/3 study (OmnImmune® (TCB008-001)) in 2021/2 aimed at treating earlier stage AML patients.



Summary of TCB's phase 1b/2a clinical trial in patients with fourth-line-of-treatment acute myeloid leukemia. Subsequent to the completion of this study TCB commenced phase 2b into 3 (pivotal) patient treatment during H1, 2022.

Pipeline and plan

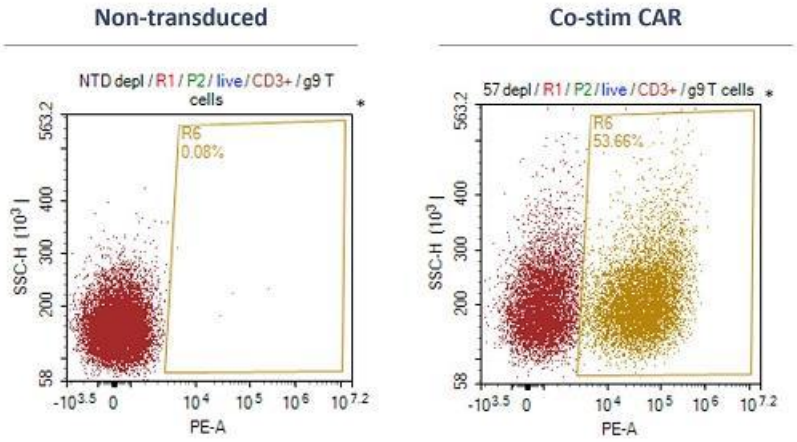
Our future pipeline is focused on treating liquid cancers with our unmodified GD-T therapies and the treatment of solid cancers with next-generation allogeneic GD-T CAR-T therapies.

Our unmodified cell therapy, used in the treatment of Acute Myeloid Leukemia, is supplied under the name OmnImmune.

OmnImmune® is an allogeneic unmodified GD-T (GD-T2) cell product. Donor-derived GD-T cells for proliferative capacity, were activated and expanded in our manufacturing facility before being infused into the patient as part of our OmnImmune® (TCB002) phase 1 trial. This trial was completed in H1 2020 at the Institute of Hematology and Blood Transfusion in Prague, Czech Republic. Having generated meaningful clinical data showing our product is well-tolerated in late-stage AML patients with no remaining treatment options, TCB commenced a phase 2b-into pivotal (phase 3) clinical studies (with OmnImmune®) during 2022 in AML patients who have failed to respond adequately to induction therapy. The aim is to provide a form of salvage therapy which will either stabilize the patient, thereby preventing disease progression, or delay the requirement for human stem cell transplant. Our initial trial centers are in the UK. Working on the premise that other blood cancers should respond to GD-Ts in a similar manner to AML, TCB plans to conduct clinical studies for OmnImmune® in other hematological malignancies in future. The initial phase 1b/2a trials were undertaken using fresh cell-based product under the program number TCB002. For ease of reference, when discussing that specific trial, we refer the program as OmnImmune® (TCB002). The subsequent planned phase 2b-into pivotal (phase 3) clinical studies uses a frozen cell-based product under the program number TCB008-001. When discussing that specific trial, we refer the program as OmnImmune®.

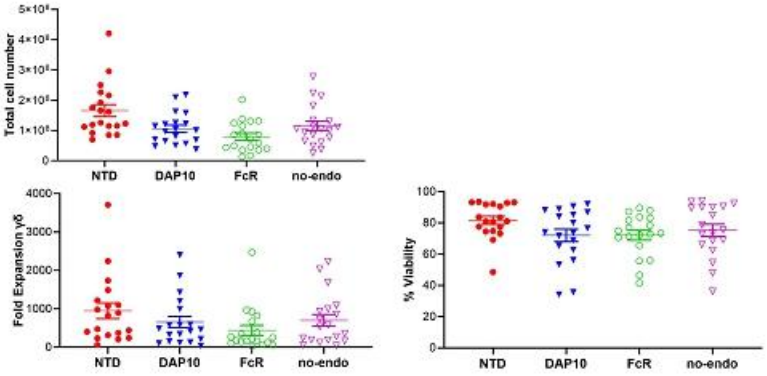
We plan to develop a range of allogeneic co-stimulatory GD-T CAR pre-clinical drug candidates which will target antigens expressed on a number of solid tumor types.

TCB has generated in-vitro preclinical data as part of our CAR-T program which demonstrated that GD-Ts are very high purity and can be CAR-transduced with high efficiency (see diagram below). Gamma delta cell purity and transduction efficiency have been measured using flow cytometry. CAR positive cells were measured by a detection reagent labelled with the fluorophore Phycoerythrin (PE). Flow cytometry analysis used the parameters of side scatter height (SSC-H) and PE area (PE-A) to define the cell populations. This is demonstrated in the figure below comparing non-transduced (NTD) and transduction with a co-stimulatory CAR construct (co-stim CAR).



CAR Expression	0%	54%
γδ T Cell Purity	99%	99%

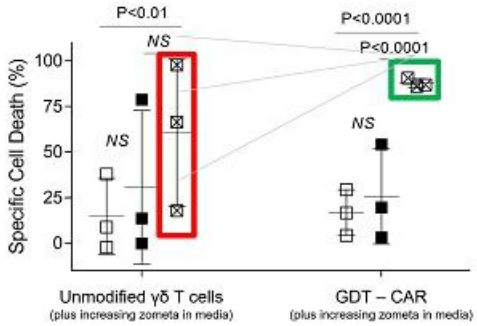
We have also demonstrated that following transduction with different CAR constructs, GD-T's can be effectively and reproducibly expanded in-vitro whilst exhibiting increased cytotoxicity in a zoledronate-dependent manner (see diagrams below – zoledronate-dependency reflects TCB's proprietary process for commercial expansion of GD-T's). The CAR constructs contained different endodomains including DNAX-activating protein 10 (DAP-10) and the high affinity IgE receptor (FcR) with no endodomain (no-endo) and non-transduced (NTD) as controls. These data outline the key preclinical parameters investigated in advance of progressing our CAR-T products into clinical trials. TCB has engaged with UK regulators to discuss the design of GD-T CAR phase1b/2a clinical studies (specifically relating to patient dosing and quality systems).



PBMCs from multiple donors were initiated into culture and γδ T cells expansion stimulated by zoledronic acid. On day 2 of expansion, cells were transduced with LVV to deliver the indicated CAR constructs. After routine feeding through the expansion process, cells were harvested on day 14 and the number, purity and viability of γδ T cells evaluated. Data present a compilation of experiments across multiple individual donors (N=9; n=1-5)

Peripheral blood mononuclear cells (PBMCs) were initiated into culture and GD-T cells expansion stimulated by zoledronic acid. On day 2 of expansion, cells were transduced with lentiviral vectors (LVV) to deliver the indicated CAR constructs. After routine feeding through the expansion process, cells were harvested on day 14 and the total cell number, fold expansion and viability of GD-T cells evaluated. Data present a compilation of experiments across multiple individual donors (N=9; n=1-5).

- GD-T cells taken from 3 donors
- High-dose zometa + CAR significantly increased target cell killing and reproducibility between donors



Manufacturing

Unlike many pre-clinical and early clinical stage biotech companies that rely on outsourcing key manufacturing and development functions with consequent complex and expensive supply chains and delays in delivery and execution, we have built a world-class fully integrated GMP grade specialist GD-T manufacturing center in Glasgow, Scotland. This facility undertakes all key functions associated with our GD-T cell development, testing, quality assurance, product manufacture, clinical trial recruitment, management design, support and interaction with regulators. This has resulted in rapid, focused development; highly efficient cost control;, controlled supply chain; speed of development and clinical delivery. We employ over 80 highly qualified people at our facility. The inspiration to create a fully integrated facility came from our founders' vision and considerable experience in cell therapy.

All advanced therapy medicinal products in the UK must be manufactured by law under a manufacturer's license granted by the MHRA TCB received its Manufacturer's Authorisation for Investigational Medicinal Products MIA (IMP) from the MHRA in January 2015 (license number MIA (IMP) 42803). In April 2016, the MHRA granted the 'Specials' license to TCB as well as approving the facility for ongoing GMP compliance, which permits the manufacture and release of Advanced Therapy Medicinal Products (ATMPs) for use in clinical trials.

The backbone of our company is TCB's Quality Management System, which TCB based on the principles of the current GMP as described in the 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors' and EudraLex Volume 4 as revised. This is achieved by the application of a Quality Management System based around the requirements of ICH Q10 and the EU GMP Guide, which address factors affecting the desired quality, namely the personnel, facilities, equipment, materials, processes, procedures training, vendor selection and approval, User Requirement Specification (URS) qualification and validation of assays and systems and the record keeping. All personnel joining TCB undergo rigorous training on everything from GMP through to formalized systems for measuring and evaluating risk.

*MHRA approved GMP compliant (last inspection December 2020 – observations only)

TCB's manufacturing facilities are equipped with two Class B clean rooms with space secured for future expansion for production of our products as it progresses from phase I to phase III clinical trials. The facility is also equipped with Development and Quality control testing laboratories together and ample stores for goods inwards and product release plus storage for intermediate and final product. Equipment is controlled and monitored through a Management Information System with 24/7 monitoring. All laboratory equipment undergoes a formal URS and once installed undergoes full qualification prior to it being put into routine use.

TCB's Quality Control team are responsible for the majority of release testing for our products. The Quality Control departments (analytical and microbiology) are responsible for product characterization using bespoke phenotyping and potency assays, safety testing assays and final release of the product to the clinic. In-house testing within TCB's Quality Control laboratories eliminates the necessity for third party involvement, resulting in reduced costs and gaining full control of scheduling. The Quality Control departments remit also extends to the microbiological monitoring of the facility to measure, assess and control the exceptionally high levels of sterility required within the aseptic manufacturing suites. Extensively equipped Quality Control microbial laboratories allow environmental monitoring of the manufacturing cleanrooms to GMP standards. The laboratories house incubators, biological safety cabinets, centrifuges, fridges, freezers, air and particle monitors.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any GD-T cell therapeutic candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future. We believe our advanced clinical products in allogeneic and unmodified GD-Ts provide us a first mover advantage in oncology and viral indications. Our continued efforts in advancing our modified platform technologies, along with our efforts in banked GD-Ts, are in direct competition with a number of public and private companies in the cell therapy space.

TC BioPharm is part of a growing number of companies commercially active in the cellular immunotherapy space. Such companies developing call-based products include AdicetBio who presented phase 1 data from patients with non-Hodgkin lymphoma using allogeneic GDT-1's modified with a CAR against CD20 – published initial results documented safety and CR/PR in some patients. Other companies include Allogene who are using various CAR-modified allogeneic alpha-beta cells to treat non-Hodgkin lymphoma, multiple myeloma, acute myeloid leukemia and renal cell carcinoma; Autolus who are conducting clinical studies using autologous alpha-beta T cells using

CAR's directed against either CD19/22 or CD20, listed indications include acute lymphoblastic leukemia, B cell non-Hodgkin lymphomas and chronic lymphoblastic leukemia; and In8Bio who have several ongoing phase 1 and 2 clinical programs including an autologous DRI resistant to alkylating agents for treating glioblastoma and an allogeneic product for treating patients with acute leukemia, In8Bio also have a bespoke GDT therapy for AML derived from hematopoietic stem cell transplantation. Apart from TCB who manufacture cell-based product in-house, we believe the above companies contract-out GMP formulation of clinical product to third-party organizations.

Commercial leaders in the CAR-T space are Novartis AG (Basel, Switzerland) and Gilead (Foster City, CA). Both of these companies market autologous CD19-targeted AB CAR-T products. Bristol Myers Squibb (New York, NY) has obtained approval for its CD19-directed CAR-T. Via third party collaborations, all three of the commercial leaders in autologous CAR-T, have accessed gene editing technology with a view to creating allogeneic products. Novartis have partnered with Intellia (Cambridge, MA), Gilead have an agreement with Sangamo Therapeutics (Richmond, CA) and Bristol Myers Squibb have an agreement with Editas Medicine (Cambridge, MA).

We do not believe that any of these competitors will offer the same commercial proposition as our GD-T cell therapeutic candidates due to our:

- Ownership of foundation IP of the co-stimulatory CAR technology within GD-Ts.
- First-mover advantage in the field of modified GD-Ts as therapeutics.
- Ability to GMP manufacture large numbers of modified GD-T cells to a high purity in a cost-effective manner.
- Established banks of allogeneic products which may be used in future (following appropriate regulatory approvals) to treat both cancer and severe viral disease.
- The potential to create CAR-T therapies with significantly improved safety profile, suitable for widespread market adoption.
- Experience of, and in-house management of, our clinical trial programs.
- Pipeline development strategy and screening tools to develop a deep pipeline of platform products for a range of diseases.

Our Strengths

Our clinical trials have provided very strong evidence of drug-toleration and some preliminary evidence of clinical benefit.

Our clinical trial of TCB001 involved treatment of patients with autologous unmodified GD-Ts. In a phase 1b/2a dose-ranging safety study (maximum total dose $30x10^9$ cells) we saw no evidence of drug-related severe adverse events. A total of eight patients were treated with escalating doses of TCB001, and no treatment-related toxicities were reported during the full six-week therapeutic course. Data from OmnImmune® (TCB002) suggests an excellent tolerability, with no observed Host versus Graft Disease (HvGD) and some preliminary indication of clinical benefit. OmnImmune® (TCB002) has been granted Orphan Drug Designation by the FDA.

Our CAR-T platform is centered on development of safer and more widely applicable therapeutic candidates and associated process and manufacturing capabilities.

Our proprietary co-stimulatory CAR-T technology platform covers identification of target cancer antigens, successful design and engineering of target sequences, preclinical safety testing and optimized manufacturing processes suitable for producing therapeutic candidates for use in clinical trials and commercialization. We believe the platform will enable development of additional GD-T cell therapeutic candidates targeting cancers that have previously been difficult to treat. We believe the products will be demonstrably safer than the current generation of AB T cell CAR-T products because they will not attack healthy non-cancerous cells and augment the natural biological process rather than bypassing it.

We have identified a large and growing pool of cancer targets for which we can develop additional therapeutic candidates.

We have identified over 20 antigens that are preferentially expressed in cancer cells and have established ongoing research programs to develop several of these into our GD-T platform. Within the terms of our agreement, bluebird bio, we have first right of refusal on a further three oncology targets. Each antigen target presents an opportunity to target many cancer types and therefore presents multiple potential represents a development, collaboration and/or an out-licensing opportunity as each target could be used to target specific cancer types. Growing the pipeline of products built on our co-stimulatory CAR-T and reaching patients is our priority.

We have historically entered collaborative arrangements with partners (bluebird bio, Inc (now 2seventybio). (USA) and Nipro Corporation (Japan), which involve funded or partly funded preclinical collaboration. It is uncertain at this time whether TCB will receive any significant revenues from these collaborations.

We retain control of key business elements, such as product manufacture and clinical research.

Whilst many companies contract out product manufacture, quality systems and clinical trial management, we have elected to build these skills in-house. TC BioPharm has a GMP (Good Manufacturing Practice) cleanroom facility where our products are manufactured. We also retain all the quality support systems such as product testing and release of final product to the clinic. Keeping these systems in-house allows the Company to control all aspects of the manufacturing process whilst significantly reducing costs of goods (CoGs). Further saving on costs are accrued by in-house manufacture, as contract manufacturing organizations (CMOs) will typically charge several times more than the actual costs to maintain their profit margins. Rather than fully outsource our clinical trial management, data management and pharmacovigilance, we maintain an inhouse clinical team that partners with a contract clinical research organization (CRO) for data management and pharmacovigilance services. The inhouse clinical team conducts and manages our own clinical trials in-house. In addition to significant cost savings, this allows us to build a strong working relationship with physicians who are treating the cancer patients; we believe this is key to successful product development as the physicians participating in our clinical studies will also be our future customers. We believe that retaining control of key elements of our business such as GMP manufacture and clinical operations, has allowed TC BioPharm to move quickly and efficiently since incorporation.

We continue to file new patent applications from new in-house product development, and have a strong growing intellectual property portfolio to protect our products and proprietary platform.

We have a strong intellectual property portfolio covering the key aspects of our manufacturing processes and product platforms. Our in-house product development team are dedicated to developing new therapeutic candidates and optimizing current manufacturing processes. All of our patent families are currently in various stages of the patent approval process, and as leaders in the path towards the commercialization of GD-Ts we hold significant first-mover advantage captured by trade secrets and know-how.

Our policy of developing strategic alliances has and will provide additional support for product development and commercialization.

We believe that strategic alliances, both historic and potential future alliances, have and will provide extensive experience in scale-up and automation, culture media manufacture and post-authorization sales and marketing with regional expertise. Additionally, we expect to use knowledge gained from our collaborations to improve

development pathways for our unpartnered CAR-T therapeutic candidate programs.

We have a highly knowledgeable and experienced management team with extensive industry experience and expertise in the United States and in Europe.

Mr. Kobel joined us as our Chief Executive Officer at the time of our IPO. Bryan brings a US presence to our executive team and over 15 years' experience in Healthcare and Life Sciences capital markets. Martin Thorp, our Chief Financial Officer has over 40 years' experience in implementing capital strategies globally from seed investment to IPO. He was global CEO of Arthur Andersen Corporate Finance based in New York.

Ability to treat patients under the 'Specials' regulatory framework.

European regulations (Regulation 167 of the Human Medicines Regulations 2012) set out the exemption from the requirement for a medicinal product, placed on the market in the UK to hold a marketing authorization. This exemption flows from Article 5(1) of EU Directive 2001/83/EC, which states that a member of the EU may, in accordance with legislation in force and to fulfil special needs, excludes from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorized healthcare professional and for use by an individual patient under his or her direct personal responsibility. Such an unlicensed medicinal product may only be supplied in order to meet the special needs of an individual patient. An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient. Responsibility for deciding whether an individual patient has "special needs" which a licensed product cannot meet should be a matter for the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber responsible for the patient's care.

In terms of time and cost, the 'Specials' scheme is an attractive strategy. We believe that accumulating evidence by this route could lead to rapid and wider product uptake through 'off-label' use.

Intellectual Property

We have a strong portfolio of patents covering manufacture and commercialization of GD-T cell products and their modification *via* CAR-T (summarized below). Our technology platform and clinical programs have enabled us to raise over $100 million in grant, equity and collaboration funding since becoming operational in 2017. This financing has allowed us to enhance and expand our clinical and preclinical programs as well as build our team of world-class scientists.

The following table provides an overview of our core technology platforms, technology assets and competencies across the business. Additional details of our intellectual property portfolio are provided below.

ASSET SUMMARY	ATTRIBUTES
GD-T Vehicle	● Readily available and expanded to high numbers. ● Not MHC-restricted, therefore no graft vs host disease – an allogeneic platform. ● Pre-programmed tropism for infiltration of diseased tissue. ● Multiple modes of innate cytotoxicity and coordinating a wider immune response. ● Clinical tolerability of the allogeneic vehicle demonstrated at high dose level. ● Naturally arising in different subtypes offering a menu of vehicles with unique properties.
Allogeneic Cell Banks	● Donor GD-Ts selection based on highest therapeutic quality. ● Reproducible product with low cost-of-goods compared with autologous (patient-bespoke) therapies, can be frozen-shipped, thawed at clinic. ● Well understood clinical and regulatory pathway to commercialization.
Co-stimulatory CAR-T	● Elimination of off-tumor toxicity. ● Reduction of cytokine release from killing healthy cells. ● Reliance on natural T cell activation and no tonic signaling ● Antigen expression on healthy tissue tolerated – greatly expanded range. ● Ability to use multiple co-stimulatory receptors to add functionality.
Integrated Business Model	● Full control of critical stages of development projects, which increases speed and reliability of development and production, optimizes operations to our specialized products and materially reduces our cost base ● No pass-through or transaction costs form external service providers, which increases efficiency and speed of development and manufacturing and materially reduces our cost base ● In-house clinical management ensures best chance of clinical success and avoids use of very expensive clinical management in early-stage trials, materially reducing our cost base.

The strength of our patents involves complex legal and scientific questions and can be uncertain.

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, including 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 therapeutic products and platform technology, preserve the confidentiality of our know-how and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

Our policy is to seek to protect our proprietary position generally by filing an initial priority filing at the U.K. Intellectual Property Office, or UKIPO. This is followed by the filing of a patent application under the Patent Co-operation Treaty claiming priority from the initial application(s) and then progressing to national applications in, for example, the United States, Europe, Japan, Australia, New Zealand, China and Canada. In each case, we determine the strategy and territories required after discussion with our patent professionals to ensure that we obtain relevant coverage in territories that are commercially important to us and our GD-T therapeutic candidates. We will additionally rely on data exclusivity, market exclusivity and patent term extensions when available, including as relevant exclusivity through orphan or pediatric drug designations. We also rely on trade secrets and know-how relating to our underlying platform technology and therapeutic products. Prior to making any decision on filing any patent application, we consider, with our patent professionals, whether patent protection is the most sensible strategy for protecting the invention concerned or whether the invention should be maintained as confidential.

As of March 22, 2024, we own 16 granted patents and 11 patent applications in 3 families, and have an exclusive license to an additional 1 family of 14 granted patents and 8 patent applications. Consistent with the filing strategy outlined above, all of our applications are either UK applications, PCT applications or national phase applications derived from a corresponding PCT application. All sets of national phase applications include a US application / patent. These patents and patent applications include claims directed to our therapeutic products and platform technology or other manufacturing and process technology to further enable our therapeutic products and manufacturing methods.

WO 2016/166544 (Modified Gamma Delta T Cells and uses thereof). International filing date April 14, 2016, earliest priority date April 15, 2015.

We own patents and patent applications covering a method of treatment for cancer using GD-T cells that express chimeric antigen receptors (CARs). The patent application claims are directed to GD-T cells expressing a co-stimulatory CAR, the advantages of the co-stimulatory CAR by inhibiting on-target, off-tumor activation due to its design, to the method and process of modifying a GD-T cell to express the co-stimulatory CAR, and to medical uses of the modified GD-T cell. A US patent application has issued as a granted patent in the US (US 10881688 B2, expires October 7, 2036 in view of USPTO calculated Patent Term Adjustment (PTA)). Applications have been granted in Australia (AU 2016250211), China (ZL 201680034862.3) Israel (IL 255011), and Japan (JP 6995624) and at the Eurasian Patent Office. National applications remain pending in: Australia, Hong Kong, and the US. A regional patent application is pending before the European Patent Office.

WO 2016/174461 (T cell which expresses a Gamma Delta T cell receptor and a Chimeric Antigen Receptor). International filing date April 29, 2016, earliest priority date April 30, 2015. Expiry date will be April 28, 2036 in most jurisdictions. Further patent term adjustments may apply in the US.

We are the exclusive licensee of patents and patent applications owned by UCL Business plc covering a method of treatment using a T cell which expresses a Gamma Delta T cell receptor and a chimeric antigen receptor. The patent application claims are directed to GD-T cells expressing a co-stimulatory CAR, the advantages of the co-stimulatory CAR by inhibiting on-target, off-tumor activation due to its design, to the method and process of modifying a GD-T cell to express the co-stimulatory CAR, and to medical uses of the modified GD-T cell. National applications have been granted in Australia (AU 2016255611, expires April 28, 2036), Canada (CA2982532), Japan (JP 6986449), Israel (IL 255186), South Africa (ZA 2017/06923), and via the Eurasian regional patent (EA 041081) in Armenia, Azerbaijan, Belarus, Kyrgyzstan, Kazakhstan, Russia, Tajikistan, Turkmenistan. Additional national applications are pending in: Brazil, China, Hong Kong, South Korea, New Zealand, Singapore, and the US. A regional patent application is pending before the European Patent Office.

WO 2016/005752 (Gamma Delta T cells and uses thereof). International filing date July 8, 2015, earliest priority date July 9, 2014. Expiry date for the patent granted in Israel will be July 7, 2035.

We own an Israeli patent and Japanese patent applications covering the method of preparing and using GD-T cells in the allogeneic treatment of subjects suffering from viral infection, fungal infection, protozoal infection or cancer. The patent application claims are directed to the process of providing GD-T cells from a first subject to a second subject (allogeneic transfer).

WO 2019/064030 (Modified CAR-T). International filing date October 1, 2018, earliest priority date September 29, 2017.

We own a US Patent (US11890302) and patent applications covering chimeric antigen receptors comprising an intracellular signaling domain derived from GD-T cell surface receptors. When expressed in GD or natural killer (NK) cells, the resultant CAR-T cells exhibit improved cytotoxicity. National applications are pending in: Hong Kong, Israel, Japan, and South Korea,. A regional patent application is pending before the European Patent Offices.

Platform technology patent applications – We have several other patent applications in the process of being drafted, improving T cell efficacy by modulating PD1 expression, additional methods of expanding GD-T1 gamma-delta T cell populations and improvements to our GD CAR-T platform

Government Regulation and Product Approval

As a biopharmaceutical company, we are subject to extensive regulation. Our product candidates, if approved, will be regulated as biological medicines. With this classification, commercial production of our products will need to occur in registered and licensed facilities in compliance with current Good Manufacturing Practices, or cGMPs, for biologics.

Human immunotherapy products are a new category of therapeutics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a Biologics License Application, or BLA, for marketing authorization.

Government authorities in the United States (at the federal, state and local level) and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, preclinical and clinical testing, manufacturing, quality control, labeling, packaging, storage, record-keeping, promotion, advertising, sale, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Product Development Process

In the United States, the FDA regulates biological products under the Public Health Service Act, or PHSA, and the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters and similar public notice of alleged non-compliance with laws, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be approved for marketing in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as Good Clinical Practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation and submission to the FDA of a Biologics License Application, or BLA, for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP to assure that the facilities, methods and controls used in product manufacture are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current Good Tissue Practices, or GTPs, for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA;

- payment of user fees for FDA review of the BLA; and

- FDA acceptance, review and approval, or licensure, of the BLA, which might include review by an advisory committee, a panel typically consisting of independent clinicians and other experts who provide recommendations as to whether the application should be approved and under what conditions.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations as well as in vitro and animal studies to assess the potential safety and efficacy of the product candidate. After sufficient preclinical testing has been conducted, the conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit an IND to the FDA before clinical testing can begin in the United States. An IND must contain the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature, a proposed clinical protocol, an investigator's brochure, a sample informed consent form, and other materials. Clinical trial protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Some preclinical testing, such as toxicity studies, may continue even after the IND is submitted.

The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials or places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials involving recombinant or synthetic nucleic acid molecules also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent.

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

- *Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition.

- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population, generally at geographically dispersed clinical trial sites. These clinical trials are intended to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk to benefit profile of the product and to provide an adequate basis for product labeling.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board, an independent group of experts that evaluates study data for safety and makes recommendations concerning continuation, modification, or termination of clinical trials, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

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

United States Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all as the FDA has significant discretion to approve or reject the BLA and to require additional preclinical or clinical studies.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for approved biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the biological product, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA GTP regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, recordkeeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the agency decides not to approve the BLA in its then current form, the FDA will issue a Complete Response Letter, which generally outlines the specific deficiencies in the BLA identified by the FDA and may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Even with the submission of additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval is limited to the conditions of use (*e.g.*, patient population, indication) described in the application.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

United States Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements that important safety information and material facts related to the product be disclosed. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative liability.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. We currently are making clinical trial product in our own facilities in Scotland, United Kingdom. In the future, however, we expect to rely, on third parties for the production of commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, with manufacturing processes, or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, complete withdrawal from the market, product recalls, warning letters from the FDA, mandated corrective advertising or communications with doctors, product seizure or detention, injunctions, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

United States Marketing Exclusivity

The Biologics Price Competition and Innovation Act amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. Biosimilars are approved pursuant to an abbreviated pathway whereby applicants need not submit the full slate of preclinical and clinical data, and approval is based in part on the FDA's findings of safety, purity, and potency for the original biologic (i.e., the reference product). Original BLAs are eligible to receive 12 years of exclusivity from the time of first licensure of the product, which prevents the FDA from approving any biosimilars to the reference product through the abbreviated pathway, but does not prevent approval of BLAs that are accompanied by a full data package and that do not rely on the reference product. A biosimilar may be approved if the product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences with the reference product in terms of the safety, purity, and potency.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

United States Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain*regulatory* approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in significant part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payers include federal and state healthcare programs, private managed care organizations, health insurers and other organizations. The process for determining whether a third-party payer will provide coverage for a product may be separate from the process of establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity of and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

Reimbursement may impact the demand for, and/or the price of, any product candidate which obtains marketing approval. Even if coverage and reimbursement is obtained for a given product candidate by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use a product, and physicians may be less likely to prescribe a product, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of the product. Therefore, coverage and adequate reimbursement is critical to new drug product acceptance.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of additional clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The downward pressure on healthcare costs in general, particularly prescription drugs and biologics, has become very intense. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. As a result, increasingly high barriers are being erected to the entry of new products. The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

United States Healthcare Laws Governing Interactions with Healthcare Providers

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws restrict our business activities, including certain marketing practices. These laws include, without limitation, anti-kickback laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The U.S. federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item, good, facility or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the U.S. federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the U.S. federal Anti-Kickback Statute has been violated. Additionally, the intent standard under the U.S. federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, or ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. federal False Claims Act.

Federal civil and criminal false claims laws and civil monetary penalties laws, including the U.S. federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Further, pharmaceutical manufacturers can be held liable under the U.S. federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims.

The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the U.S. federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose certain requirements on "covered entities," including certain healthcare providers, health plans and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their covered subcontractors, relating to the privacy, security, transmission and breach of individually identifiable health information. Further, HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions.

Additionally, the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives.

Additionally, similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union (including health data).

Finally, the majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures. Some states and local jurisdictions require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

United States Healthcare Reform Efforts

A primary trend in the United States healthcare industry and elsewhere is cost containment. Over the last several years, there have been federal and state proposals and legislation enacted regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, and making changes to healthcare financing and the delivery of care in the United States.

There continues to be heightened Congressional scrutiny in the United States of pharmaceutical pricing practices designed to, among other things, bring more transparency in product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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.

In addition, other federal health reform measures have been proposed and adopted in the United States that could impact cell therapy. Most notably, there has been political support for rules related to value-based payment alternatives in the Medicaid program. Medicaid is a jointly run federal and state program that provides health benefits coverage for low-income residents and children. In exchange for broad coverage in Medicaid, drug manufacturers are required to sign a Medicare Drug Rebate agreement which requires them to offer Medicaid programs the "best price" available for a particular product. This "best price" takes into consideration any rebates or concessions manufacturers offer, with some exceptions. The final rule would exempt value-based or outcomes-based payment arrangements from the definition of "best price" which provides manufacturers more flexibility to work with commercial payers and states on innovate payment mechanisms for high-cost cell and gene therapies. While Medicaid is not a significant driver of cell therapy sales it is a bellwether program and one we watch closely.

United States FCPA, the Bribery Act and Other Laws

The FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of

internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

Our operations are also subject to non-U.S. anti-corruption laws such as the Bribery Act. As with the FCPA, these laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as trade control laws.

Failure to comply with the Bribery Act, the FCPA and other anti-corruption laws and trade control laws could subject us to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses.

Review and Approval of New Drug Products in the European Union

In the European Union, medicinal products, including advanced therapy medicinal products, or ATMPs, are subject to extensive pre- and post-market regulation by regulatory authorities at both the European Union and national levels. ATMPs comprise gene therapy products, somatic-cell therapy products and tissue engineered products, which are cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to regenerate, repair or replace a human tissue. We anticipate that our therapy products will be regulated as ATMPs in the European Union. There is legislation at a European Union level relating to the standards of quality and safety for the collection and testing of human blood and blood components for use in cell-based therapies, which could apply to our products. Additionally, there may be local legislation in various European Union Member States, which may be more restrictive than the European Union legislation, and we would need to comply with such legislation to the extent it applies.

EU Clinical Trials

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of ATMPs. The sponsor must take out a clinical trial insurance policy, and in most European Union countries, the sponsor is liable to provide "no fault" compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is to take effect in December 2021, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and European Union-wide regulatory requirements also apply.

During the development of a medicinal product, the EMA and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. In accordance with the EMA's policy, scientific advice will not be legally binding with regard to any future marketing authorization application of the product concerned.

EU Marketing Authorizations

In order to market a new medicinal product in the European Union, a company must submit and obtain approval from regulators of a marketing authorization application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization, or MA, granted by the European Commission that is valid across the EEA (i.e., the European Union as well as Iceland, Liechtenstein and Norway). The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated orphan medicines and (iv) advanced-therapy medicines, such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases. Therefore, the centralized procedure would be mandatory for the products we are developing.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a marketing authorization application is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long-term efficacy and potential adverse reactions of ATMPs. Although these guidelines are not legally binding, we believe that our compliance with them is likely necessary to gain and maintain approval for any of our product candidates.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this is opinion favorable, the Commission may then adopt a decision to grant an MA. In exceptional cases, the CHMP might perform an accelerated review of an MAA in no more than 150 days. This is usually when the product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances". Such authorization is intended for products for which

the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;

- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radiopharmaceutical, by an authorized person; and

- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual reassessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of a marketing authorization of a medicinal product under exceptional circumstances, however, follows the same rules as a "normal" marketing authorization. Thus, a marketing authorization under exceptional circumstances is granted for an initial five years, after which the authorization will become valid indefinitely, unless the EMA decides that safety grounds merit one additional five-year renewal.

The European Commission may also grant a so-called "conditional marketing authorization" prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products), if (i) the risk-benefit balance of the product candidate is positive, (ii) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (iii) the product fulfills an unmet medical need and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

EU Data Exclusivity

Marketing authorization applications for generic medicinal products do not need to include the results of preclinical and clinical trials, but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the European Union. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

EU Pediatric Development

In the European Union, companies developing a new medicinal product must agree to a Pediatric Investigation Plan, or PIP, with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a deferral or waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

EU Post-Approval Controls

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

All new marketing authorization applications must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

EU Pricing and Reimbursement in the European Union

Governments influence the price of medicinal products in the European Union through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU Member States allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom officially withdrew from the European Union on January 31, 2020 ("Brexit"). Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Brexit may influence the attractiveness of the United Kingdom as a place to conduct clinical trials. The European Union's regulatory environment for clinical trials is being harmonized as part of the Clinical Trial Regulations, which come into full effect at the end of 2021, but it is currently unclear as to what extent the United Kingdom will seek to align its regulations with the European Union. Failure of the United Kingdom to closely align its regulations with the EU may have an effect on the cost of conducting clinical trials in the United Kingdom as opposed to other countries and/or make it harder to seek a marketing authorization for our product candidates on the basis of clinical trials conducted in the United Kingdom.

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 a trial site in the United Kingdom without further oversight until January 1, 2022, and to Northern Ireland beyond such date. The United Kingdom is now a "third country" for the purpose of clinical trials that have sites in the EEA. For such trials the sponsor/legal representative must be based in the EEA, and the trial must be registered on the EU Clinical Trials Register (including data on sites outside of the EEA).

The data exclusivity periods in the United Kingdom are currently in line with those in the European Union, but the Trade and Cooperation Agreement provides that the periods for both data and market exclusivity are to be determined by domestic law, and so there could be divergence in the future. It is currently unclear whether the MHRA in the United Kingdom is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive.

Orphan designation in the United Kingdom following Brexit is based on the prevalence of the condition in the United Kingdom as opposed to the current position where prevalence in the European Union is the determinant. It is therefore possible that conditions that are currently designated as orphan conditions in the United Kingdom will no longer be and that conditions that are not currently designated as orphan conditions in the European Union will be designated as such in the United Kingdom.

EU Orphan Drug Designation

The European Medicines Agency (EMA) and FDA play a central role in facilitating the development and authorization of medicines for rare diseases, which are termed 'orphan medicines' in the medical world. In the EU, sponsors who obtain orphan designation benefit from protocol assistance, a type of scientific advice specific for designated orphan medicines, and market exclusivity once the medicine is on the market. Fee reductions are also available depending on the status of the sponsor and the type of service required. When planning the development of their medicinal product, sponsors should consult the relevant scientific guidelines.

The general therapeutic strategy for the treatment of AML has not changed substantially over the past 30 years. Excluding APL (which should be treated with all trans-retinoic acid), AML management is based primarily on induction, incorporating an anthracycline and cytarabine, and consolidation therapy, and/or allogeneic Hematopoietic Stem Cell Transplantation (alloHSCT). Induction/consolidation therapy leads to high CRs rates in those who are eligible for treatment and present a favorable risk profile.

Several novel agents are in various stages of development for the treatment of AML. Novel approaches include antibody-based immunotherapy and adoptive cell therapy that aim to improve anti-leukaemia T cell function, such as the therapies developed by TCB (OmnImmune®). OmnImmune® (TCB002) was initially studied in patients with active relapsed or refractory AML who are not eligible or do not consent to high dose salvage chemotherapy and/or alloHSCT. In July 2019, OmnImmune® (TCB002) was granted 'orphan medicine' status from the FDA for Acute Myeloid Leukaemia (AML). As a follow on to OmnImmune® (TCB002), TCB intends to conduct phase 2b/3 studies to treat earlier stage AML and expects to commence treating patients in these trials (as OmnImmune® (TCB008-001)) in H1 2022.

Legal Proceedings

From time to time, we may be party to litigation that arises in the ordinary course of our business.

In accordance with the terms of a Convertible Loan Note ('Note') on August 9, 2022 (the Conversion Date) the Company issued 183,820 Ordinary Shares and 367,640 listed warrants to the Note holder in full satisfaction of the Note in the aggregate amount of $781,233. The holder filed a claim in the English courts on June 19, 2023 asserting that notice was provided such that the Company should have paid it the value of the Note in cash, rather than by settling it through the issuance of Ordinary Shares and listed warrants. The holder is demanding payment of the face value of the Note, together with interest, (approximately $860,000). The litigation process is in its early stages and is not expected to conclude until late 2024 or later. The Company has retained English solicitors and is contesting the claim in its entirety. The Company believes that it acted correctly under the terms of the Note and has accounted for the transaction on that basis, and that no further amounts are payable to the holder.

Segment Information

We operate in a single operating segment and a single reporting segment. Operating segments are defined as components of an enterprise about which separate financial information is regularly evaluated by the chief operating decision maker function (which is fulfilled by our chief executive officer) in deciding how to allocate resources and in assessing performance. Our chief executive officer allocates resources and assesses performance based upon financial information at the level. Since we operate in one operating segment, all required financial segment information is presented in the financial statements.

Corporate Information

Our corporate headquarters and most of our operations, including our research and manufacturing facilities, are located at Maxim 1, 2 Parklands Way, Holytown, Motherwell, ML1 4WR, United Kingdom. The lease for this space expires February 28, 2029 and covers a total leasable area of approximately 26,300 square feet. We believe that our office facilities and the production and research facilities in the United Kingdom are sufficient to meet our current needs.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Available Information

We maintain a public website at https://tcbiopharm.com and use our website as a routine channel of distribution of company information, including press releases, analyst presentations, and supplemental financial information, as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Our website includes an investors' section through which we make available, free of charge, our Annual Reports on Form 10-K (for the year ended December

31, 2023), our Annual Reports on 20-F (for periods prior to December 31, 2023), Reports on Form 6-K, as well as any amendments to those reports filed or furnished pursuant to the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Accordingly, investors should monitor our website in addition to following press releases, filings with the SEC, and public conference calls and webcasts.

Item 1A. Risk Factors

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties, including those risks discussed at length in the section below titled "Risk Factors." These risks include among others the following:

- We have generated operating losses since inception and expect to continue to generate losses. We may never achieve or maintain profitability. We will continue to require financing to continue to implement our business plan and sustain operations.
- We, as well as our independent registered public accounting firm, in relation to our financial position, have expressed substantial doubt about our ability to continue as a going concern.
- Our lack of any approved products and our limited operating history may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- GD-T cell therapies are a novel approach to treating cancers and infectious diseases, which have development risks and will require us to obtain regulatory approvals for development, testing, commercialization, manufacturing and distribution. We may not achieve all the required regulatory approvals or approvals may not be obtained as timely as needed.
- Because GD-T cell therapies are a novel approach, potential side effects, and long-term efficacy, regulatory approval will require considerable time for trials, data collection, regulatory submissions and funding for the process.
- Enrolling patients in clinical trials may be difficult for many reasons, including high screen failure, GD-T cell proliferation capacity, timing, proximity and availability of clinical sites, perceived risks, and publicity about the success or lack of success in the methods of treatment.
- Because GD-T cell therapies are novel, our research and development and clinical trial results may not support our products intended purposes and regulatory approval. We are heavily dependent on the success of our lead product candidate (OmnImmune®), and intend to seek breakthrough therapy designation for some or all of our other therapeutic candidates in due course.
- Market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments. This class of patient may be limited in number, difficult to locate and service, require special governmental approval, and unable to pay or obtain reimbursement.
- We rely on many third parties for aspects of our product development and commercialization, such as raw material supply, clinical trials, obtaining approvals, aspects of manufacturing, development of additional product candidates and distribution. We may not be able to control these parties and their business practices, such as compliance with good manufacturing requirements or their ability to supply or service us timely, which will likely disrupt our business.
- We face substantial competition: others may discover, develop and/or commercialize competing products before or more successfully than TCB.
- Even if we are able to commercialize any product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies. Commercialized products may not be adopted by the medical profession.
- Because we operate internationally, we are subject to a wide array of regulation of the United Kingdom, European Union and United States. In addition to regulation surrounding new drug development and their manufacture, distribution and use, we will be subject, for example to data protection rules relating to medical records, medical and general privacy laws, environmental laws regarding medical waste, and bribery and corrupt practices law, in addition to all the drug related approval, manufacturing and distribution rules.

- Product liability claims are frequent in drug development of novel therapies and insurance is mandatory and expensive. The inability to obtain insurance may prevent product development and claims may surpass our ability to pay and call into question the efficacy of a product with resulting reputational damage.
- Protecting our intellectual property is paramount in our ability to be able to commercialize our products and generate revenues and investment return for our stockholders. We may not be able to obtain the intellectual property protection we seek due to its cost, requirement to pursue it in many jurisdictions, challenges by others and patent office rejection.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies acting in multiple jurisdictions, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- As part of product development, we may need to license aspects of our research and products from third parties or if our IP is challenged, we may have to seek license accommodation, any of which may be expensive, limited in scope, or unavailable.
- We currently have a limited number of employees, and our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel at all levels.
- We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth including, but not limited to, operating as a public company and taking a therapeutic through to market approval and acceptance.
- We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in achieving and managing our growth, which could disrupt our operations. We expect to require further funding for these expansions of activity.
- We incur substantial costs as a result of operating as a public company in the United States, and our management is required to devote substantial time to required SEC compliance and corporate governance practices.
- If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our business and our stock price.

- Certain of our existing shareholders, members of our board of directors and senior management maintain the ability to exercise significant control over us. The interests of investors may conflict with the interests of these other stockholders.

- Our ADSs provide rights that are different from directly holding our ordinary shares. The outstanding warrants do not have the rights of shareholders until exercised. Our warrants form a substantial part of our capitalization, and they have substantial protective provisions, which may limit our ability to raise capital.

- Future sales, or the possibility of future sales, of a substantial number of our ordinary shares, through the additional deposit of ordinary shares for ADSs, issuances and/or exercises of our warrants, could adversely affect the price of our ADSs or warrants in the market. After any lock up period, a substantial number of our issued and outstanding ordinary shares will be eligible for trading on the public securities market by their being deposited with the depositary for ADSs.

- Shareholder rights and recourse will be governed by and ultimately determined by Scottish and United Kingdom law and judicial process, which in many ways are more limited than United States law and practice. Most of our assets are located in the United Kingdom.

- If we fail to meet the requirements for continued listing on Nasdaq, our ADSs could be delisted from trading, which would decrease the liquidity of our ADSs and our ability to raise additional capital.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses every year since our inception and expect to continue to incur net losses in the future and may never achieve profitability.

We have generated losses since our inception in 2013. Since then, we have devoted substantially all of our resources to research and development efforts relating to our genetically unmodified and genetically engineered GD-T cell candidates, including engaging in activities to manufacture and supply our GD-T cell candidates for clinical trials, conducting initial clinical trials of our lead candidates, general and administrative support for these operations, and protecting our intellectual property. Based on our current plans, we do not expect to generate product or royalty revenues until we obtain marketing approval for, and commercialize, any of our GD-T cell-based candidates.

For the fiscal years ended December 31, 2023 and 2022, we incurred net losses of £5.9 million and £1.3 million, respectively. As of December 31, 2023, we had an accumulated deficit of £38.8 million. We expect to continue incurring significant losses as we continue with our research and development and clinical programs and to incur general and administrative costs associated with our operations. The extent of funding required to develop our product candidates is difficult to estimate given the novel nature of our GD-T cell-based cell therapy candidates and their un-proven route to market. Ultimately, our profitability is dependent upon the successful development, approval, and commercialization of our GD-T cell-based therapeutic candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability and until we do, we will continue to need to raise additional cash.

Our ability to generate revenue from sales of our therapeutic candidates and become profitable depends significantly on our success in a number of factors.

We continue to focus on development activities for our technologies and implementation of the early parts of our business plan. We may never achieve commercial success and continue to operate in the research and development stage, without commercially launching any products at this time. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. Our limited operating history makes it difficult for potential investors to evaluate our potential product candidates, drug therapies or prospective operations and business prospects. As a development stage company, we are subject to all the risks inherent in the initial organization, business development, financing, unexpected expenditures, and complications and delays that often occur in a new business. Investors should evaluate an investment in us in light of the uncertainties encountered by developing companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to attain profitability.

We have no GD-T cell-based therapeutic candidates approved for commercial sale and have not generated any revenue from sales of our GD-T cell-based therapeutic candidates, and do not anticipate generating any revenue from sales of our GD-T cell-based therapeutic candidates until sometime after we receive regulatory approval, if at all, for the commercial sale of a GD-T cell-based therapeutic candidate. We intend to fund future operations through our existing and future collaboration and licensing agreements for other therapeutic targets and through additional equity financings. Our ability to generate revenue and achieve profitability depends on our success in many factors, including:

- completing research regarding, and preclinical and clinical development of, our GD-T cell-based therapeutic candidates;

- obtaining regulatory approvals and marketing authorizations for our GD-T cell-based therapeutic candidates for which we complete clinical trials;

- developing sustainable and scalable manufacturing and supply processes for our GD-T cell-based therapeutic candidates, including establishing and maintaining commercially viable supply relationships with third parties and pursuing our own commercial manufacturing capabilities and infrastructure;

- launching and commercializing GD-T cell-based therapeutic candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;

- obtaining market acceptance of our GD-T cell-based therapeutic candidates as viable treatment options;

- addressing any competing technological and market developments;

- identifying, assessing, acquiring and/or developing new GD-T cell-based therapeutic candidates;

- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

- attracting, hiring and retaining qualified personnel.

Even if one or more of our GD-T cell-based therapeutic candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved GD-T cell-based therapeutic candidate. Our expenses will increase beyond our current expectations if the U.S. Food and Drug Administration, the FDA, or the United Kingdom Medicines and Healthcare products Regulatory Agency, the MHRA, or any other regulatory agency require changes to our manufacturing processes or assays, or for us to perform preclinical programs and clinical or other types of trials in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our GD-T cell-based therapeutic candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the GD-T cell-based therapeutic candidate, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales or supplies of such GD-T cell-based therapeutic candidates, even if approved. If we are not able to generate revenue from the sale of any approved GD-T cell-based therapeutic candidates, we may never become profitable.

If we fail to obtain additional financing as needed, we may be unable to complete the development and commercialization of our GD-T cell-based product candidates.

Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the development of our GD-T cell-based therapeutic candidates, including for clinical trials. We expect to use our operating capital to advance and accelerate the clinical development of our therapeutic candidates, therefore, changing circumstances beyond our control may cause us to increase our spending significantly faster than we currently anticipate, we believe we will require additional capital, likely in significant amounts, for the further development and commercialization of our GD-T cell-based therapeutic candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our GD-T cell-based therapeutic candidates or other research and development initiatives. Our license and supply agreements may also be terminated if we are unable to meet the milestone obligations under these agreements. We could be required to seek collaborators for our GD-T cell-based therapeutic candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our GD-T cell-based therapeutic candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of either of our ADSs or Warrants, or both, to decline.

We, as well as our independent registered public accounting firm, have expressed substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations and negative cash flow raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2023 with respect to this uncertainty.

Our ability to continue as a going concern ultimately is dependent upon our generating cash flow from sales that are sufficient to fund operations or finding adequate financing to support our operations. To date, we have had no product revenues and relied on equity-based financing from the sale of securities subscribed by our founders and related parties and in various private placements, and receipts from collaboration partners. Our research and development plans may not be successful in creating a marketable product, and our business plan may not be successful in achieving a sustainable business and generating revenues. We completed our initial public offering ("IPO") in February 2022, which, together with additional funds that we have raised since then and funds we plan to raise during 2024, we believe will provide funding to enable us to progress our planned clinical trial program in our lead product, *OmnImmune®,* into 2024 and beyond. We have no firm arrangements in place for all the anticipated, required financing to be able to fund our operations during and beyond 2024 and otherwise to implement fully our business plan. If we are unable to continue our operations as planned, we may have to curtail some or all of our business plan and operations. In such case, investors will lose all or a portion of their investment.

We anticipate needing additional financing over the longer term to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all.

The proceeds from our February 2022 IPO, together with additional capital raised since then and funds that we plan to continue to raise during 2024, are expected to provide capital to further develop our drug product candidates and fund our overall business plan until at least the end of 2024. We will require additional capital in the future to fully develop our technologies and potential products to the stage of a commercial launch. We cannot give now any indication of the amount of future funding that we will need or give any assurance that we will be able to obtain all the necessary funding that we may need. We may pursue additional funding through various financing sources, including the private and public sale of our equity and debt securities, licensing fees for our product candidates, joint ventures with capital partners and project type financing. We also may seek government-based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all. If financing is not available on satisfactory terms, we may be unable to pursue further our business plan and we may be unable to continue operations, in which case investors may lose their entire investment. Alternatively, we may consider changes in our business plan that might enable us to achieve aspects of our business objectives and lead to some commercial success with a smaller amount of capital, but we cannot assure that changes in our business plan will result in revenues or maintain value in an investment in the company.

On March 22, 2024, the Group had cash on hand of $1.7 million (£1.4 million), which will not be sufficient to enable the Group to meet the cash requirements required to enable it to conduct its business plan through the going concern period (being to April 1, 2025) ("Going Concern Period"). With existing resources, we expect to be able to fund current operations to May 2024.

Risks Related to Development, Clinical Testing and Commercialization of Our Investigational Therapies and Any Future Therapeutic Candidates

Our GD-T cell therapies represent a novel approach to cancer treatment that could result in heightened regulatory scrutiny, delays in clinical development, or delays in or our ability to achieve regulatory approval or commercialization of our therapeutic candidates.

Our products are novel cancer treatment approaches that carry inherent development risks. We are therefore constantly evaluating and adapting our therapeutic candidates following the results obtained during development work and the ongoing clinical trials. Further development, characterization and evaluation may be required, depending on the results obtained, in particular where such results suggest any potential safety risk for patients. The need to develop further assays, or to modify in any way the protocols related to our therapeutic candidates to improve safety or effectiveness, may delay a clinical program, regulatory approval or commercialization, if approved at all, of any therapeutic candidate. Consequently, this may have a material impact on our ability to receive milestone payments and/or generate revenues from our therapeutic candidates and raise equity capital. In addition, given the novelty of our GD-T cell therapeutic candidates, the end users and medical personnel require a substantial amount of education and training in their administration of our cell therapy. Regulatory authorities have very limited experience with commercial cell therapies for disease treatment. As a result, regulators may be more risk averse or require substantial dialogue and education as part of the normal regulatory approval process for each stage of development of our therapeutic candidates.

GD-T cell therapy creates significantly increased risk in terms of side-effect profile, ability to satisfy regulatory requirements associated with clinical trials, and the long-term efficacy of administered cells.

Development of a pharmaceutical or biologic therapy product has inherent risks based on differences in patient population and responses to therapy and treatment. The mechanism of action and impact on other systems and tissues within the human body following administration of GD-T cell therapy products is not completely understood, which means that we cannot predict the long-term effects of treatment with the GD-T cell therapy product. We are aware that certain patients may not respond to GD-T cell therapy and other patients may relapse. The percentage of the patient population in which these events may occur is unknown, but the inability of patients to respond and the possibility of relapse may impact our ability to conduct clinical trials, to obtain regulatory approvals, if at all, and to successfully commercialize our therapeutic products.

Our GD-T cell therapeutic candidates and their application are not fully scientifically understood and are still undergoing validation and investigation. The utility of our GD-T cell products may depend on persistence, potency, durability and infiltration capacity of the GD-T cells within a patient's body. The level of persistence and the factors affecting such persistence, potency and infiltration capacity in patients are not completely understood, which presents an additional risk to the ongoing development and use of our therapeutic candidates. Certain steps involved in validating and carrying out testing require access to samples (for example tissue samples or cell samples) from third parties. Such samples may be obtained from universities or research institutions and will often be provided subject to satisfaction of certain terms and conditions. There can be no guarantee that we will be able to obtain samples in sufficient quantities to enable development of and use of the full preclinical safety testing program for CAR-T therapeutic candidates undergoing development. In addition, the terms under which such samples are available may not be acceptable to us or may restrict our use of any generated results

or require us to make payments to third parties.

Our products, before they can be commercialized, will require regulatory approval.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Approval by the FDA, the MHRA and comparable other regulatory authorities is lengthy and unpredictable, and depends upon numerous factors. 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, which may cause delays in the approval or the decision not to approve an application. We have not obtained commercialization regulatory approval for any product candidate, and it is possible that any of our product candidates will never obtain regulatory approval.

Applications for product candidates we may develop could fail to receive regulatory approval for many reasons, including but not limited to:

- our inability to demonstrate to the satisfaction of the regulatory authorities that a product candidate we develop is safe and effective;
- the regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the regulatory authorities' requirement for additional preclinical studies or clinical trials;
- the regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of a new drug application, or NDA, or other submission for regulatory approval;

- we may be unable to demonstrate to the regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the regulatory authorities may change in a manner that renders our clinical trial design or data insufficient for approval.

The lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market a product candidate in the United States, the UK, the EU or elsewhere, which would significantly harm our business, prospects, financial condition and results of operations.

We may encounter substantial delays in completing our clinical trials, which in turn will result in additional costs and may ultimately prevent successful or timely completion of the clinical development and commercialization of our product candidates.

We must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans before commercialization. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching, or any failure to reach, a consensus with regulatory agencies on study design;
- delays in obtaining FDA required Institutional Review Board, or IRB, approval at each clinical trial site;
- delays in recruiting a sufficient number of suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical trial operations or study sites;
- failure by third parties or us to adhere to clinical trial, regulatory or legal requirements;
- failure to perform in accordance with good clinical practices ("GCP"), or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of sufficient quantities of our product candidates to the clinical sites;
- delays in having patients' complete participation in a study or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a trial;
- delay or failure to address any patient safety concerns that arise during the course of a trial;
- unanticipated costs or increases in costs of clinical trials of our product candidates;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could also encounter delays if a clinical trial is suspended or terminated by us or by regulators and related reviewing authorities such as IRBs of the institutions in which such trials are being conducted, by an independent Safety Review Board. Suspension or termination of a clinical trial might be 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 resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, or failure to demonstrate a benefit from using a therapy. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to obtain regulatory approvals, commence product sales and generate revenues. Any of these occurrences may significantly harm our business, prospects, financial condition and results of operations.

Manufacturing and administering our GD-T cell-based therapeutic candidates is complex, and we may encounter difficulties in production, particularly with respect to

process development or scaling-up of our manufacturing capabilities. If we encounter such difficulties, our ability to supply of our GD-T cell therapeutic candidates for clinical trials or for commercial purposes could be delayed or stopped.

Manufacturing and administrating our GD-T cell-based therapeutics candidates is complex and highly regulated. The manufacture process of our GD-T cell-based therapeutics involves complex processes, including peripheral blood mononuclear cell isolation from leukapheresis material, stimulation of the GD-T cells, expansion of the cells to obtain a desired dose, and ultimately infusion of the cells to the patient's body. On occasions the GD-T cell therapeutic could be genetically modified, which could involve manufacturing of lentiviral vectors containing the gene of our interest (for example Chimeric Antigen Receptor) and transducing the cells or a method such as electroporation or nucleofection of a plasmid containing the gene of interest to the cells. As a result of the complexities, our manufacturing and supply costs are likely to be higher than those in more traditional manufacturing processes and the manufacturing process is less reliable and more difficult to reproduce. Our manufacturing process is, and will be, susceptible to product loss or failure due to logistical issues, including manufacturing issues associated with the differences in patients' white blood cells, interruptions in the manufacturing process, contamination, equipment or reagent failure, supplier error and variability in GD-T cell-based therapeutic candidate and patient characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral or other contaminations are discovered in our GD-T cell-based therapeutic candidates or in the manufacturing facilities in which our GD-T cell based therapeutic candidates are made or administered, the manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. As our GD-T cell-based therapeutic candidates progress through preclinical programs and clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing and administration process will be altered in an effort to optimize processes and results.

We have identified some improvements to our manufacturing and administration processes, but these changes may not achieve the intended objectives, and could cause our GD-T cell-based therapeutic candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. The changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any GD-T cell-based therapeutic candidate. For example, we are planning to introduce automated enclosed systems to our production process. This will require development work to ensure that these modifications do not alter the characteristics of the product. If the GD-T cell-based therapeutic candidate manufactured under the new process has a worse safety or efficacy profile than the prior investigational product, we may need to re-evaluate the use of that manufacturing process, which could significantly delay the progress of our clinical trials.

Developing a commercially viable process is a difficult and uncertain task and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We may ultimately be unable to reduce the expenses associated with our GD-T cell-based therapeutic candidates to levels that will allow us to achieve a profitable return on investment. If we are unable to demonstrate that our commercial scale product is comparable to the product used in clinical trials, we may not receive regulatory approval for that product without additional clinical trials. Even if we are successful, our manufacturing capabilities could be affected by increased costs, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy, which in turn could have a material adverse effect on our business.

We may seek expedited approval in the European Union and United States for our therapeutic candidates, but we may not be able to obtain or maintain such designation.

The FDA and the European Medicines Agency, the EMA, have established programs to expedite drug development and regulatory review. The FDA has four main expedited programs: fast track (introduced in 1987), accelerated approval (1992), priority review (1992), and breakthrough therapy (2012). A priority review designation in North America will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Significant improvement may be demonstrated by the following examples:

- evidence of increased effectiveness in treatment, prevention, or diagnosis of condition;
- elimination or substantial reduction of a treatment-limiting drug reaction;
- documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or
- evidence of safety and effectiveness in a new subpopulation.

We intend to seek breakthrough therapy designation for some or all of our therapeutic candidates, but there can be no assurance that we will receive breakthrough therapy designation. Additionally, other treatments from competing companies may obtain the designations and impact our ability to develop and commercialize our therapeutic candidates, which may adversely impact our business, financial condition or results of operation. We may also seek fast track designation. If a drug or biologic candidate is intended for the treatment of a serious or life-threatening condition or disease and the drug demonstrates the potential to address unmet medical needs for the condition, the sponsor may apply for fast track designation. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Even if we do apply for and receive fast track designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. We may also seek accelerated approval for products that have obtained fast track designation. Under the FDA's fast track and accelerated approval programs, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For drugs granted accelerated approval, post-marketing confirmatory trials have been required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence.

The EMA has three programs, the accelerated assessment (2005), conditional marketing authorization (2006), and the Priority Medicines (PRIME) scheme (2016). These programs are intended to prioritize the most important medicines for faster access by patients. As part of its marketing authorization process, the EMA may grant conditional marketing authorizations for certain categories of medicinal products on the basis of less complete data than is normally required, when doing so may meet unmet medical needs of patients and may serve the interest of public health. In these cases, it is possible for the Committee for Medicinal Products for Human Use, the CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products. A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, the risk-benefit balance of the medicinal product is positive. The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing trials or to conduct new trials with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data. Granting a conditional marketing authorization allows medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product are generated, submitted, assessed and acted upon. Although we may seek a conditional marketing authorization for our therapeutic candidates, the EMA or CHMP may ultimately not agree that the requirements for conditional marketing authorization have been satisfied and hence delay the commercialization of our therapeutic candidates.

In the European Union, accelerated assessment can reduce the timeframe for EMA's CHMP to review a marketing-authorization application. Applications may be eligible for accelerated assessment if the CHMP decides the product is of major interest for public health and therapeutic innovation. The evaluation of a marketing-authorization application can take up to 210 days. However, the CHMP can reduce the timeframe to 150 days if the applicant can provide sufficient justification for an accelerated assessment. The Priority Medicines (PRIME) scheme was introduced by the EMA in 2016 to support the development of medicines addressing unmet medical needs which offer a therapeutic advantage over existing treatments. To be accepted in the PRIME scheme, the treatments must meet the eligibility criteria for accelerated assessment including a strongly substantiated mechanism of action, supportive preclinical data, and first-in-human tolerance data. PRIME has been compared to the U.S. Breakthrough Therapy Designation.

Withdrawal of expedited approval will delay trials and likely increase cost.

The FDA or EMA may withdraw expedited approval of our therapeutic candidate or indication approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our therapeutic candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug;
- other evidence demonstrates that our therapeutic candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our therapeutic candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant therapeutic candidate.

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

We plan on submit marketing applications in multiple jurisdictions and countries, including the UK, the EU and the United States. Regulatory authorities in each jurisdiction have requirements for approval of therapeutic candidates with which we must comply prior to marketing in those jurisdictions. Obtaining regulatory approvals and compliance with regulatory requirements of multiple jurisdictions and countries could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our therapeutic candidates 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 therapeutic candidates will be harmed.

Obtaining and maintaining regulatory approval of our therapeutic 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 our key products in the United States, comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion of our products in those countries. Approval procedures vary among jurisdictions and may require additional preclinical programs or clinical trials. In many jurisdictions a therapeutic candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our therapeutic candidates is also subject to approval.

We may face difficulty in enrolling patients in our clinical trials.

We may find it difficult to enroll patients in our clinical trials. For example, in our TCB-001 clinical trial we experienced a high screen failure rate. Identifying and qualifying patients, including testing of patients for their GD-T cells' proliferation capacity, to participate in clinical trials of our therapeutic candidates, are critical to our success. The timing of our current and future clinical trials depends on the speed at which we can recruit patients to participate in testing our therapeutic candidates. If patients are unwilling to participate in our trial(s) because of negative publicity from adverse reactions or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products may be delayed or prevented. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve sufficient diversity in a given trial in order to complete our clinical trials in a timely manner. Patient enrolment is affected by factors including:

- eligibility criteria for the trial in question;
- severity of the disease under investigation;
- design of the trial protocol;
- trial duration and number and complexity of visits and procedures;
- size of the patient population;
- perceived risks and benefits of the therapeutic candidate under trial;
- novelty of the therapeutic candidate and acceptance by oncologists;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrolment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- macro political or economic factors that impact the availability and efficiency of available trial centers.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

The outcome of clinical trials is uncertain and our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our T cell therapeutic candidates, which would prevent or delay regulatory approval and commercialization.

There is a risk in any clinical trial that side effects from our therapeutic candidates will require a hold on, or termination of, our clinical program(s) or further adjustments to our clinical program(s) in order to progress our therapeutic candidates. Our T cell therapeutic candidates will require evidence that they are safe before permitting clinical trials to commence and evidence that the therapeutic candidates are safe and effective before granting any regulatory approval. In particular, because our therapeutic candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in each target indication. The therapeutic candidate must demonstrate an acceptable risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease and/or an improvement in survival. For example, response rates from the use of our therapeutic candidates will not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response.

We may not be able to submit INDs, or the foreign equivalent outside of the United States, to continue our CAR-T clinical trials.

We are currently conducting preclinical development of our CAR-T therapeutic candidates. Progression of our CAR-T therapeutic candidates from pre-clinical to clinical development (first-in-human, phase 1) is inherently risky and dependent on the results obtained in preclinical programs, the results of other clinical programs and results of third-party programs that utilize common components used for production and administration of our therapeutic candidates. If results are not available when expected or problems are identified during therapy development, we may experience significant delays in development of pipeline products and of existing clinical programs, which may impact our ability to receive regulatory approval. This may also impact our ability to achieve certain financial milestones and the expected timeframes to market any of our therapeutic candidates. Failure to submit further INDs or the foreign equivalent and commence additional clinical programs will significantly limit our opportunity to generate revenue.

Our research and development efforts may not result in the progression of our product candidates into clinical trials.

Our research and development efforts and our selection of the product candidates to pursue remain subject to all of the risks associated with the development of new treatment modalities. Development of the underlying technology and appropriate assay development may be affected by unanticipated technical or other problems, among other development and research issues, and the possible insufficiency of funds needed in order to complete development of these products. Safety, regulatory and efficacy issues, clinical hurdles or challenges also may result in delays and cause us to incur additional expenses that will increase our need for capital and result in additional losses. If we cannot complete, or if we experience significant delays in developing our medical products for use in potential commercial applications, particularly after incurring significant expenditures, our business may fail and investors may lose the entirety of their investment.

We will need to obtain regulatory approval for our product candidates, which is time consuming, costly and complicated. We may not obtain regulatory approval.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Approval by the FDA and comparable foreign regulatory authorities is lengthy and unpredictable, and depends upon numerous factors. 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, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any product candidate, and it is possible that any of our product candidates will never obtain regulatory approval.

Applications for product candidates we may develop could fail to receive regulatory approval for many reasons. For example, under FDA regulation, approval may not be obtained for many reasons such as:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate we may develop is safe and effective;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA's or comparable foreign regulatory authorities' requirement for additional preclinical studies or clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, or other submission for regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change in a manner that renders our clinical trial design or data insufficient for approval.

The lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market a product candidate in the United States or elsewhere, which would significantly harm our business, prospects, financial condition and results of operations.

We are heavily dependent on the success of our lead product candidate, OmnImmune®, and our subsequent product development program, If we are unable to successfully complete clinical development, obtain regulatory approval for, or commercialize these products, or experience delays in doing so, our business will be materially harmed.

Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize our aforementioned lead product candidate which is in its clinical development phase. Before we can generate any revenues from sales of products, we will be required to conduct additional clinical development and conduct longer-term clinical trials and, if our clinical trial of these products is successful, we will be required to seek and obtain regulatory approval, secure adequate manufacturing supply to support larger clinical trials and commercial sales and build a commercial organization, or to work with commercialization partners. Further, the success of these products will depend on patent and trade secret protection, acceptance of these products by patients, the medical community and third-party payers, its ability to compete with other therapies, healthcare coverage and reimbursement, and maintenance of an acceptable safety profile following approval, among other factors. If we do not achieve any of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our products which would materially harm our business.

Laboratory conditions differ from clinical conditions and commercial conditions, which could affect the effectiveness of our potential products. Failures to effectively move

from laboratory to the field would harm our business.

Observations and developments that may be achievable under laboratory circumstances may not be replicated in commercial settings or in the use of any of the proposed products in the field. The failure of our product candidates under development or other future product candidates to be able to be tested, approved and manufactured in available manufacturing facilities or to be able to meet the demands of users in the field would harm our business.

Results of earlier studies may not be predictive of future clinical trial results, and initial studies may not establish an adequate safety or efficacy profile for our drugs and other product candidates that we may pursue to justify proceeding to advanced clinical trials or an application for regulatory approval.

The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Additionally, any positive results generated in our Phase 1b/2a clinical trials in adults would not ensure that we will achieve similar results in larger, pivotal clinical trials or in clinical trials in general populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy 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 adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if early-stage clinical trials are successful, we may need to conduct additional clinical trials for product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to demonstrate the required characteristics to support marketing approval for our product candidates in any ongoing or future clinical trials would substantially harm our business, prospects, financial condition and results of operations.

We manufacture and test all our therapeutic candidates in-house, and may experience logistic issues.

The manufacture, testing and release of TCB's cell therapies for clinical trials may not meet with the regulatory requirements and result in the delay of clinical trials. Logistical issues which may prevent timely completion of manufacture and testing include:

- failure in integrity of facility infrastructure;
- failure of High Efficiency Particulate Absorbing (HEPA) filters to prevent airborne cross-contamination;
- delays in the procuring test materials/reagents due to supplier, shipping issues or discontinued supply;
- failure by third parties to notify a change in material product specifications that are not GMP ("Good Manufacturing Practice") compliant;
- equipment failure within production, quality control and stores;
- failure of quality control equipment;
- delays in cleanroom supplies from third parties such as PPE or cleaning reagents;
- failure in the cleanroom resulting in insufficient quantities of our product candidates being available to the clinical sites;
- increase in our costs of materials;
- failure of third party specialist couriers to deliver the product to clinical sites;
- failure due to resource issues associated with personnel illness; and
- failure in recruitment of cleanroom operators and quality staff as we progress through clinical trials.

We conduct and manage clinical studies using internal staff trained to perform such studies and loss of these staff may delay our clinical program.

We are highly dependent upon the principal members of our management team and the members of our scientific team. These people have significant experience and knowledge within our operational sector, and the loss of any team member could impair our ability to design, identify, and develop clinical trials, new intellectual property and new scientific or product ideas.

We expect to operate in a highly competitive, ever-evolving, market.

The broader market for our products is becoming more focused and potentially more competitive. Over time, we believe this field will become subject to more rapid change and new drugs, therapies and other products will emerge. We may not be able to compete effectively against these companies or their products. We may find ourselves in competition with companies that have competitive advantages over us, such as:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates, higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance and may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Rapidly changing medical technology within the life sciences could make the product candidates that we are developing obsolete.

The medical industry is characterized by rapid and significant medical technological and therapy changes, frequent new product candidates and product introductions and enhancements and evolving industry standards. Our future success will depend on our ability to continually develop and then improve the product candidates that we design and to develop and introduce new product candidates that address the evolving needs of the physicians and patients on a timely and cost-effective basis. Any new product candidates and products developed by us may not be accepted in the intended markets. Our inability to gain market acceptance of new products could harm our future operating results.

The market opportunities for certain of our product candidates may be small, due to the fact that the products may be limited to those patients who are ineligible for or have failed prior treatments, and our projections regarding the size of the addressable market may be incorrect.

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When blood cancers are detected, they are treated with first line of therapy with the intention of curing the cancer. This generally consists of chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. In addition, sometimes a bone marrow transplantation can be added to the first line therapy after the combination chemotherapy is given. If the patient's cancer relapses, then they are given a second line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these, or bone marrow transplant. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy in the treatment of lymphoma and myeloma is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenues without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

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

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, CROs ("Contract Research Organizations") and strategic partners to support our clinical trials under agreements with the Company.

We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and its reliance on third parties does not relieve us of our regulatory responsibilities. TCB and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials will involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet its desired clinical development timelines.

We do not have any current sales, marketing, commercial manufacturing and distribution capabilities or arrangements, and will need to create these as we move towards commercialization of our products.

We do not yet have commercial sales, marketing, manufacturing and distribution capabilities or arrangements. We will need to develop all of the foregoing or partner with organizations who have expertise in all the foregoing. We do not have any corporate experience in establishing these commercial sized capabilities. We believe that setting up the commercialization aspects of a company such as ours, in our field, will take a substantial amount of capital and time. Therefore, we may seek development and marketing partners and license our drug technologies or product candidates to others in order to avoid our having to provide the marketing, manufacturing and distribution capabilities within our organization. There can be no assurance that we will find any development and marketing partners or companies that are interested in licensing our drug technology or any of our product candidates or products. If we are unable to establish and maintain adequate sales, marketing, manufacturing and distribution capabilities, independently or with others, we will not be able to generate product revenue, and may not become profitable.

We may rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.

Although to date, we have used our internal capabilities to manufacture clinical trial supplies, we do not yet have sufficient information to reliably estimate the cost of commercially manufacturing and processing of our product candidates. The actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

Our manufacturing plant is located in Scotland and as we develop clinical trials outside the UK and in particular into the USA we anticipate that we will rely on a limited number of third-party manufacturers for commercial production, but this will expose us to the following risks.

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products.

- Third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.

- Future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Manufacturers are subject to strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.

- Third-party manufacturers could breach or terminate their agreement(s) with us.

Contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the regulatory approval, if any, of our product candidates or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

Cell-based therapies rely on the availability of specialty materials, which may not be available to us on acceptable terms or at all.

Our product candidates require specialized materials, including viral vectors that deliver the targeting moiety (CAR) and other genes to the product candidate. We currently manufacture some of our requirements through contract manufacturers, some of which are manufactured by companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver materials to our specifications. In addition, those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials to support clinical or commercial manufacturing.

In addition, some materials utilized in the manufacture of our candidates are currently available from a single supplier, or a small number of suppliers. For example, principal suppliers for the purchase of equipment and reagents critical for the manufacture of our product candidates include Cytiva (Global Life Sciences Solutions Operations UK Ltd), Wilson Wolf Manufacturing Corporation, Octapharma AG, Sexton Biotechnologies, Miltenyi Biotech, Thermo Fisher Scientific and other suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event that we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, for example:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold £5.0 million in clinical study liability annual insurance cover for each clinical study, with a per patient limit of £5.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Governmental Regulations

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 and file income tax returns in multiple jurisdictions. Our consolidated effective income tax rate could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration (such as those related to the Organization for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project, the European Commission's state aid investigations and other initiatives); the practices of tax authorities in jurisdictions in which we operate; the resolution of issues arising from tax audits or examinations and any related interest or penalties. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which we operate, could increase the estimated tax liability that we have expensed to date and paid or accrued on our balance sheets, 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.

Changes in our business strategy or operations may result in grant income being repaid to government grant awarding bodies.

We have been awarded and received grant income from government agencies with respect to a number of research and development programs totaling £5.6 million since incorporation through December 31, 2023. In some cases, the grant award contains commitments for the business that extend beyond the specific program period. If the Company changes strategy or the nature of its operations, some grant awarding bodies may view this as a breach of the original terms of the grant and all or part of the original grant award may become subject to repayment. In the event of our having to return funds under prior grant awards, the Company may be required to repay up to an aggregate of £5.6 million.

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 United States Internal Revenue Service, 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.

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

As a UK incorporated and tax resident entity, we are subject to UK corporate taxation. Due to the nature of our business, we have generated losses since inception and therefore have not paid any UK corporation tax. As of December 31, 2023, we had cumulative carryforward tax trading losses of £11.1 million. Subject to any relevant utilization criteria and restrictions (including those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half of our ordinary shares (including those represented by the ADSs) and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits arising in the United Kingdom. The use of loss carryforwards in relation to UK profits incurred on or after April 1, 2017 are limited each year to £5.0 million per group plus, broadly, an incremental 50% of UK taxable profits.

As a company that carries out extensive research and development activities, we seek to benefit from the UK 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 us by third parties, the Research and Development Expenditure Credit program, or RDEC Program. 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 14.5% of such qualifying research and development expenditures. The majority of our 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 in the future if we cease to qualify as a SME, based on size criteria concerning employee headcount, turnover and gross assets.

We may benefit in the future from the UK's "patent box" regime, which allows certain profits attributable to revenue from patented products (and other qualifying income) to be taxed at an effective rate of 10% by giving an additional tax deduction. We own several patents which cover our investigational therapies, and accordingly, future upfront fees, milestone fees, product revenue 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 UK 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.

Failure to comply with United States health and data protection laws and regulations could lead to enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators are subject to data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, which are subject to privacy and security requirements under HIPAA, as amended by HITECH. To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Additionally, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018, or CCPA, which came into effect on January 1, 2020 and provides new data privacy rights for consumers (as that term is broadly defined) and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Compliance with U.S. and foreign privacy and data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

European data collection is governed by restrictive privacy and security regulations governing the use, processing and cross-border transfer of personal information.

The collection, use, storage, disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials) (i) regarding individuals in the EU, and/or (ii) carried out in the context of the activities of our establishment in any EU member state, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018, as well as other national data protection legislation in force in relevant member states (including the Data Protection Act 2018 in the UK).

The GDPR is wide-ranging in scope and imposes numerous additional requirements on companies that process personal data, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenue, whichever is greater. The GDPR provides individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR. While we have taken steps to comply with the GDPR, and implementing legislation in applicable EU member states, including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing our security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful.

Following the UK's withdrawal from the EU on January 31, 2020 and following the end the of the transitional arrangements on December 31, 2020, it is likely that the data protection obligations of the GDPR will continue to apply to UK-based organizations' processing of personal data in substantially unvaried form, for at least the short term thereafter.

Risks Related to Our Business Operations, Managing Growth and Employee Matters

We may have difficulty managing growth in our business.

Because of our small size, growth in accordance with our business plan, if achieved, will place a significant strain on our financial, technical, operational and management resources. As we expand our activities, there will be additional demands on these resources. The failure to continue to upgrade our technical, administrative, operating and financial control systems or the occurrence of unexpected expansion difficulties, including issues relating to our research and development activities and retention of experienced scientists, managers and engineers, could have a material adverse effect on our business, financial condition and results of operations and our ability to timely execute our business plan. If we are unable to implement these actions in a timely manner, our results may be adversely affected.

We depend upon our key personnel and our ability to attract and retain employees

We are heavily dependent on the ongoing employment and involvement of certain key employees in particular our principal executive officers (i) Bryan Kobel, our Chief Executive Officer and Martin Thorp, our Chief Financial Officer.

We anticipate, overtime, a requirement to expand our current personnel, who will be based in the UK, the EU and the USA, potentially very rapidly in order to achieve our planned business activities and aims to further engage in clinical trials. Such expansion is dependent on our ability to recruit experienced and suitably trained employees or consultants, and to retain such employees on a long-term basis. Our ability to take our existing pipeline of GD-T cell therapeutics and to meet the demands of our clinical programs may be compromised or delayed if we are unable to recruit sufficient personnel on a timely basis.

The loss of key managers and senior scientists could delay our research and development activities. In addition, our ability to compete in the highly competitive pharmaceutical industry depends upon our ability to attract and retain highly qualified management, scientific and medical personnel. Many other companies and academic institutions 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. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable. Moreover, some qualified prospective employees may choose not to work for us due to negative perceptions regarding the therapeutic use of psilocybin or other objections to the therapeutic use of a controlled substance. Furthermore, we will need to recruit new managers and qualified scientific personnel to develop our business if we expand into fields that will require additional skills. Our inability to attract and retain these key people could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

In addition, certain key academic and scientific personnel play a pivotal role in our collaborative partners' research and development activities. If any of those key academic and scientific personnel who work on development of our research programs, our investigational GD-T cell therapy and any future therapeutic candidates leave our collaborative partners, the development of our research programs, our investigational GD-T cell therapy and any future therapeutic candidates may be delayed or otherwise adversely affected.

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

As of March 7, 2024, we have 41 full-time equivalent employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we will have to add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to commercialize our GD-T therapeutic candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our business and our stock price.

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. We may discover material weaknesses in our internal financial and accounting controls and procedures that need improvement from time to time.

Management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes. Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company will have been detected.

Pursuant to Section 404(a) of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an EGC we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm (Section 404(b)). To prepare for eventual compliance with Section 404(b), once we no longer qualify as an EGC, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are unable to produce accurate financial statements on a timely basis, investors could lose confidence in the reliability of our financial statements, which could cause the market price of either of our ADSs or Warrants, or both, to decline and make it more difficult for us to finance our operations and growth.

The Company notes that the auditors identified that the Company experienced difficulty in the accounting for complex financial instruments and leases, and the Company lacked adequate internal control over the account and assessment of complex financial instruments following control deficiencies which they believed constituted a material weakness in the Company's internal control over financial reporting as of December 31, 2023. The Company recognizes this error as a material weakness and has established controls to support assessment and review of accounting for complex financial instruments and leases.

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.

We are subject to risks related to public health crises such as the COVID-19 pandemic. The COVID-19 pandemic continues throughout the world. The pandemic and policies and regulations implemented by governments in response to the pandemic, often directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical service and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The full extent to which COVID-19 will ultimately impact our business, preclinical trials and financial results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Global health concerns, such as the COVID-19 pandemic, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

In response to the COVID-19 pandemic, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including flexibility for employees to work remotely where appropriate, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, all of which could negatively affect our business. The extent of the impact of the COVID-19 pandemic on our preclinical studies or clinical trial operations, our supply chain and manufacturing and our office-based business operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of the COVID-19 pandemic, or the effectiveness of actions to contain and treat coronavirus.

While we are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to current and any future therapeutic candidates as a result of the COVID-19 pandemic, if the COVID-19 pandemic continues and persists for an extended period of time, we expect there will be significant and material disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of current and any future therapeutic candidates. Any such supply disruptions would adversely impact our ability to generate sales of and revenue from our approved products and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

The COVID-19 pandemic may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. As COVID-19 continues to be present and spread around the globe, we may experience additional disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of sites or facilities serving as our clinical trial sites and staff supporting the conduct of our clinical trials, including our trained therapists, or absenteeism due to the COVID-19 pandemic that reduces site resources;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or national governments, employers and others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from our trials;

- limitations in employee resources that would otherwise be focused on conducting 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;

- delays in receiving authorizations from 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 the cell therapy used in our clinical trials;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;

- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;

- 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

- refusal of the FDA, the EMA, the MHRA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States or the EU or other relevant local geography.

Any negative impact the COVID-19 pandemic has on patient enrolment or treatment or the development of our investigational cell therapies and any future therapeutic candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our investigational cell therapies and any future therapeutic candidates, if approved, increase our operating expenses, and have a material adverse effect on our financial results.

The COVID-19 pandemic has also caused significant volatility in public equity markets and disruptions to the United States and global economies. This increased volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. We cannot currently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial conditions. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also heighten many of the other risks described in this "Risk Factors" section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

Our current operations are headquartered in one location, and we or the third parties upon whom we depend may be adversely affected by unplanned natural disasters, as well as occurrences of civil unrest, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our current business operations are headquartered and principally located in our offices and laboratories in Glasgow, UK. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents, including events of civil unrest 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 investigational GD-T cell therapy or any future therapeutic candidates or interruption of our business operations.

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, but in the final result may not be sufficient to satisfy any damages and losses.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our investigational GD-T cell therapy or any future therapeutic candidates are being developed to treat, and we may use appropriate social media in connection with our commercialization efforts of our investigational GD-T cell therapy following approval of our GD-T cell therapy or any future therapeutic candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve, and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to certain prohibited activities. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrolment may be adversely impacted, we fail to monitor and comply with applicable adverse event reporting obligations, or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational GD-T cell therapy or any future therapeutic candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Risks Related to Intellectual Property

If we or our licensors are unable to protect our/their intellectual property, then our financial condition, results of operations and the value of our drug technology and product candidates could be adversely affected.

Patents and other proprietary rights are essential to our business, and our ability to compete effectively with other companies is dependent upon the proprietary nature of our drug technologies and product candidates. We also rely upon trade secrets, know-how, continuing innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with employees, consultants and other parties. Our success will depend in part on the ability of TCB and our licensors to obtain, to maintain (including making periodic filings and payments) and to enforce patent protection for the licensed

intellectual property, in particular, those patents to which we have secured rights. We, and our licensors, may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of these patent applications, TCB or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such enforcement less aggressively than we ordinarily would for our own patents. Without adequate protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Even if issued, patents may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products.

Litigation or third-party claims of intellectual property infringement or challenges to the validity of our patents would require us to use resources to protect our rights and may prevent or delay our development, regulatory approval or commercialization of our product candidates.

If we are the target of claims by third parties asserting that our product candidates and products or intellectual property infringe upon the rights of others we may be forced to incur substantial expenses or divert substantial employee resources from our current business endeavors. If successful, those claims could result in our having to pay substantial damages or could prevent us from developing one or more product candidates or commercializing a product. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product candidate or product that is the subject of the suit.

If we or our collaborators experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their having greater financial resources. 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. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

If we are unable to obtain and maintain patent protection for our GD-T cell technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends on our ability to obtain and maintain patent protection in the United States, the European Union, Japan and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications related to our technology and product candidates in the major pharmaceutical markets, including the United States, major countries in Europe and Japan. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary positions, we file patent applications related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

Patent applications are generally in the form of composition of matter or method patents. A composition of matter (COM) patent protects an actual drug molecule or engineered cell or other therapeutic agent and will be infringed by a third party making any use of the protected composition. COM patents provide de-facto protection for any and all uses of the protected composition and are generally held to be the strongest and most valuable form of patent protection. Method patents protect, for example, a method of manufacturing a product or a method of using it. They can be valuable but typically are more limited in scope than COM patents, particularly method of use patents which only protect a particular application of a product. Where our patent applications are limited in their scope, such as a patent protecting the method of use, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products.

Prosecution of our owned and in-licensed patent portfolio is at a relatively early stage in some instances. This status of these patent rights is discussed above.. Neither priority applications nor PCT applications can themselves give rise to issued patents. Rather, protection for the inventions disclosed in these applications must be further pursued by applicable deadlines via applications that are subject to examination. As applicable deadlines for the priority and PCT applications become due, we will need to decide whether to and in which countries or jurisdictions to pursue patent protection for the various inventions claimed in these applications, and we will only have the opportunity to pursue and obtain patents in those jurisdictions where we pursue protection.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the countries in which we pursue patent protection. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could threaten our ability to commercialize our product candidates. Any such outcome could have a negative effect on our business.

Patent and other intellectual property rights may not be upheld, in which case we will suffer a loss of our intellectual property position and the value of our assets.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws of the various jurisdictions in which we pursue patents may diminish the value of our patents or narrow the scope of our patent protection. In addition, the protections offered by laws of different countries vary. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in many jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical technologies, such as our cell technologies, commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, whether owned or in-licensed, are highly uncertain. Furthermore, the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights may change as the related patent and intellectual property laws change over time. Additionally, in the United States, one of the jurisdictions in which we purse patent protection, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection

available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future.

We may be unaware of the rights of others which may ultimately be used to limit our intellectual property rights.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in many jurisdictions typically are not published until 18 months or more after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Similarly, should we own or in-license any patents or patent applications in the future, we may not be certain that we or the applicable licensor were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, in the United States, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, re-examination, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could significantly harm our business and results of operations.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

If we fail in defending any the claims we have made, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

Technologies and other proprietary rights for which we seek patent protection may not be obtained, which would potentially limit the value of our intellectual property.

Our pending and future patent applications, whether owned or in-licensed, may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents, should they issue, by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the jurisdictions in which we have filed for patent protection. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

We may be subject to claims challenging the inventorship or ownership of our owned or in-licensed patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, disputes may arise from conflicting obligations of consultants or others who are involved in developing our technology and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. The owners of intellectual property in-licensed to us could also face such claims. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

We believe that we have proprietary and modular T cell programming technology that does not infringe the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including in the area of programmed T cell therapies. Some are patents held by our competitors. If any third-party patents cover our product candidates or technologies, we may not be free to manufacture or commercialize our product candidates as planned.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the relevant patent office. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights and claims may also come from competitors against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we

are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization. There are and may in the future be additional third-party patents or patent applications with claims to, for example, materials, compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of any one or more of our product candidates.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required or may choose to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if successful, the defense of any claim of infringement or misappropriation is time-consuming, expensive and diverts the attention of our management from our ongoing business operations.

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

A third party may hold intellectual property rights, including patent rights, which are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

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

Competitors may infringe our patents, if issued, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. While we have a corporate trademark, we have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the jurisdiction in which we operate or intend to operate are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the patent offices and patent agencies over the lifetime of the patent to maintain the patents that have been issued. Additionally, these offices and agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules,

there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in-licensed from a third party, any failure on our part to maintain the in-licensed rights could jeopardize our rights under the relevant license and may expose us to liability.

If we fail to comply with our obligations in the agreements under which we license our development or commercialization rights to products or drug technologies from third parties, we could lose license rights that are important to our business.

We hold a license from UCL Business plc ("UCLB") for its technology related to co-stimulatory CAR-T in GD-T cells. This is in addition to the intellectual property that we own. Our license with UCLB is for a single CAR-T binder, where we pay an annual license fee, certain performance-based milestone payments and a single-digit royalty on sales arising from use of that binder together with certain cumulative sales-based milestone payments. Through December 31, 2023 we have paid UCLB approximately $0.65 million (taking into consideration fluctuation in exchange rates) in license fee payments. Furthermore, the Company has a duty not to breach terms of the license agreement. If we fail to meet specific obligations, the licensor will have the right to terminate the applicable license or modify certain terms of the license agreement. Royalty provisions cease upon termination or upon expiry of the license which occurs, on a country-by-country basis, upon the later of the tenth (10^{th}) anniversary of the first commercial sale of a licensed product or the lapse, expiry, or revocation of all patents.

Risks Related Ownership of Our ADSs and Warrants

Control by a limited number of shareholders may limit the ability of investors to influence the outcome of director elections and other transactions requiring shareholder approval.

As of March 22, 2024, we had outstanding warrants to acquire 1,956,918 ADSs, and share options to purchase 920,230 ADSs. A significant number of such warrants have exercise prices above our ADSs' recent trading prices, but the holders have the right, in certain circumstances, to effect a cashless exercise of such warrants. If a significant number of such warrants and share options are exercised by the holders, such persons together, along with several other long term significant shareholders, may have influence over corporate actions requiring shareholder approval, including the following actions:

- to elect our directors;
- to amend or prevent amendment of our articles of association;
- to effect or prevent a merger, sale of assets or other corporate transaction; and
- to influence the outcome of any other matter submitted to our shareholders for vote.

These persons' share ownership or warrant ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company, which in turn could reduce the market price of our ADSs and Warrants or prevent our shareholders from realizing a premium over the market price of our ADSs and Warrants.

If we fail to meet the requirements for continued listing on the Nasdaq Capital Market or Nasdaq, our ADSs could be delisted from trading, which would decrease the liquidity of our ADSs and our ability to raise additional capital.

Our ADSs are currently listed for quotation on The Nasdaq Capital Market. We are required to meet specified financial requirements in order to maintain our listing on the Nasdaq Capital Market. These requirements include maintaining a minimum bid price of at least $1.00 per share for our ADSs, which is referred to as the Bid Price Rule, and maintaining a minimum market value of listed securities, or the MVLS, of $35,000,000. On July 12 and 15, 2022, we received deficiency letters from the Listings Qualifications Department of the Nasdaq Stock Market notifying that we were not in compliance with the Bid Price Rule and the MVLS, respectively. On December 6, 2022, we received written notification from the listing qualifications staff of the Nasdaq Stock Market, LLC ("Nasdaq") indicating that the Company regained compliance with the Bid Price Rule. On January 12, 2023, we received written notification from the listing qualifications staff of the Nasdaq indicating that we have not regained compliance with the MVLS and that our securities would be subject to delisting unless we timely request a hearing before a Nasdaq Hearings Panel (the "Panel"). On March 9, 2023 the Company presented a formal plan to regain compliance to the Panel. On March 17, 2023, the Company announced that the TC BioPharm (Holdings) plc has been granted a formal extension until June 30, 2023, to regain compliance under Nasdaq Listing Rule 5550(b)(2) or its alternative criteria. On July 27, 2023, the Company received a letter, dated July 26, 2023 (the "Letter") from Nasdaq notifying the Company that the Panel has concluded that the Company has regained compliance with Nasdaq's continued listing requirements. The Letter stated that, pursuant to Listing Rule 5815(d)(4)(A), the Company will be subject to a Panel Monitor for a period of one year from the date of the Letter. If, within that one-year monitoring period, the Listing Qualifications staff (the "Staff") finds the Company again out of compliance with any continued listing requirement, notwithstanding Rule 5810(c)(2), the Company will not be permitted to provide the Staff with a plan of compliance with respect to any deficiency and the Staff will not be permitted to grant additional time for the Company to regain compliance with respect to any deficiency, nor will the Company be afforded an applicable cure or compliance period. Instead, the Staff will issue a Delist Determination Letter and the Company will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable.

On June 22, 2023, we received a written notification from Nasdaq indicating that the minimum closing bid price per share for our ADSs was below $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we had a compliance period of 180 calendar days, or until December 19, 2023 (the "Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement. If at any time during the Compliance Period, the closing bid price per share of our ADSs is at least $1.00 for a minimum of ten consecutive business days, Nasdaq will provide us with a written confirmation of compliance and the matter will be closed. On December 28, 2023, we received a letter from Nasdaq indicating that we had not regained compliance with the rule and are not eligible for a second 180 day period. On January 2, 2024, we received written confirmation from Nasdaq that it has determined that for the last 10 consecutive business days, from December 15, 2023 to December 29, 2023, the closing bid price of our securities was at $1.00 per share or greater. Accordingly, we regained compliance with Listing Rule 5550(a)(2) and the matter was closed. If we are deficient in maintaining the necessary listing requirements in the future, our common stock may be delisted. If our common stock is delisted, an active trading market for our common stock may not be sustained and the market price of our common stock could decline. Delisting of our common stock could adversely affect our ability to raise additional capital through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations.

We do not intend to list any of our securities on any public securities exchange in the United Kingdom. This may limit the information available to our security holders.

Our ordinary shares and public warrants are not listed in the United Kingdom. As a result, we are not, and will not be, subject to the reporting and other requirements of companies listed on a securities exchange in the United Kingdom. Accordingly, there may be less publicly available information concerning our company than there would be if we were a public company listed in the United Kingdom, notwithstanding our reporting under the SEC rules.

An active and liquid market for the ADSs and/or public warrants may fail to continue, which could harm the market price of the ADSs and/or Warrants, and an investor may not be able to resell their ADSs and/ or warrants at or above the acquisition price.

An active public trading market for the ADSs and public warrants on the United States securities markets may not continue or be sustained. In the absence of an active trading market for the ADSs and/or warrants, investors may not be able to sell their ADSs and warrants at or above the price they paid for their securities or at the time when they would like to sell.

The market price of the ADSs and public warrants is volatile and investors could lose all or part of their investment.

The price of the securities of publicly traded emerging pharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. As a result of this volatility, investors may not be able to sell their ADSs and warrants at or above the purchase price or when they want to sell their securities. The market price of the ADSs and Warrants may fluctuate significantly due to a variety of factors, including the following:

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in entering into strategic relationships with respect to development or commercialization of our investigational GD-T cell therapy or any future therapeutic candidates;
- entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial therapeutic introductions by competitors;
- changes in government regulations and healthcare payment systems;
- developments concerning proprietary rights, including patent and litigation matters;
- public concern relating to the commercial value or safety of any of our investigational GD-T cell therapy or any future therapeutic candidates;
- negative publicity or public perception of the use of GD-T cells as a treatment therapy;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- the trading volume of the ADSs and warrants on Nasdaq;
- sales of our ordinary shares, including through deposit of additional ordinary shares with the depositary for the ADSs, by us, members of our senior management and directors or our shareholders or the anticipation that such sales may occur in the future;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- general economic, political, and market conditions and overall market volatility in the United States or the UK as a result of the COVID-19 pandemic or other pandemics or similar events; and
- other events and factors, many of which are beyond our control.

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

The public warrants are speculative in nature.

The public warrants merely represent the right to acquire our ordinary shares at a fixed cash price, for a limited period of time. If the warrants are not exercised before they expire, in six years from date of issue, the warrants will never provide any value to the holder thereof. It is usual that the price of a warrant in the public market is more volatile than that of the corresponding shares for which it is exercisable. Therefore, investors should expect the price of a warrant to be fluctuate to a greater degree than our ADSs, and correspondingly be more speculative.

Holders of our public and private warrants will not have any rights of the holders of ordinary shares until such warrants are exercised.

The public and private warrants do not confer any of the rights afforded to the holders of our ordinary shares, even those ordinary shares held through ADSs, such as voting rights or the right to receive dividends, but rather represent the right to acquire ordinary shares at a fixed price.

We have a significant number of public warrants outstanding, with fifty warrants to purchase one ADS, which may be exercised at a current cash exercise price of $500.00 per ADS. There is no assurance that they will be exercised and that they will provide funding for the Company.

As at March 8, 2024, there were approximately 16,166,260 public warrants outstanding where fifty of each warrant are exercisable for one ordinary share. Following the ratio change twenty ordinary shares can be dematerialized into one ADS. For the public Warrants to be exercised on a cash basis, we must maintain an effective registration statement with the SEC at the time of their exercise. It is not expected that any of the derivative securities will be exercised for cash unless the price of an ADS in the market is substantially above the then exercise price. There can be no assurance that our ADS price will be sufficiently high on a sustained basis to encourage warrant holders to exercise their derivative securities.

The public warrants have a number of restrictions and reset provisions which may limit aspects of our operations and capital raising.

The public warrant terms have restrictions on our ability to issue ordinary shares in a number of situations. For example, for the period during which the lock up agreements are in place, we have limits on our ability to issue ordinary shares under our incentive plans. Another restriction, one on our capital raising, is an exercise price reset provision; if we issue any ordinary shares, including instruments convertible into ordinary shares, at a per share price or conversion price less than the exercise price, the then

the exercise price of the warrants will be reduced to the lower issue price permanently. The warrants have anti-dilution provisions including those for recapitalization transactions such as a reverse stock split, stock dividend and forward stock split, and protective provisions in the event of a rights offering, cash or asset dividend, and fundamental transactions consummated by the company where it is not the survivor. The warrant has buy-in protection and cash penalties if we do not issue the securities underlying them on a timely basis. The six-year term and number of warrants in combination with the registration obligation will be an overhang on the market while the warrants are outstanding. This overhang may limit our ability to raise capital when needed at a price that represents the value of the company. The warrants do not have a redemption provision by which we can either encourage their exercise or terminate the warrants.

We have a significant number of private, Series E Warrants outstanding each warrant to purchase one ADS, which may be exercised at a current cash exercise price of £1.5814 per ADS. There is no assurance that they will be exercised and that they will provide funding for the Company.

As at March 22, 2024, there were approximately 1,750,000 private Series E warrants with an exercise price of £1.5814, each of which currently is exercisable for 20 ordinary shares. For these private Warrants to be exercised on a cash basis, we must maintain an effective registration statement with the SEC at the time of their exercise. It is not expected that any of the derivative securities will be exercised for cash unless the price of an ADS in the market is substantially above the then exercise price. There can be no assurance that our ADS price will be sufficiently high on a sustained basis to encourage warrant holders to exercise their derivative securities, such as the private warrants.

The private warrants have a number of restrictions and reset provisions which may limit aspects of our operations and capital raising.

The private warrant terms have restrictions on our ability to issue ordinary shares in a number of situations. For example, for the period during which the lock up agreements are in place, we have limits on our ability to issue ordinary shares. The private warrants have anti-dilution provisions including those for recapitalization transactions such as a reverse stock split, stock dividend and forward stock split, and protective provisions in the event of a rights offering, cash or asset dividend, and fundamental transactions consummated by the company where it is not the survivor. The private warrants have buy-in protection and cash penalties if we do not issue the securities underlying them on a timely basis. The term and number of warrants in combination with the registration obligation will be an overhang on the market while the private warrants are outstanding. This overhang may limit our ability to raise capital when needed at a price that represents the value of the company. The private warrants do not have a redemption provision by which we can either encourage their exercise or terminate the private Warrants.

We incur increased costs as a result of operating as a Scottish public company listed in the U.S., and our board of directors is required to devote substantial time to compliance requirements and corporate governance practices.

As a Scottish public company listed in the U.S., we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on foreign reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors, management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our annual legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

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

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

We are implementing appropriate accounting policies, processes and controls to comply with our expected expansion in scale of operations and with Section 404. These activities include identifying and recruiting additional individuals with requisite expertise to assist in implementation activities designed to strengthen our internal control over financial reporting to avoid future control deficiencies and initiating the design and implementation of improvements to our financial control environment to address our future needs. However, we cannot give assurance that the measures we have taken to date, and actions we plan to take in the future, will be sufficient to prevent or avoid potential future additional material weaknesses in our controls.

If we are unsuccessful in building an appropriate accounting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures, or comply with existing or new reporting requirements. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that would materially harm our business. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on the price of our publicly traded securities or our ability to sell other securities.

We are an "emerging growth company" under the federal securities laws and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If some investors, including persons considering an investment in the company, find our securities less attractive as a result, there may be a less active trading market for our public securities, and the prices of these securities may be more volatile.

We will remain an "emerging growth company" for up to five years, although we will lose that status sooner if our revenues exceed $1.07 billion (or equivalent), if we issue more than $1 billion (or equivalent) in non-convertible debt in a three-year period, or if the market value of our ordinary shares that is held by non-affiliates exceeds $700 million (or equivalent) as of any June 30.

Holders of our ordinary shares will have their rights as a shareholder governed by Scottish law, and those rights differ from the rights of shareholders under U.S. law.

We are a public limited company under the laws of Scotland and United Kingdom. Therefore, the rights of holders of our ordinary shares, including those represented by ADSs, are governed by the corporate law of Scotland and the United Kingdom and by our memorandum of association and articles. The statutory framework that governs the Company is the Companies Act 2006 which is a UK-wide act and references to the "UK Law" are to UK-wide legislation. These rights differ from the typical rights of shareholders in U.S. corporations. In certain cases, facts that, under U.S. law, would entitle a shareholder in a U.S. corporation to claim damages may not give rise to a cause of action or claim for damages under Scottish law. For example, the rights of shareholders to bring proceedings against the Company or against our directors or officers in relation to public statements are more limited under Scottish law and UK Law than under the civil liability provisions of the U.S. securities laws.

Investors may face difficulties in protecting their interests, and their ability to protect their rights through the U.S. federal courts may be limited, because we are incorporated outside the United States, conduct most of our operations outside the United States, and most of our directors and senior management reside outside the United States.

We are incorporated and have our registered office in, and are currently existing under the laws of, Scotland. In addition, most of our tangible assets are located, and most of our senior management and certain of our directors reside, outside of the United States. As a result, it may not be possible to serve process within the United States on certain directors or us or to enforce judgments obtained in U.S. courts against such directors or us based on civil liability provisions of the securities laws of the United States.

The United States and the UK do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment of money given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the UK. In addition, uncertainty exists as to whether courts of Scotland would entertain original actions brought in Scotland against us or our directors or senior management predicated upon the securities laws of the U.S. or any state in the U.S. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of Scotland as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met.

Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is subject to determination by the court making such decision. If the courts of Scotland give a judgment for the sum payable under a U.S. judgment, the Scottish judgment will be enforceable by methods generally available for this purpose. These methods generally permit the courts of Scotland discretion to prescribe the manner of enforcement.

As a result, U.S. investors may not be able to enforce against us or certain of our directors any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

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

Scottish law provides that a board of directors may only allot shares (or grant rights to subscribe for or to convert any security into shares) with the prior authorization of shareholders, 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 ordinary resolution passed by shareholders at a general meeting. Once allotted, the board of directors are free to issue the shares without further shareholder approval. The authority from our shareholders to allot additional shares for a period of five years from January 14, 2022 was included in the ordinary resolution passed by our shareholders on January 14, 2022, 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).

Scottish law also generally provides shareholders with pre-emptive 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 the members (or of a class of members) of a company by a majority of not less than 75%, to disapply pre-emptive rights. Such a disapplication of pre-emptive 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, but not longer than the duration of the authority to allot shares to which this disapplication relates or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years). Such authority from our shareholders to disapply pre-emptive rights for a period of five years was included in the special resolution passed by our shareholders on, January 14, 2022, which disapplication will need to be renewed upon expiration (i.e., at least every five years) to remain effective, but may be sought more frequently for additional five-year terms (or any shorter period).

Scottish law also generally prohibits a public company from repurchasing its own shares without the prior approval of shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, and other formalities. Such approval may be for a maximum period of up to five years.

Our business and results of operations may be negatively impacted by the UK's withdrawal from the EU.

The UK withdrew from the EU effective on January 31, 2020, and the transition period ended on December 31, 2020, which we refer to as Brexit. The future regulations that will apply in the UK following the transition period (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations medicine licensing and regulations, immigration laws and employment laws), have yet to be fully addressed and continue to be in transition, subject to change. The overall lack of clarity on future UK laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the UK, increase costs, depress economic activity and restrict access to capital. As we are headquartered in the UK and have operations and clinical trials in the United Kingdom and EU, it is possible that Brexit may impact some or all of our current operations and otherwise how we conduct business. For example, Brexit may impact our ability to freely move employees from our headquarters in the UK to other locations in Europe, and it may impact the ability of European therapists to move freely to the UK in order to complete part of their training or work on our clinical trials there.

The long-term effects of Brexit will depend in part on the agreements the UK made during the Brexit transition period and thereafter to retain access to markets in the EU. The Brexit withdrawal from the EU is unprecedented, and it is unclear how the UK's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the UK In addition to the foregoing, our UK operations support our current and future operations and clinical activities in the EU and European Economic Area, or EEA, and these operations and clinical activities could be disrupted by Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations as a result of Brexit. The UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its member states, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Since the regulatory framework in the UK covering quality, safety and efficacy of therapeutic substances, clinical trials, marketing authorization, commercial sales and distribution of therapeutic substances is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our GD-T cell therapy or any future therapeutic candidates in the UK. For instance, in November 2017, EU member states voted to move the EMA, the EU's regulatory body, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. It remains to be seen how, if at all, Brexit will impact regulatory requirements for therapeutic candidates and therapies in the UK. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would delay or prevent us from commercializing our investigational GD-T cell therapy or future therapeutic candidates in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. We may be forced to restrict or delay efforts to seek regulatory approval in the UK and/or EU for GD-T cell therapy or any future therapeutic candidates, which could significantly and materially

harm our business.

We expect that Brexit, in the near and middle term will lead to certain legal uncertainties and potentially divergent national laws and regulations as the UK determines which EU laws to replicate or replace, including those related to data privacy and the regulation of medicinal products, as described above. Any of these effects of Brexit, and others we cannot anticipate, could negatively impact our business and results of operations.

Our business may be subject to risks related to possible Scottish independence from the UK

The possibility of Scottish independence from the UK creates a range of uncertainties for Scotland based business in general, which would require careful assessment by the board of directors and management as political events develop. There could be changes in currency, taxation, general legislation, regulations and trading arrangements and agreements, together with economic prospects more generally. It is not possible to predict the effect of Scottish independence if it were to occur and the changes introduced could have only limited effect on the business, be beneficial to the business or could have a material adverse effect on the business' revenue, financial condition, profitability, prospects and results of operations.

A transfer of ordinary shares, other than one effected by means of the transfer of book-entry interests, such as through our ADS program, may be subject to United Kingdom stamp duty.

The transfer of our ordinary shares effected by means of the transfer of book entry interests through our ADS program will generally not be subject to United Kingdom stamp duty. However, if an investor holds its ordinary shares directly rather than beneficially through the ADS program, any transfer of ordinary shares (including into the ADS program with a view to trading) would be likely to be subject to United Kingdom stamp duty currently at the rate of 1.5% of the higher of the price paid or the market value of the shares acquired.

General Risk Factors

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

Due to the international scope of our operations, the financial reporting of our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, when comparing our results among different currencies such as the U.S. dollar, the pound sterling and the euro. Our reporting currency and our functional currency is the pound sterling and the majority of our operating expenses are paid in pound sterling. We regularly acquire services, consumables and materials in U.S. dollars, pound sterling and the euro. Further potential future revenue may be derived from non-United Kingdom jurisdictions, particularly from the United States. As a result, our business and the value of our ordinary shares, including those represented by the ADSs and underlying the Warrants, may be affected by fluctuations in foreign exchange rates between the pound sterling and these other currencies, 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.

Collaborations, whether through joint ventures, licensing, development arrangements, and other forms of agreements, will be important to our overall business development.

In common with many development stage biotechnology companies an element of our business plan is consider entering into collaborative arrangements with larger pharmaceutical and biotechnology companies. We expect that future collaborations will provide us with important expertise, aid in product development, conducting drug trials, facilitate market entry and may provide some level of funding or future revenue. Notwithstanding our belief that collaborations will be beneficial to us, any collaboration arrangement may by their nature pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a project;
- collaborators may not perform their obligations as expected;
- collaborators may dispute the amounts of payments owed;
- 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 or license arrangements

In the past, we have entered into collaborative arrangements with two partners, bluebird bio, Inc. (USA) and Nipro Corporation (Japan), which involved funded or partly funded preclinical collaboration. Neither collaboration involve us in any current clinical or development activity or are generating any current cash receipts for us. It is uncertain if these collaborations will generate any future cash receipts or obligations for TCB.

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

Our business is based in the United Kingdom and 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, primarily in the United Kingdom and in the EU. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political change;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;

- changes in non-U.S. currency exchange rates of the pound sterling, U.S. dollar, euro and currency controls;
- changes in a specific country's or region's political or economic environment, including the implications of the recent action of the United Kingdom withdrawing from the European Union and efforts related to Scottish independence;

- customs, tariffs and trade barriers, trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing medical product reimbursement regimes and price controls;
- 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 Kingdom and the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Unstable market and economic factors could adversely affect our business, financial condition or results of operations.

Uncertain or unfavorable global economic or market conditions, such as a recession, an economic slowdown, inflation or reduced growth rates, could significantly impact our operating results or lead to significant reductions in funding sources available to the Company, which could adversely affect our business, results of operations or financial condition. Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the development of our GD-T cell-based therapeutic candidates, including for future clinical trials. In the event of unstable markets and unfavorable market conditions, we cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our GD-T cell-based therapeutic candidates or other research and development initiatives. Furthermore, uncertain or unfavorable global economic or market conditions may cause our manufacturers, suppliers, distributors, contractors, logistics providers and other external business partners to suffer financial or operational difficulties, which could impact their ability to provide us with or distribute finished product, raw and packaging materials or services in a timely manner or at all. We could also face difficulty collecting or recovering accounts receivables from third parties facing financial or operational difficulties.

The conflict between Russia and Ukraine currently does not have any material impact on the company.

Our operations primarily are undertaken in the United Kingdom and the resources we use primarily are domestically available. We have not specifically sourced any resources for our operations from the Ukraine. We may be generally impacted by the macro-economic effects of international sanctions and the effects of inflation, as it would affect all businesses.

Computer system failures, cyber-attacks or deficiencies in our or related parties' cyber security could result in a material disruption of our product development programs, compromise sensitive information related to our business or trigger contractual and legal obligations, any of which could potentially expose us to liability or reputational harm or otherwise adversely affect our business and financial results.

We have implemented our security measures designed to protect the information (including but not limited to intellectual property, proprietary business information and personal information) in our possession, custody or control. Our internal computer systems and those of current and future third parties (such as vendors, CROs, collaborators or others) on which we rely may fail and are vulnerable to breakdown, breach, interruption or damage from computer viruses, computer hackers, malicious code, employee error or malfeasance, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromise. Despite our security practices, there is a risk that we may be subject to phishing and other cyberattacks in the future. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. 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 cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. 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 rely on third parties for the manufacture of our product candidates or 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate use, disclosure of or access to confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates or any future product candidates could be hindered or delayed. 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 to counterparties, data subjects, regulators or others could be material. In addition, our remediation efforts may not be successful. Moreover, if the information technology systems of our vendors, CROs, collaborators or other contractors or consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding clinical trial participants or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, cause us to breach our contractual obligations, subject us to mandatory corrective action, and otherwise subject us to liability under laws, regulations and contracts that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages. As cyber threats continue to evolve, we may be required to incur significant additional expenses in order to enhance our protective measures or to remediate any information security vulnerability.

In addition, in response to the ongoing COVID-19 pandemic, varying parts of our workforce are currently working remotely on a part- or full-time basis. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are not able to maintain and enhance our reputation and brand recognition, our business, financial condition and results of operations will be harmed.

We believe that maintaining and enhancing our reputation and brand recognition is critical to our relationships with existing and future third-party therapy locations, therapists, patients and collaborators, and to our ability to attract clinics to become our third-party therapy locations offering our therapies. The promotion of our brand may require us to make substantial investments, and we anticipate that, as our market becomes increasingly competitive, these marketing initiatives may become increasingly difficult and expensive. Brand promotion and marketing activities may not be successful or yield increased revenue, and to the extent that these activities yield increased revenue, the increased revenue may not offset the expenses we incur and our business, financial condition and results of operations could be harmed. In addition, any factor that diminishes our reputation or that of our management, including failing to meet the expectations of our network of third-party therapy locations, therapists and patients, could harm our reputation and brand and make it substantially more difficult for us to attract new third-party therapy locations, therapists and patients. If we do not successfully maintain and enhance our reputation and brand recognition, our business may not grow and we could lose our relationships with third-party therapy sites, therapists and patients, which would harm our business, financial condition and results of operations.

We are subject to anti-corruption laws, export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from manufacturing our products and developing and selling our investigational therapies or any future therapeutic candidates or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the UK Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage.

The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, a financial or other advantage to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior).

Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We, along with those acting on our behalf 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.

Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. 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. If we expand our operations, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the UK and the U.S., and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from manufacturing our products and developing and selling our investigational therapies or any future therapeutic candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by UK, U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, manufacture, handling, release and disposal of and the maintenance of a registry for, hazardous materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens.

We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. Furthermore, if we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous materials and, as a result, may incur material liability as a result of such release or exposure. Environmental, health and safety laws and regulations are becoming more stringent. We may incur substantial expenses in connection with any current or future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected. In the event of an accident involving such hazardous materials, an injured party may seek to hold us liable for damages that result.

Our internal computer systems, or those of our future collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

We do not intend to pay dividends on our ordinary shares, including those represented by ADSs, so any returns will be limited to the market value of the ADSs.

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

Investors in our ADSs may not receive distributions on our ordinary shares or any other value applicable to 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 the ADS holders 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. ADS holders will receive these distributions in proportion to the number of our ordinary shares that the ADSs represent. In accordance with the limitations set forth in the deposit agreement, however, 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 ADS holders 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 the ADS holder. These restrictions may have an adverse effect on the value of the ADSs.

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

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

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

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

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

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

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of the 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.

Holders of ADSs 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, owners and holders of ADSs irrevocably waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to 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 oppose 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 law of the State of New York, which governs the deposit agreement, by a federal or state court in the City and County 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 investors consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

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

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

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

The deposit agreement governing the ADSs provides that: (i) the deposit agreement and the ADSs will be interpreted in accordance with the law of the State of New

York; and (ii) as an owner of ADSs, the investor irrevocably agrees that any legal action arising out of the deposit agreement and the ADSs involving us or the depositary may only be instituted in a state or federal court sitting in the City and County of New York. Any person or entity purchasing or otherwise acquiring any the ADSs, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to these provisions. This choice of forum provision may increase costs and limit the ability to bring a claim in a judicial forum that the ADS holder finds favorable for disputes with us, the depositary or our and the depositary's respective directors, officers or employees, which may discourage such lawsuits against us, the depositary and our and the depositary's respective directors, officers or employees. However, it is possible that a court could find such choice of forum provisions to be inapplicable or unenforceable. The enforceability of similar choice of forum provisions has been challenged in legal proceedings. It is possible that a court could find this type of provisions to be inapplicable or unenforceable.

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

If we are a "passive foreign investment company," or a PFIC, in any particular year, a U.S. shareholder may be subject to adverse U.S. federal income tax consequences.

Under the Internal Revenue Code of 1986, as amended, or the Code, we will be a PFIC for any taxable year in which, after the application of certain look-through rules with respect to our subsidiaries, either (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income (including cash). Passive income includes, among other things, dividends, interest, certain non-active rents and royalties, and capital gains. Based on our operations, income, assets and certain estimates and projections, including as to the relative values of our assets and the treatment of amounts in respect of refundable tax credits from governmental entities we received, or are or may become entitled to receive, as gross income that is not passive income, we do not believe that we were a PFIC in 2020 and do not expect to be a PFIC for our 2021 taxable year. However, the determination whether we are a PFIC is a fact-intensive determination that must be made on an annual basis applying principles and methodologies that are in some circumstances unclear, and whether we will be a PFIC in 2022 or any future taxable year is uncertain because, among other things, (i) we currently own a substantial amount of passive assets, including cash, (ii) the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may depend in part of the market price of the ADSs or, if applicable, our ordinary shares from time to time, which may fluctuate substantially, (iii) the treatment of amounts in respect of refundable tax credits from governmental entities we received, or are or may become entitled to receive, as gross income that is not passive income is uncertain, and (iv) the composition of our income may vary substantially over time. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year, and our U.S. counsel expresses no opinion with respect to our PFIC status, or with respect to our expectations regarding our PFIC status in 2023 or any future taxable year.

If we are a PFIC for any taxable year during which a U.S. investor holds ADSs or ordinary shares, we would continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds the ADSs or ordinary shares, even if we ceased to meet the threshold requirements for PFIC status, unless certain exceptions apply. Such a U.S. investor may be subject to adverse U.S. federal income tax consequences, including (i) the treatment of all or a portion of any gain on the disposition of the ADSs or ordinary shares as ordinary income (and therefore ineligible for the preferential rates that apply to capital gains with respect to some U.S. investors), (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends on the ADSs or the ordinary shares and (iii) compliance with certain reporting requirements. We do not intend to provide the information that would enable investors to make a qualified electing fund election, or a QEF Election, with respect to their holding of ADSs or ordinary shares that could mitigate the adverse U.S. federal income tax consequences to a U.S. investor should we be classified as a PFIC.

If we are a controlled foreign corporation for U.S. federal income tax purposes, there could be adverse U.S. federal income tax consequences to certain U.S. holders who own, directly, indirectly or by attribution, ten percent or more of our ordinary shares.

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "controlled foreign corporation," or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income", investment of earnings in U.S. property, and "global intangible low-taxed income", even if the CFC has made no distributions to its shareholders. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly, indirectly or constructively (through attribution), more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation.

A "Ten Percent Shareholder" is a United States person (as defined by the Code) who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote of such corporation or 10% or more of the total value of the stock of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. A failure by a United States shareholder of a CFC to comply with its reporting obligations may subject the United States shareholder to significant monetary penalties and other adverse tax consequences, and may extend the statute of limitations. We cannot provide any assurances that we will assist U.S. holders in determining whether we or any of our non- U.S. subsidiaries are CFCs or whether any holder is a Ten Percent Shareholder. We also cannot guarantee that we will furnish information that may be necessary to comply with the aforementioned obligations. U.S. holders should consult their own advisors regarding the potential application of these rules.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

TC BioPharm recognizes the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data.

Managing Material Risks & Integrated Overall Risk Management

Currently, TC BioPharm does not have a formalized cybersecurity risk management process. However, the organization is working toward implementing a framework for assessing, identifying, and managing material risks from cybersecurity threats. The IT department will work to continuously evaluate and address cybersecurity risks in alignment with our business objectives and operational needs. This includes assessing cybersecurity risk as part of an overall risk assessment and considering the likelihood and potential consequences of each risk. Plans also include the identification of critical cybersecurity risks (e.g., malware, phishing, ransomware, and unauthorized access) and the implementation of formalized mitigants to address those risks such as cybersecurity policies and incident response strategy.

Third-Party Risk

TC BioPharm does not currently engage with third parties in connection with cybersecurity risk management. Third-party consultants including cybersecurity auditors are being considered for future engagement, at which point any risks stemming from the use of third parties will be incorporated in the cybersecurity risk assessment.

Risks from Cybersecurity Threats

TC BioPharm has not encountered any cybersecurity risks or incidents that have materially impacted our business strategy, operational results, or financial condition. We remain dedicated to maintaining a strong cybersecurity posture by continually analyzing and improving our security procedures to reduce potential risks. This approach to cybersecurity is critical for protecting sensitive information and guaranteeing the reliability of our business operations.

Governance

Board of Directors Oversight

The Board of Directors is acutely aware of the critical nature of managing risks associated with cybersecurity threats. The Board is committed to effective governance in managing risks associated with cybersecurity threats because we recognize the significance of these threats to our operational integrity and stakeholder confidence.

The Board of Directors is informed of relevant cybersecurity risks and related updates during quarterly Board meetings by the CFO who is also a Board member. There have been no critical, time sensitive cybersecurity updates thus far, but if this did occur it would be escalated to the Board immediately.

Management's Role Managing Risk

Within the management team, the responsibility for assessing and managing cybersecurity risk falls under the purview of the Senior IT Manager, whose background includes a Qualification in Network System Engineering coupled with over two decades of experience in fortifying cybersecurity for various companies. Moreover, TC BioPharm partners with a Managed IT service provider. This enriches our collective capabilities by leveraging their extensive experience and specialized skills. This collaboration significantly bolsters our overall cybersecurity stance, creating a well-rounded and robust defense against emerging threats.

Monitoring Cybersecurity Incidents

TC BioPharm's Senior IT Manager monitors cybersecurity events and logs for unusual activity or potential security breaches within the network. E-mail alerts are sent in real time as notification for any suspicious activity including phishing attempts, suspicious attachments, and other e-mail-related security concerns. The Senior IT Manager also actively utilizes the WatchGuard & Webroot Advance Security tools to conduct regular and thorough scans of the network infrastructure. The tools help identify vulnerabilities, malware, and other potential threats, enabling a proactive measure to prevent and mitigate cybersecurity incidents.

Reporting to Board of Directors

The CFO holds biweekly meetings with the Senior IT Manager to discuss any pertinent information regarding cybersecurity risks. This includes briefings on existing threat scenarios, updates on incident response efforts, and recommendations for enhancing our cybersecurity stance. As a member of the Board of Directors, the CFO communicates key information to the remaining Board members.

Item 2. Properties

Our corporate headquarters and most of our operations, including our research and manufacturing facilities, are located at Maxim 1, 2 Parklands Way, Holytown, Motherwell, ML1 4WR, United Kingdom. The lease for this space expires February 28, 2029 and covers a total leasable area of approximately 26,300 square feet. We believe that our office facilities and the production and research facilities in the United Kingdom are sufficient to meet our current needs.

Item 3. Legal Proceedings

From time to time, we are involved in various disputes, claims, suits, investigations, and legal proceedings arising in the ordinary course of business. We believe that the resolution of current pending legal matters will not have a material adverse effect on our business, financial condition, results of operations or cash flows. Nonetheless, we cannot predict the outcome of these proceedings, as legal matters are subject to inherent uncertainties, and there exists the possibility that the ultimate resolution of these matters could have a material adverse effect on our business, financial condition, results of operations or cash flows.

In accordance with the terms of a Convertible Loan Note ('Note') on August 9, 2022 (the Conversion Date) the Company issued 183,820 Ordinary Shares and 367,640 listed warrants to the Note holder in full satisfaction of the Note in the aggregate amount of $781,233. The holder filed a claim in the English courts on June 19, 2023 asserting that notice was provided such that the Company should have paid it the value of the Note in cash, rather than by settling it through the issuance of Ordinary Shares and listed warrants. The holder is demanding payment of the face value of the Note, together with interest, (approximately $860,000). The litigation process is in its early stages and is not expected to conclude until late 2024 or later. The Company has retained English solicitors and is contesting the claim in its entirety. The Company believes that it acted correctly under the terms of the Note and has accounted for the transaction on that basis, and that no further amounts are payable to the holder.

Item 4. Mine Safety Disclosures

None.

PART II

Item 5. Market for Registrants Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our share capital currently consists of ordinary shares. We may issue new classes of shares with such rights or restrictions as may be determined by special (75%) resolution of the shareholders, including shares which are to be redeemed, or are liable to be redeemed at our option or the option of the holder of such shares. The ADSs and public Warrants have been listed on the Nasdaq Capital Market under the symbols "TCBP" and "TCBPW," respectively, since February 11, 2022.

Dividends

We have never declared or paid a dividend, and we do not anticipate declaring or paying dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Under Scottish law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

Recent Sales of Unregistered Securities

During the year ended December 31, 2023, all sales of unregistered securities by the Company have been previously reported on a Form 6-K as the Company qualified as a foreign private issuer during this period.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the period covered by this Annual Report.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements (prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and related notes included elsewhere in this Annual Report on Form 10-K (this "Form 10-K"). The following discussion contains forward-looking statements that are subject to risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks, and assumptions associated with those statements. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Form 10-K, particularly in the section entitled "Risk Factors." Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our" and the "Company" refer to TC BioPharm (Holdings) Limited and its subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company with a cell-based product pipeline capable of treating a variety of disorders including cancer and infectious disease. We are currently developing a pipeline of unmodified allogeneic GD-T therapies and next generation GD CAR-T treatments with a number of advantages over conventional approaches. We own our main patent families in the GD CAR-T space, providing robust IP protection and manufactures all products in-house, leading to a much lower cost of goods than competitor products.

Components of Our Results of Operations

Revenues

We do not have any approved products. Accordingly, we have not generated any revenue from the sale of products, and we do not expect to generate any such revenue unless and until we obtain regulatory approvals for, and commercialize any of, our product candidates. In the future, we will seek to generate revenue primarily from product sales and, potentially, regional or global collaborations with strategic partners, which may produce license fee income.

During the year ended December 31, 2022, we had two collaboration agreements. Revenue arose under these contracts as a result of (i) our recharging development costs incurred by us under those agreements to our partners and (ii) on upfront payments received under those collaboration agreements, which were taken to revenue on a straight-line basis over the estimated term over which the services promised will be provided. This term was estimated by management at the inception of each contract and re-evaluated at each reporting date. The Company ceased to have an effective obligation to continue to provide unpaid services from December 7, 2022. Thus, noting that a) the Company did not have any additional obligations to the collaboration partner and 2) the upfront payment (that was recognized as deferred revenue) was non-refundable we recognized any remaining deferred revenue upon termination of the contract in December of 2022.

Since inception through December 31, 2023, the Company has received £14.5 million in pre-clinical payments connected with CAR-T development partnerships. These partnerships are no longer actively being progressed and it is unlikely that we will receive any future milestone revenues.

Operating Expenses

We classify our operating expenses into two categories: research and development expenses and administrative expenses. Personnel costs, including salaries, benefits, bonuses and share-based payment expense, comprise a significant component of each of these expense categories. We allocate expenses associated with personnel costs based on the function performed by the respective employees.

Research and Development Expenses

The largest component of our total operating expenses since inception has been costs related to our research and development activities, including the preclinical and clinical development of our product candidates.

Research and development costs are expensed as incurred, with our development activities not yet at the point at which capitalization can occur under GAAP. Our research and development expense primarily consist of:

- consumable costs related to research and development of pharmaceutical or biologic therapy products for preclinical studies and clinical trials;
- costs related to manufacturing active pharmaceutical or biologic therapy products for preclinical studies and clinical trials;
- salaries and personnel-related costs, including bonuses, benefits and any share-based payment expense, for our personnel performing research and development activities or managing those activities that have been out-sourced;
- fees paid to consultants and other third parties who support our product candidate development;

- third party costs incurred in connection with preclinical studies and clinical trials from investigative sites and contract research organizations, or CROs;
- other costs incurred in seeking regulatory approval of our product candidates;
- costs of related office space allocated to our research and development function, materials and equipment; and
- payments under our license agreements.

The successful development of our product candidates is highly uncertain. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. In addition, the cost of development of our CAR-T range of products is likely to be substantially higher than costs incurred historically in the development of our unmodified products. Accordingly, we expect research and development costs to increase significantly for the foreseeable future as programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. We are also unable to predict when, if ever, material net cash inflows will commence from our product candidates to offset these expenses. Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors including:

- the scope, rate of progress, results and expenses of our ongoing and future clinical trials, preclinical studies and research and development activities;
- the potential need for additional clinical trials or preclinical studies requested by regulatory agencies;
- potential uncertainties in clinical trial enrolment rates or drop-out or discontinuation rates of patients;
- competition with other drug development companies in, and the related expense of, identifying and enrolling patients in our clinical trials and contracting with third-party manufacturers for the production of the drug product needed for our clinical trials;
- the achievement of milestones requiring payments under in-licensing agreements;
- any significant changes in government regulation;
- the terms and timing of any regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ease, cost and ability to market, commercialize and achieve market acceptance for any of our product candidates, if approved.

We track research and development expenses on a program-by-program basis for both clinical-stage and preclinical product candidates. Manufacturing, clinical trial and preclinical research and development expenses are assigned or allocated to individual product candidates. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee research and development as well as for managing our preclinical development, process development, manufacturing and clinical development activities.

Administrative Expenses

Administrative expenses consist of personnel costs, other administrative expenses and other expenses for outside professional services, including legal, audit and accounting services. Personnel costs consist of salaries, bonuses, benefits and share-based compensation expense. Other administrative expenses include office space-related costs not otherwise allocated to research and development expense, professional fees and costs of our information systems. We anticipate that our administrative expenses will continue to increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We expect to continue to incur additional expenses as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance expenses, and expenses related to investor relations activities and other administrative and professional services.

Administrative Expenses – Costs to prepare for listing

Administrative costs to prepare for our IPO consist of professional services such as legal, investor relations, accounting, audit, and other administrative services.

Change in fair value of derivative liability

The gain/loss relates to the movement in the estimated fair value of the embedded derivative related to the issue of Convertible Loan Notes, calculated by using a Black Scholes option pricing model at the end of each reporting period. The gain/loss relates to the movement in the estimated fair value of our warrants, calculated by using a Black Scholes option pricing model at the end of each reporting period. As it pertains to the issued warrants, it is important to note that as of December 31, 2023 they were primarily equity classified and therefore are no longer required to be re-measured to fair value at the end of each reporting period.

Interest Expense

Interest expense includes the effective interest charge accrued in relation to the Convertible Loan Notes. Interest expense is offset by interest income related to interest earned on our cash and cash equivalents and short-term deposits.

Income Tax Credit

We are subject to corporate taxation in the United Kingdom. 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.

As a company that carries out extensive research and development activities, we benefit from the United Kingdom research and development tax credit regime and 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.

There can be no certainty that we will be able to continue to claim research and development tax credits in the future. Tax losses that have not been utilized to offset taxable income or surrendered in connection with the aforementioned research and development tax credits are carried forward to be offset against future taxable profits. In the event we generate revenues in the future, we may benefit from the United Kingdom's government's "patent box" initiative that allows profits attributable to revenues from patents and/or patented products registered in the United Kingdom or European Union to be taxed at a lower rate than other streams of revenue. The current rate of tax for relevant streams of revenue for companies receiving this relief is 10%.

Results of Operations

Comparison of the Years Ended December 31, 2023, and 2022

The following table summarizes our results of operations:

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022	£ Change	% Change
Revenue	**£ -**	£ 3,844,532	£ (3,844,532)	(100)%
Operating expenses:				
Research and development expenses	7,771,391	7,592,470	178,921	2%
Administrative expenses	6,467,932	7,030,972	(563,040)	(8)%
Administrative expenses - costs to prepare for listing	-	1,305,087	(1,305,087)	(100)%
Total operating expenses	14,239,323	15,928,529	(1,689,206)	(11)%
Loss from operations	(14,239,323)	(12,083,997)	(2,155,326)	18%
Other income (expense):				
Loss on modification of convertible loan	(645,845)	(140,344)	(505,501)	360%
Change in fair value of derivative liability	8,052,581	16,064,945	(8,012,364)	(50)%
Foreign currency losses	(80,070)	(120,974)	40,904	(34)%
Interest expense	(83,025)	(6,753,231)	6,670,206	(99)%
Total other income (expense), net	7,243,641	9,050,396	(1,806,755)	(20)%
Net loss before income taxes	(6,995,682)	(3,033,601)	(3,962,081)	131%
Income tax credit	1,088,729	1,720,000	(631,271)	(37)%
Net loss	**£ (5,906,953)**	£ (1,313,601)	£ (4,593,352)	350%

Revenue

Revenue decreased by £3.8 million for the year ended December 31, 2023 compared to for the year ended December 31, 2022. Revenue from upfront payments in connection with collaboration agreements is recognized over the estimated term over which the services promised will be provided. This term was estimated by management at the inception of each contract and evaluated at each reporting date. Management reviewed the status of the contract and specific contractual terms and concluded that at December 31, 2022, no further services were required to be provided under the contract. As such, the remaining deferred revenue, which reflected a non-refundable upfront payment received from our collaboration partner was fully recognized during December 2022. Thus, no revenue stemming from the upfront payment was recognized during the year ended December 31, 2023.

Research and Development Expenses

	Year Ended December 31,			
	2023	2022		
	£'000's	£'000's	£ Change	% Change
Direct research and development expenses by program:				
Unmodified cell therapy programs(1)	£ 3,212	£ 1,257	£ 1,955	155.5%
Other research and development programs(2)	64	136	(72)	(52.7)%
Total direct research and development expense	3,276	1,393	1,883	135.2%
Research and development and unallocated costs:				
Personnel related (including share-based compensation)	3,365	4,504	(1,139)	(25.3)%
Indirect research and development expense(3)	1,130	1,695	(565)	(33.4)%
Total research and development expenses	£ 7,771	£ 7,592	£ 179	2.4%

(1) Unmodified cell therapy programs include OmnImmune® and ImmuniStim®
(2) Other research and development programs include expenditure on areas such as our CAR-T program and induced pluripotent stem cells (iPSCs).
(3) Indirect research and development expense includes property related costs and depreciation and amortization.

Research and development expenses increased by 2.4% to £7.8 million for the year ended December 31, 2023 from £7.6 million for the year ended December 31, 2022 reflecting the increased work on unmodified cell therapy programs, which increased by 156%. Personnel costs partially offset the increase, which decreased by 25% for the year ended December 31, 2023 compared to December 31, 2022.

General and administrative

	Year Ended December 31,			
	2023	2022	£ Change	% Change
	£'000's	£'000's		
Share-based compensation expense	295	719	£ (424)	(59.0)%
Employee-related costs	2,443	2,396	47	2.0%
Legal & professional fees	3,383	3,569	(186)	(5.2)%
Other expenses	347	347	-	0.0%
Total administrative expenses	6,468	7,031	(563)	(8.0)%

Administrative expenses decreased by 8% to £6.5 million for the year ended December 31, 2023 from £7.0 million for the year ended December 31, 2022. The decrease was primarily driven by a decrease in share-based compensation expense and a decrease in legal and professional fees.

Loss on modification of convertible loan

The change in the loss on modification of convertible loan primarily relates to modifications made to the loan in 2023 as compared to 2022. The convertible loan was

fully settled (via either cash settlement or conversion) during the year ended December 31, 2023.

Change in fair value of derivative liability

The change in fair value of derivative liability is comprised of the change in fair values of the convertible loan derivative, warrant derivative, and other derivatives. The change in the fair value of the embedded convertible loan derivatives relates to the movement in the estimated fair value of the embedded derivatives during the year ended December 31, 2023 (ie. as compared to December 31, 2022), which was calculated by using the Black Scholes option pricing model. The convertible loan was fully settled (via either cash settlement or conversion) during the year ended December 31, 2023.

The change in fair value of the warrant derivatives of £8.1 million for the year ended December 31, 2023 relates to the movement in the estimated fair value of our issued detachable warrants. The warrants were issued at the time of the IPO and at various times during each of the two years ended December 31, 2023. In addition, certain warrants were both modified and induced over the course of our fiscal year ended December 31, 2023. All of our issued warrants are valued by using the Black Scholes option pricing model.

Foreign Currency Losses

The decrease in foreign currency losses for the year ended December 31, 2023 compared to for the year ended December 31, 2022 was primarily due to a lower foreign exchange rate during 2023.

Interest Expense

Interest expense was approximately £0.1 million for the year ended December 31, 2023 compared to £6.8 million for the year ended December 31, 2022. The decrease was due to the Convertible Loan Note being paid off during the year. Interest expense was partially offset by interest income earned on cash accounts.

Income tax credit

The research and development tax credit of £1.1 million was 37% lower for the year ended December 31, 2023 compared to £1.7 million for the year ended December 31, 2022. This was due to lower levels of expenditure eligible for research and development tax credits.

After accounting for tax credits receivable, there were accumulated tax losses for carry forward in the United Kingdom of £16.4 million as of December 31, 2023. Unrecognized deferred tax assets totaling £4.2 million as of December 31, 2023 consist of temporary differences on tax losses and share-based compensation arrangements. No deferred tax asset is recognized in respect of accumulated tax losses or temporary differences on share-based compensation arrangements because future profits are not sufficiently certain.

Going Concern

Our existing cash of £2.5 million at December 31, 2023 will not be sufficient to enable us to conduct our business 12 months from the issuance of these financial statements. We will need additional funding to complete the development and research of our products. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and development efforts.

As a result of the Company's recurring losses from operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern.

Liquidity and Capital Resources

For the years ended December 31, 2023 and 2022, we incurred net losses of £5.9 million and £1.3 million, respectively. We used £10.5 million of cash in operating activities in the year ended December 31, 2023 and used £15.3 million of cash in operating activities for the year ended December 31, 2022.

As of December 31, 2023, and December 31, 2022, we had cash and cash equivalents of £2.5 million and £4.8 million, respectively. From incorporation through December 31, 2023, we have financed our operations primarily through our IPO, private placements of equity securities, convertible loans, government grants, research and development tax credits, and receipts from partner for collaborative research and development services totaling £82.1 million.

While we work towards obtaining regulatory approval to advance any of our GD-T cell therapeutic candidates into pivotal clinical trials or to commercialization, we will incur significant research and development expenses, and also commercialization expenses related to product sales, marketing, manufacturing and distribution and additional funding would be required. Where appropriate, we will seek to fund our operations through milestone payments under our agreements with collaboration partners and additional equity financings.

Cash Flows

The following tables summarize the results of our cash flows for the below respective periods:

	Year Ended December 31,	
	2023	2022
Net cash provided by (used in):		
Operating activities	£ (10,544,870)	£ (15,292,297)
Investing activities	£ (208,789)	£ (310,197)
Financing activities	£ 8,520,376	£ 18,653,214
Change in cash	£ (2,345,451)	£ (3,241,372)

Operating Activities

Net cash used in operating activities was £10.5 million for the year ended December 31, 2023. The net loss for the year ended December 31, 2023 was £5.9 million, which was offset by noncash items of £6.2 million, consisting of £0.6 million in depreciation and amortization, £0.4 million in share-based compensation expense, a £0.6 million loss on modification of the Convertible Loan Note, an £8.1 million change in the fair value of the derivative liability, a £0.1 million net foreign exchange loss, and £0.1 million in noncash interest expense. Changes in working capital amounted to £1.5 million, which consisted of an increase in the corporation tax receivable, operating lease right of use assets, and accounts payable and accrued expenses. Prepaid expenses and other current assets and lease liabilities decreased working capital.

Net cash used in operating activities was £15.3 million for the year ended December 31, 2022. The net loss for the year ended December 31, 2022 was £1.3 million, which was offset by noncash items of £7.3 million, consisting of £0.8 million in depreciation and amortization, £1.1 million in share-based compensation expense, a £0.1 million loss on modification of the Convertible Loan Note, a £16.1 million change in the fair value of the derivative liability, a £0.1 million net foreign exchange loss, and £6.6

million in noncash interest expense. Changes in working capital used £6.7 million in cash.

Investing Activities

Net cash used in investing activities was £0.2 million and £0.3 million for the years ended December 31, 2023 and 2022, respectively. These amounts relate primarily to purchases of property, plant and equipment related to our facility and patent filing costs.

Financing Activities

Net cash from financing activities was £8.5 million and £18.7 million for the years ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023, these amounts consisted of net proceeds from sale of own shares and warrants for £9.3 million offset by issuance costs of £0.8 million. For the year ended December 31, 2022, these amounts consisted of net proceeds from sale of own shares and warrants for £22.2 million offset by the repayment of convertible loan notes of £2.6 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. Our expenses will increase as we (i) advance our product candidates through phases of clinical development and, potentially, registration, (ii) fund our research and development activities to further expand our GD-T cell technologies and develop future product candidates and follow-on versions of our more advanced product candidates, (iii) fund our manufacturing activities and the expansion of our plant to support our ongoing and future clinical trials and potential commercial launch; and (iv) fund our general operations.

Since February 10, 2022, we have been a publicly traded company and incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and The Nasdaq Stock Market, requires public companies to implement specified corporate governance practices. We expect to continue to incur substantial legal and financial compliance costs, which may make some activities more time-consuming and costly.

We will require additional capital to continue to conduct our business and implement our business plans.

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

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the costs, timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the costs of future sales and marketing activities, including cost of product sales, medical regulatory affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount and timing of the receipt of any future revenue from commercial sale of our products, should any of our product candidates receive marketing approval and become successful in the market;
- the impact of the COVID-19 pandemic on our ability to progress research and development and clinical trials;
- the costs and timing of hiring new employees to support our future growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the cost of and extent to which we in-license or acquire additional product candidates or technologies.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our future cash needs through equity offerings and debt and a combination thereof, including securities convertible into ordinary shares and through development collaborations with partners. To the extent that we raise additional capital through the sale of equity, our shareholders' ownership interest will be diluted.

If we raise additional funds through other third-party funding, collaborations agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves. If we raise funding through borrowings, we may have to enter into onerous covenants which may adversely impact our operations and our ability to obtain further funding.

There is no assurance that we will be able to raise any further funding, or if further funding is offered, it will be on terms that are acceptable to us and may bring dilution which is unacceptable to our shareholders.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2023 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
	Total	Less Than 1 Year	1 - 3 Years	4 - 5 Years	More Than 5 Years
Trade payables	£ 1,847,279	£ 1,847,279	£ –	£ –	£ –
Lease liabilities	2,235,075	447,015	894,030	894,030	–
Payables related to clinical trial testing	1,177,500	1,177,500	–	–	–

Other payables	1,407,061	1,407,061	–	–	–
Total commitments	£ 6,666,915	£ 4,878,855	£ 894,030	£ 894,030	£ -

Lease liabilities

Amounts shown as lease liabilities and similar reflect minimum payments due for our leases of office, laboratory and manufacturing space. We entered into a lease for our corporate headquarters in April 2014 and, as part of this agreement, exercised an option to lease additional space in January 2017 and March 2019. The overall lease expires in February 2029.

Other commitments

We enter into contracts in the normal course of business with third parties who support us in the conduct of certain specialist aspects of clinical trials and preclinical research studies and testing. These contracts are generally cancellable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table, as the amount and timing of such payments are not known.

We have not included any contingent payment obligations that we may incur upon achievement of clinical, regulatory and commercial milestones, as applicable, or royalty payments that we may be required to make under in-licensing agreements which we have or may enter into which could be payable if any of our products generate future sales or license revenue as the amount, timing and likelihood of such payments are not known and are not anticipated in the near term or before we generate significant revenues.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our financial statements and accompanying notes have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses, and related disclosures. On an ongoing basis, we continually evaluate our estimates and assumptions believed to be reasonable under current facts and circumstances. Actual amounts and results may materially differ from these estimates made by management under different assumptions and conditions.

Certain accounting policies that require significant management estimates and are deemed critical to our results of operations or financial position, are described below. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition and results of operations.

Going Concern

Our evaluation of our ability to continue as a going concern requires us to evaluate our future sources and uses of cash sufficient to fund our currently expected operations in conducting research and development activities one year from the date our consolidated financial statements are issued. We evaluate the probability associated with each source and use of cash resources in making our going concern determination. The research and development of cell therapies is inherently subject to uncertainty.

Management believes that its existing cash balances will only be able to fund current operations to May 2024. Should the additional planned financings not occur as expected, management will implement alternative arrangements and such arrangements could have a potentially significant negative impact on the current net asset value of the Company. These alternatives include: (1) raising additional capital by means other than those planned through equity and/or debt financings; (2) entering into new commercial relationships to help fund future clinical trial costs (i.e. licensing and partnerships); (3) reducing and/or deferring discretionary spending on general corporate overheads and one or more of our research and development and / or clinical programs; and/or (4) restructuring operations to change our overhead structure and make use of our manufacturing facilities to generate revenues from through third party manufacturing contracts. In the medium term, the Company's future liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates and key development and regulatory events and its decisions in the future.

As a result of the Company's recurring losses from operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern.

Revenue from contracts with customers

Identification of contracts with pharma partners

The Company entered into collaboration agreements with a number of parties. Application of Accounting Standard Codification ("ASC") 606, *Revenue from Contracts with Customers,* on collaboration agreements requires judgement around whether these contracts fall within the scope of ASC 606. The Company's core business is around researching and developing immunotherapies and the contracts entered into with pharma partners were consistent with those objectives and the outputs are in line with the Company's ordinary activities. The contracts with pharma partners did not involve sharing the risks and benefits of a joint arrangement in the sense of Topic 808 "Collaborative arrangements". In light of work undertaken with pharma partners, and the fact that these agreements had commercial substance with clearly defined milestones and rights and obligations for each party, management concluded that these collaboration agreements met the definition of a contract with a customer and fall within the scope of ASC 606.

Identification of performance obligations in contracts

The collaboration agreements entered into by the Company included obligations to fulfil the research and development programs. The Company identified, from reviews of the relevant agreements, that there are no specific obligations but an implied performance obligation to deliver each overall contracted research and development program. Due to the broad nature of these obligations, spanning the full duration of the contract, the obligations were satisfied over the expected duration of the relevant contract.

Determination and allocation of the transaction price

The collaboration agreements included a number of elements of consideration and were allocated to the satisfaction of the relevant obligation. The Company can receive upfront payments as part of the consideration. The Company has determined that upfront payments are in connection with the performance of the research and development program and are satisfied during the duration of the contract.

The business is entitled to receive contractual milestone payments on achievement of certain performance obligations, with revenue being recognized in the same way. The relevant transaction price is allocated to the related milestone.

Key Sources of Estimation Uncertainty

The key assumptions concerning the future, and other key sources of estimation uncertainty at the balance sheet date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next year are discussed below.

Convertible loan

The Company established a $20.0 million convertible loan note instrument in April 2021. During the year ended December 31, 2023, the Company converted loan notes totaling $809,692 (£619,315) into ordinary shares and warrants over ordinary shares such that no loan notes were outstanding as at December 31, 2023. During the year to December 31, 2022, the Group converted loan notes totaling $14,228,245 (£10,506,174) into ordinary shares and warrants over ordinary shares and repaid loan notes totaling $3,195,765 (£2,632,324). The Company analyzed the conversion feature of the convertible loan note under ASC 815-Derivatives and Hedging. Where there are outstanding amounts under the convertible loan note, these are recorded as a liability on the consolidated balance sheet at the reporting date. The conversion feature for any such outstanding amounts requires liability treatment on the consolidated balance sheet and was recorded at fair value with changes to the fair value being recorded through the consolidated statement of operations.

Except for the loan notes described below, all other loan notes were repaid or converted into ordinary shares and warrants over ordinary shares 180 days after the listing date.

On August 9, 2022, the Company agreed with one of the loan note holders not to exercise the right to require the loan notes to be repaid in cash in accordance with the terms of the loan notes and to amend certain other aspects of the loan notes ("amended loan notes"). As additional consideration, the Company has issued warrants to subscribe for 233,560 ordinary shares in the share capital of the Company. Except for the amended loan notes, all other loan notes were repaid or converted into ordinary shares and warrants over ordinary shares 180 days after the listing date.

The changes note above represent a substantial amendment as the modifications are related to:

(i) Removing the exercise of the right to require the loan in cash as of August 9, 2022.
(ii) Extending the repayment date to January 31, 2023 and modifying the structure to be repaid in shares if not redeemed before in cash.
(iii) Revising the conversion price for the conversion of the loan notes in shares. The revised conversion price would be $0.50 and, if the 5-day trailing VWAP of the Company's ADS is above that and $0.20 as a floor.
(iv) Giving the option to the holder for redemption in cash, which will occur no later than February 10, 2023 and to the Company for an early redemption at any moment but having the Holder an option to convert into shares using the revised conversion price at that moment.

On April 3, 2023, the Company agreed with the loan note holder not to exercise the right to require the loan notes to be repaid in cash in accordance with the terms of the loan notes and to amend certain other aspects of the loan notes ("2023 amended loan notes"). As additional consideration, the Company issued warrants to subscribe for 4,000,000 ordinary shares of the Company. These warrants contained a condition whereby if a registration statement, to be filed by the Company, registering all of the securities underlying the note holder's amended convertible loan note, was not declared effective by July 31, 2023, the note holder will be entitled to receive 0.30 Ordinary Shares for each share it was originally entitled to purchase under these warrants without the payment of any additional consideration. No such registration statement was filed. The related fair value of the issue of any additional securities is approximately $37,000 and is not considered material to the financial statements.

The modifications to the 2023 amended loan notes represent as substantial amendment as the modifications are related to:

(i) A waiver to any defaults arising in connection with the 2022 amended loan notes.

(ii) Extending the repayment date to January 15, 2024; and

(iii) Amend the Conversion Price (as defined in the Loan Note) of the outstanding loan notes to be the lesser of $1.00 or the lowest closing price of the Ordinary Shares during the ten (10) day period prior to the date the Noteholder delivers a notice of conversion to the Company, not to be lower than $0.20.

In accordance with ASC 470, an exchange between an existing borrower and lender of debt instruments with substantially different terms shall be accounted for as an extinguishment of the original financial liability (with the associated gain or loss presented in the statement of operations) and the recognition of a new financial liability. In addition, as consideration for these modifications, the Company has issued additional warrants to subscribe for 4,000,000 ordinary shares of the Company.

The original financial instrument was derecognized, including any unamortized transaction costs, and the new instrument was initially recognized at fair value and subsequently measured at amortized cost at each reporting date.

The conversion option is a single embedded derivative that is separately recognized as a liability and accounted for at fair value through the statement of operations. The conversion options are financial liabilities in accordance with ASC 815 because the Company issues shares such that the fair value of the shares delivered is always equal to the amount of the contractual obligation (i.e. a variable number of shares depending on the share price of the stock). As a result, the conversion options are part of the financial liability debt instrument and should be evaluated under the embedded derivatives guidance. Because the conversion options are indexed to the equity of the issuer, these are not closely related to the host contract. This instrument is considered a new freestanding financial instrument and constitutes an embedded derivative liability that is separately recognized as a liability and subsequently adjusted to its fair value at each reporting period, which is presented in the statement of operations.

As noted earlier, the Company converted loan notes totaling $809,692 (£619,315) into ordinary shares and warrants over ordinary shares such that no loan notes were outstanding as at December 31, 2023.

Derivative liability

We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC 480 and ASC 815. Warrants that do not meet the criteria for equity treatment in accordance with the guidance contained in ASC 815-40 have been recorded as liabilities. Accordingly, we classify these warrants as liabilities at their fair value and adjust the warrants their fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in our statement of operations.

Pre-funded warrants

The Pre-Funded Warrants are classified as a component of equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of ordinary shares upon exercise (foreign exchange on nominal value of the shares is not considered relevant for the analysis because not more than an insignificant amount related to the value of the share remains outstanding which is the $0.0001 nominal amount that remains open to be paid upon exercising it). In addition, Pre-Funded Warrants do not provide any guarantee of value or return.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to a variety of risks in the ordinary course of our business, including, but not limited to, currency risk, liquidity risk and credit risk, as discussed below. We regularly assess each of these risks to minimize any adverse effects on our business as a result of those factors.

Credit risk

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Company's receivables from customers and from its financing activities, including deposits with banks and financial institutions, foreign exchange transactions and other financial instruments. The Company only engages with banks and financial institutions with a Standard and Poor credit rating of BBB or greater. The Company has a small number of customers as part of its collaboration agreements. To manage the credit risks around collaboration agreements, the Company will assess the creditworthiness of partners as part of the engagement process. The Company has monitoring procedures in place to identify and follow up on any overdue debts. Credit risk from balances with banks and financial institutions is managed by the Company's finance department in accordance with the Company's policy to only place funds with approved counterparties with the appropriate credit rating. The Company is exposed to no material credit risk.

Liquidity risk

Liquidity risk is the risk that necessary sources of funding for the Company's business activities may not be available. The Company manages liquidity risk by maintaining adequate reserves, banking facilities and reserve borrowing facilities, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities. The Company is utilizing shareholder funds, collaboration agreements, grant funding and asset finance to support its working capital requirements. All cash funds are held with a maturity of three months or less.

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

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company is not exposed to any material interest rate risk.

Currency risk

The Company has transactions denominated in various currencies, with the principal currency exposure being fluctuations in U.S. Dollars and Euros against pound sterling. The Company's exposure to the risk of changes in foreign exchange rates relates primarily to the Company's Convertible Loan Notes that are denominated in US Dollars and a limited number of supplier agreements denominated in currencies other than pound sterling.

Equity price risk

The Convertible Loan Notes issued by the Group contained an embedded derivative component that was accounted for at fair value at each period end. As such, a change in the estimated underlying price per share impacted the valuation of the embedded derivative. The convertible debt was fully settled as of December 31, 2023.

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
TC BioPharm (Holdings) plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TC BioPharm (Holdings) plc (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022 , and the results of its operations and its cash flows for each of the two years in the period ended December 31 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Change in Reporting Framework

As discussed in Note 3 to the financial statements, the Company has changed its reporting framework from International Financial Reporting Standards as issued by the International Accounting Standards Board to accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Marcum llp

Marcum LLP

We have served as the Company's auditor since 2022.

New York, NY
April 1, 2024

TC BIOPHARM (HOLDINGS) PLC
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	£ 2,462,609	£ 4,808,060
Corporation tax receivable	1,043,593	1,720,000
Prepaid expenses and other current assets	2,194,725	919,456
Total current assets	5,700,927	7,447,516
Non-current assets:		
Property, plant, and equipment, net	1,274,798	1,761,171
Operating lease right of use assets	1,340,769	1,530,274
Intangible assets, net	615,170	553,016
Total assets	8,931,664	11,291,977
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	4,431,840	2,159,058
Convertible loan	-	653,484
Derivative liability	13,437	6,023,302
Current portion of operating lease liability	305,324	328,033
Total current liabilities	4,750,601	9,163,877
Non-current operating lease liability	1,495,833	1,796,835
Total liabilities	6,246,434	10,960,712
Shareholders' Equity:		
Ordinary shares, £0.0001 par value, 20,570,088 and 949,958 authorized, issued, and outstanding as of December 31, 2023 and 2022, respectively	2,057	95
Deferred shares, £0.4999 par value, 794,955 and 794,955 authorized, issued, and outstanding as of December 31, 2023 and 2022, respectively	397,398	397,398
Additional paid-in capital	41,123,065	33,308,568
Accumulated deficit	(38,837,290)	(33,374,796)
Total shareholders' equity	2,685,230	331,265
Total liabilities and shareholders' equity	£ 8,931,664	£ 11,291,977

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

TC BIOPHARM (HOLDINGS) PLC
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
Revenue	£ -	£ 3,844,532
Operating expenses:		
Research and development expenses	7,771,391	7,592,470
Administrative expenses	6,467,932	7,030,972
Administrative expenses - costs related to preparing for listing	-	1,305,087
Total operating expenses	14,239,323	15,928,529
Loss from operations	(14,239,323)	(12,083,997)
Other income (expense):		
Loss on modification of convertible loan	(645,845)	(140,344)
Change in fair value of derivative liability	8,052,581	16,064,945
Foreign currency losses	(80,070)	(120,974)
Interest expense	(83,025)	(6,753,231)
Total other income (expense), net	7,243,641	9,050,396
Net loss before income taxes	(6,995,682)	(3,033,601)
Income tax credit	1,088,729	1,720,000
Net loss	**£ (5,906,953)**	**£ (1,313,601)**
Weighted-average ordinary shares outstanding, basic and diluted	6,178,423	687,199
Basic and diluted net loss per share	£ (0.96)	£ (1.91)

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

TC BIOPHARM (HOLDINGS) PLC
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	Ordinary shares		Deferred shares		Additional Paid-in	Accumulated	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance, January 1, 2022	390,952	£ 195,476	-	£ -	£ 16,710,757	£ (33,465,282)	£ (16,559,049)
Share-based compensation expense	-	-	-	-	-	1,123,250	1,123,250
Issuance of ordinary shares, net of issuance costs	559,006	202,017	-	-	16,597,811	-	16,799,828
Redesignation of nominal value to deferred shares	-	(397,398)	794,955	397,398	-	-	-
Adjustments to convert from IFRS to GAAP	-	-	-	-	-	280,837	280,837
Net loss	-	-	-	-	-	(1,313,601)	(1,313,601)
Balance, December 31, 2022	949,958	£ 95	794,955	£ 397,398	£ 33,308,568	£ (33,374,796)	£ 331,265

	Ordinary shares		Deferred shares		Additional Paid-in	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2023	949,958	£ 95	794,955	£ 397,398	£ 33,308,568	£ (33,374,796)	£ 331,265
Share-based compensation expense	-	-	-	-	-	444,459	444,459
Issuance of ordinary shares, net of issuance costs	19,620,130	1,962	-	-	5,231,151	-	5,233,113
Reclassification of warrants to equity	-	-	-	-	1,550,367	-	1,550,367
Issuance of warrants	-	-	-	-	1,032,979	-	1,032,979
Net loss	-	-	-	-	-	(5,906,953)	(5,906,953)
Balance, December 31, 2023	20,570,088	£ 2,057	794,955	£ 397,398	£ 41,123,065	£ (38,837,290)	£ 2,685,230

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

TC BIOPHARM (HOLDINGS) PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	£ (5,906,953)	£ (1,313,601)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	596,726	714,550
Amortization of intangible assets	36,282	55,046
Share-based compensation expense	444,459	1,123,250

Loss on modification of convertible loan	645,845	140,344
Change in fair value of derivative liability	(8,052,581)	(16,064,945)
Net foreign exchange loss	80,070	120,974
Noncash interest expense	71,568	6,628,406
Loss on disposal of property, plant, and equipment, net	-	8,646
Changes in operating assets and liabilities:		
Change in corporation tax receivable	676,407	(312,801)
Change in prepaid expenses and other current assets	(1,275,269)	(37,503)
Change in operating lease right of use assets	189,505	196,577
Change in accounts payable and accrued liabilities	2,272,782	(1,944,557)
Change in lease liabilities	(323,711)	(762,150)
Change in deferred income	-	(3,844,533)
Net cash used in operating activities	(10,544,870)	(15,292,297)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant, and equipment	(110,353)	(240,712)
Disposal of property, plant, and equipment	-	55,000
Purchase of intangible assets	(98,436)	(124,485)
Net cash used in investing activities	(208,789)	(310,197)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of convertible loan, net of issuance costs	-	18,110
Repayment of convertible loan	-	(2,632,324)
Proceeds from sale of warrants	5,127,260	18,806,153
Issuance of ordinary shares	4,186,862	3,369,877
Ordinary shares and warrants issuance costs	(793,746)	(908,602)
Net cash provided by financing activities	8,520,376	18,653,214
Foreign exchange (loss) gain on cash and cash equivalents	(112,168)	190,652
NET CHANGE IN CASH	(2,345,451)	3,241,372
Cash - Beginning of period	4,808,060	1,566,688
Cash - End of period	£ 2,462,609	£ 4,808,060

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

TC BIOPHARM (HOLDINGS) PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – NATURE AND DESCRIPTION OF BUSINESS

TC BioPharm (Holdings) plc ("TC BioPharm" or the "Company") was incorporated on October 25, 2021 as a Public limited company, limited by shares, in Scotland and domiciled in the United Kingdom and has the following wholly owned subsidiaries: TC BioPharm Limited, TC BioPharm (North America) Inc. and TC BioPharm BV (together the "Group" and "Company").

The principal activity of the Company is as a clinical stage immuno-therapy company pioneering commercialization of allogeneic, 'off-the-shelf' gamma-delta T cell ('GD-T') therapies, ranging from unmodified GD-T therapies to treat haematological cancers and viral infections, to sophisticated proprietary GD-T CAR-T products designed to reach and treat solid tumors.

The Company has historically been classified as a foreign private issuer ("FPI"). However, as of June 30, 2023, the Company determined that, pursuant to the definition provided in Rule 405 of the Securities Act of 1933, it no longer satisfied the criteria to be considered an FPI. As such, beginning on January 1, 2024, the Company was required to begin utilizing the SEC's domestic reporting forms. A reconciliation from International Financial Reporting Standards ("IFRS") to accounting principles generally accepted in the United States ("U.S. GAAP") has been presented (see Note 3).

On December 15, 2023, the Company changed its ratio of American Depositary Shares ("ADSs")ordinary shares from one ADS representing one ordinary share to one ADS representing 20 ordinary shares (the "ADS Ratio Change"). As a result of the ratio change, all references in these consolidated financial statements and accompanying notes to units of ordinary shares underlying ADSs are reflective of the ratio change for all periods presented. In addition, the exercise prices and the numbers of ordinary shares issuable upon the exercise of any outstanding options to purchase ordinary shares were proportionally adjusted pursuant to the respective anti-dilution terms of the share-based payment plans.

The Company's ADSs began trading on the Nasdaq Capital Market ("Nasdaq") under the ticker symbol "TCBP" on February 10, 2022, following its initial public offering ("IPO"). As part of the IPO, the Company, issued 4,117 American Depositary Shares ("ADSs") representing 82,353 ordinary shares with nominal value of £41,176 and warrants to buy 9,470 ADSs for proceeds before expenses of $17.5 million. Funding costs of $3.0 million including underwriter fees were incurred. On February 10, 2022, the Company issued 3,164 ADSs representing 63,280 ordinary shares with nominal value of £31,640 and warrants to buy 6,278 ADSs on conversion of loan notes totaling $13.4 million. Between June 7, 2022 and June 8, 2022, the Company issued and sold 11,500 ADSs representing 230,000 ordinary shares generating proceeds of $4.6 million before deductions for offering expenses of approximately $0.8 million (£0.6 million).

On November 18, 2022 the Company undertook a reverse share split such that fifty issued ordinary shares were exchanged for one new ordinary share. As a result of the share split, all references in these consolidated financial statements and accompanying notes to units of ordinary shares or per share amounts are reflective of the reverse share split for all periods presented. In addition, the exercise prices and the numbers of ordinary shares issuable upon the exercise of any outstanding options to purchase ordinary shares were proportionally adjusted pursuant to the respective anti-dilution terms of the share-based payment plans.

On November 27, 2022, the Company entered into a Securities Purchase Agreement (the "First Purchase Agreement") with certain accredited investors (the "Investors") as purchasers. Pursuant to the First Purchase Agreement, the Company sold, and the Investors purchased in a private placement an aggregate of 7,750 ADSs, pre-funded warrants to purchase up to 65,750 ADS (the "Pre-Funded Warrants"), Series A purchase warrants to purchase up to73,500 ADSs (the "Series A Ordinary Warrants") and Series B purchase warrants to purchase up to 73,500 ADSs (the "Series B Ordinary Warrants" and together with the Series A Ordinary Warrants, the "Ordinary Warrants") for aggregate gross proceeds of $7,350,000 (£6,073,376), excluding any proceeds that may be received upon exercise of the Ordinary Warrants. The purchase price for each ADS and associated Ordinary Warrants was $100 (on a post-split basis) and the purchase price per each Pre-Funded Warrant and associated Ordinary Warrants was $99.98 (on a post-split basis).

On March 27, 2023, the Company, entered into a Second Securities Purchase Agreement (the "Second Purchase Agreement") with Investors, pursuant to which the Company agreed to issue and sell an aggregate of 10,750 ADSs, pre-funded warrants to purchase up to 161,125 ADS (the "Pre-Funded Warrants"), and Series C purchase warrants to purchase up to 171,875 ADSs (the "Ordinary Warrants" and together with the Pre-Funded Warrants and the ADSs, the "Securities"). In addition, the Company also issued placement agent warrants to purchase 12,891 ADSs. The purchase price for each ADS and associated Ordinary Warrants was $32 (on a post-split basis) and the purchase price per each Pre-Funded Warrant and associated Ordinary Warrants was $31.98. The Ordinary Warrants were immediately exercisable, expire five (5) years from the date of issuance and the Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The total net proceeds from this offering were approximately $4.9 million, after deducting estimated offering expenses of approximately $0.6 million.

On March 27, 2023 the Company also agreed that certain existing warrants to purchase up to an aggregate of 140,000 ADSs of the Company that were previously issued on November 30, 2022, at an exercise price of $100 (on a post-split basis) per ADS and expiration dates of May 30, 2025 and May 30, 2028, were amended so that the amended warrants had a reduced exercise price of $35 (on a post-split basis) per ADS.

On August 30, 2023, the Company entered into an agreement with its Series A and B warrant holders whereby it induced 70,000 and 70,000 of the outstanding warrants, respectively. In addition, the Company also entered into an agreement with its Series C warrant holders to induce all of the outstanding warrants (171,875). The inducement resulted in gross proceeds to the Company of approximately $2.8 million. In order to incentivize the inducement, the Company issued 623,750 Series D warrants to the Series, A, B and C warrant holders. In addition, the Company also issued placement agent warrants to purchase 23,391 ADSs. The Company received aggregate gross proceeds of approximately £2.2 million (approximately $2.8 million) from the exercise of the Existing Warrants by the Holders, before deducting placement agent fees payable by the Company.

On December 18, 2023, the Company entered into a Third Securities Purchase Agreement (the "Third Purchase Agreement") with a certain institutional investor (the "Investor") pursuant to which the Company agreed to issue and sell to the Investor in a best-efforts public offering 75,000 ADSs representing 1,500,000 ordinary shares, pre-funded warrants to purchase up to 1,675,000 ADS representing 33,500,000 Ordinary Shares (the "Pre-Funded Warrants"), and series E purchase warrants to purchase up to 1,750,000 ADSs representing 35,000,000 Ordinary Shares (the "Warrants" and together with the Pre-Funded Warrants and the ADSs, the "Securities"). The purchase price for each ADS and associated Warrant was $2.00 and the purchase price per each Pre-Funded Warrant and associated Warrant was $1.999. The Warrants are immediately exercisable, will expire five years from the date of issuance and have an exercise price of £1.5814. The Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full at an exercise price of $0.001 per ADS. Additionally, the Company agreed that a certain number of existing warrants to purchase up to an aggregate of 623,750 ADSs of the Company that was previously issued on September 5, 2023, at an exercise price of £7.00 per ADS and an expiration date of March 5, 2029, were amended effective upon the closing of the offering so that the amended warrant will have a reduced exercise price of £1.5814 (or $2.00, as translated for illustration to U.S. dollars at the rate of £1.00 to $1.264 as of December 18, 2023) per ADS. The Securities Purchase Agreements resulted in gross proceeds of $3.5 million.

Risks and Uncertainties

The Company is exposed to a variety of risks in the ordinary course of business, including, but not limited to, currency risk, liquidity risk, equity price risk and credit risk. The Company regularly assesses each of these risks to minimize any adverse effects on the business as a result of those factors.

Going Concern

The Company has been focused on the development of therapeutic products based around its gamma delta T cell platform technology, with the objective of conducting clinical trials to demonstrate safety and efficacy and eventually being granted regulatory approval to market and sell its products since its incorporation. This activity was expected to be in development for several years and has incurred considerable expenditures to date in research and development expenses and in conducting clinical trials. Similar to most development and/or clinical stage biotechnology companies, the Company has not yet generated any revenues from sales of products, but has obtained cash to finance its research, development and clinical trial activities from equity, debt and grant financings and from receipts from partners under collaborative co-development agreements. The Company is expected to continue in this clinical development phase for a number of years before any product becomes marketable. The Company therefore expects to continue to incur significant losses in the foreseeable future.

As of December 31, 2023, the Company's cash and cash equivalents amounted to £2.5 million. As of December 31, 2023, the Company had working capital of £1.0 million. Cash used in operating activities for the year ended December 31, 2023 was £10.5 million, and the Company expects to incur continued outflow of cash for the foreseeable future. Net loss for the year ended December 31, 2023 was £5.9 million.

On March 22, 2024, the Group had cash on hand of $1.7 million (£1.4 million), which will not be sufficient to enable the Group to meet the cash requirements required to enable it to conduct its business plan through the going concern period (being to April 1, 2025) ("Going Concern Period"). With existing resources, we expect to be able to fund current operations to May 2024.

Similar to many clinical development stage biotechnology companies, the Company's future liquidity needs, and ability to address them, will largely be determined by the availability of capital, both generally and in particular to fund product candidates and key development and regulatory projects. As a pre-revenue biotechnology Company, operations have been financed though continuously raising capital, and management expects to continue to raise capital routinely. The Company is currently and continuously progressing various funding options to fill the projected working capital gap, which could be in the form of an equity raise or other forms of financings such as debt funding, collaborations or licensing arrangements. Management believes that the ongoing financing initiatives should provide sufficient capital to finance planned operations through 2024, and thereafter we would expect to be in a position to raise significantly greater capital as the clinical program progresses. However, there can be no certainty that these initiatives will be successful and, if they are not, management will seek to deploy alternative plans, which could have a potentially significant negative impact on stockholder and asset value. Such plans could include all or any of the following: raising additional capital through low priced and/or complex equity and/or debt financings, entering transactions involving sales, joint venturing or licensing of intellectual property, reducing and/or deferring discretionary spending on research and development or clinical programs, restructuring our operating model to take advantage of our manufacturing capability to generate short term revenues or reducing our cash burn rate through reduction in planned operating costs.

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern, which assumes the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has not established a source of revenues sufficient to cover its operating costs, and as such, has been dependent on ongoing funding operations primarily through ongoing initiatives to raise capital. The Company expects to require substantially more capital to fund its clinical, development and operational requirements, and therefore incur further losses over the next several years as it develops its clinical products. The Company has utilized, and expects to continue to utilize, substantial amounts of funding to implement its business strategy. If the Company is unable to maintain adequate liquidity, future operations will need to be scaled back or discontinued. Based on these circumstances, management has determined that there is substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND NEW ACCOUNTING STANDARDS

Basis of Presentation

The accompanying consolidated financial statements have been prepared and presented in accordance with U.S. GAAP and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). In the opinion of management, these consolidated financial statements include all adjustments necessary for a fair statement of the financial position, results of operations and cash flows of the Company, and the adjustments are of a normal and recurring nature.

Principals of Consolidation

The consolidated financial statements include the accounts of TC BioPharm and its 100% controlled subsidiaries, TC BioPharm Limited, TC BioPharm Inc. and TC BioPharm BV. All significant intercompany balances and transactions have been eliminated. "TC BioPharm", the "Company", "we", "our" or "us" is intended to mean TC BioPharm (Holdings) plc, including the subsidiaries indicated above, unless otherwise indicated.

Emerging Growth Company

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's consolidated financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Use of Estimates

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Accordingly, the actual results could differ significantly from those estimates.

Segment Reporting

The Company operates in one operating segment. Operating segments are reported in a manner consistent with the internal reporting provided to the Company's chief operating decision maker ("the CODM"). The Company's CODM, its Chief Executive Officer, views the Company's operations and manages its business as a single operating segment, which is the business of a clinical stage immune-therapy Group pioneering commercialization of allogeneic, 'off-the-shelf' gamma-delta T cell ('GD-T') therapies.

Income and Other Taxes

Income taxes are accounted for using the asset and liability method in accordance with Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") 740, *Income Taxes* ("ASC 740"), which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company records net deferred tax assets to the extent they believe these assets will more-likely-than-not be realized. In making such determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. In the event the Company was to determine that it would be able to realize its deferred income tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the valuation allowance which would reduce the provision for income taxes.

Income Tax Credit

The Company carries out extensive research and development activities, where it benefits from the United Kingdom's research and development tax relief and expenditure credit regimes. The Company is able to surrender some of its income tax losses for a cash rebate of up to 33.35% of expenditures related to eligible research and development projects. Such credits are accounted for, depending on the appropriate tax relief, either within the tax provision or other income, in the year in which the expenditures were incurred.

Cash and cash equivalents

The Company defines cash and cash equivalents as cash on hand, deposits held on call with banks and other short-term liquid investments with maturities of three months or less. As of December 31, 2023 and 2022, cash and cash equivalents was £2.5 million and £4.8 million, respectively.

Concentration of Risk

Financial instruments that subject the Company to significant concentrations of credit risk primarily consist of cash and cash equivalents. The Company maintains substantially all of its cash and cash equivalents with financial institutions, which, at times, may exceed federally insured limits. The Company has not incurred any losses associated with this concentration of deposits.

The Company currently has bank deposits with financial institutions in the U.S. of approximately £0.2 million as of December 31, 2023 which are below the FDIC insurance limits. FDIC insurance provides protection for bank deposits up to $250,000. The Company had approximately £2.3 million in uninsured bank deposits with financial institutions outside the U.S. All uninsured bank deposits are held at high quality credit institutions.

Foreign currency translation and transactions

The Company uses the British pound sterling as the reporting currency for its financial statements. Functional currency is the currency of the primary economic

environment in which an entity operates. The functional currency of the Company's subsidiaries are the local currencies. The Company has transactions denominated in various currencies, with the principal currency exposure being fluctuations in U.S. Dollars and Euros against pound sterling. The Company's exposure to the risk of changes in foreign exchange rates relates primarily to the a limited number of supplier agreements denominated in currencies other than pound sterling.

Property, Plant and Equipment

Property and equipment consist of computer equipment, facility, and scientific equipment and office equipment, which are stated at cost, net of accumulated depreciation and amortization, and depreciated over their estimated lives using the straight-line method.

Depreciation is provided for by the straight-line method over the estimated useful lives as follows:

Property and Equipment	Estimated Useful Life
Facility and scientific equipment	4-10 years
Computer equipment	3 years
Office equipment	5 years

Expenditures for repairs and maintenance are expensed as incurred. When assets have been retired or sold, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in the results of operations.

Intangible assets

Intangible assets consist of software, patents and licenses. Intangible assets are recognized where it is probable that there will be a future economic benefit and that this can be reliably measured. Software represents the historical cost of installation of third-party software used within the Company to maintain and control the Company's quality system. The software is hosted and controlled on the Company's servers and can be used independently of the related hardware. Software is amortized, on a straight-line basis, over the life of the relevant license of three to four years. Patent costs represent the costs of securing patents in relation to the Company's intellectual property. Patent costs are amortized, on a straight-line basis, over the remaining legal life of the relevant patents, which has an average estimated patent life of 16 years. License costs represent costs incurred for securing use of third-party technology. License costs are amortized, on a straight-line basis, over the life of the relevant license of three years. Amortization methods and useful lives are reviewed at each reporting date and adjusted as appropriate.

The Company reviews the carrying amounts of its tangible and intangible assets where there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss (if any). The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets in which case the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs. Recoverable amount is the higher of fair value less costs to sell and value-in-use. In assessing value-in-use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted. If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognized immediately in the statement of operations. There was no impairment of tangible or intangible assets during the years ended December 31, 2023 and 2022.

Fair Value Measurements

The fair value of the Company's assets and liabilities which qualify as financial instruments under ASC 820, *Fair Value Measurement*, approximates the carrying amounts represented in the accompanying consolidated balance sheets.

Net Loss per Share

Basic net loss per share ordinary share is calculated based on the weighted-average number of ordinary shares outstanding in accordance with ASC Topic 260, *Earnings per Share.* Diluted net loss per share is calculated based on the weighted-average number of ordinary shares outstanding plus the effect of dilutive potential ordinary shares. When the Company reports a net loss, the calculation of diluted net loss per share excludes potential ordinary shares as the effect would be anti-dilutive. Potential ordinary shares are composed of ordinary shares issuable upon the exercise of options and warrants. The following table shows the basic and diluted loss per share for the years ended December 31, 2023 and 2022:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Net loss	(5,906,953)	(1,313,601)
Basic and diluted weighted average number of shares outstanding[(1)]	6,178,423	687,199
Basic and diluted loss per share	**(0.96)**	**(1.91)**

(1) On November 18, 2022, the Company completed a reverse stock split of one (1) new share for every fifty (50) existing shares effective November 21, 2022. As a result of the share split, all references in these financial statements and accompanying notes to units of ordinary shares or per share amounts are reflective of the reverse share split for all periods presented. In addition, the exercise prices and the numbers of ordinary shares issuable upon the exercise of any outstanding options to purchase ordinary shares were proportionally adjusted pursuant to the respective anti-dilution terms of the share-based payment plans.

Share-Based Compensation

The Company accounts for share-based compensation arrangements with employees, directors, and consultants and recognizes the compensation expense for share-based awards based on the estimated fair value of the awards on the date of grant. Compensation expense for all share-based awards is based on the estimated grant-date fair value and recognized in earnings over the requisite service period (generally the vesting period).

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. The Company accounts for revenue contracts with customers by applying the requirements of ASC 606, *Revenue from Contracts with Customers*, which includes the following five steps:

i. Identification of the contract with a customer.

ii. Identification of the performance obligations in the contract.
iii. Determination of the transaction price.
iv. Allocation of the transaction price to the performance obligations in the contract.
v. Recognition of revenue as the entity satisfies a performance obligation.

The Company earns revenue from collaboration agreements and contracts with customers (see Note 4). Revenue is recognized on upfront collaboration payments on a straight-line basis over the estimated term over which the services promised will be provided. The Company is entitled to receive contractual milestone payments on achievement of certain performance obligations and these are recognized when the milestones are certain to occur.

Research & Development Expenses

Research expenditure is expensed in the year in which it is incurred. Identifiable development expenditure is capitalized to the extent that the technical, commercial and financial feasibility can be demonstrated. The Company has not capitalized any development expenditures since inception.

Commitments and Contingencies

The Company accounts for contingencies in accordance with ASC 450-20,*Contingencies*. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or un-asserted claims that may result in such proceedings, the Company evaluates the perceived merits of any legal proceedings or un-asserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's consolidated financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed.

Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed. Further details are included within Note 9 to the financial statements.

Recent Accounting Pronouncements

The Company has implemented all new accounting pronouncements that are in effect and that may impact its consolidated financial statements. Further, during December 2023, the FASB issued Accounting Standards Update ("ASU") 2023-09-Income Taxes (Topic 740)-Improvements to Income Tax Disclosures, which requires entities to provide additional information in the rate reconciliation and additional disclosures about income taxes paid. The guidance should be applied prospectively and is effective for annual periods beginning after December 15, 2024. The Company does not expect the issued standard to have a material impact on its financial statements or results of operations.

NOTE 3. CONVERSION FROM IFRS TO GAAP

The Company has retrospectively converted its consolidated financial statements from IFRS to GAAP. Refer to Note 1 for additional details.

The significant differences between IFRS and GAAP as they relate to these financial statements are as follows:

(a) Leases

Under IFRS 16, the Company, as lessee, applied the single lease model that is similar to the accounting for a finance lease under GAAP. The expense recognition presented a higher portion of the total expense earlier in the term as a combination of straight-line depreciation of the right-of-use asset and the effective interest rate method applied to the lease liability which resulted in a decreasing rate of interest expense recognition throughout the lease term.

Under GAAP, there is dual classification lease accounting model for lessees: finance leases and operating leases. Specifically, in accordance with ASC 842, the Company, as lessee, must determine whether a lease is a finance or operating lease at the inception of the contract. Further, operating leases are recognized utilizing a single lease expense model, which takes the expected payments to be made over the life of the lease and recognizes those payments on a straight-line basis throughout the lease term.

As a result of the cutover from IFRS to GAAP, the Company began accounting for its office lease space as an operating lease (in lieu of the "finance lease" model under IFRS 16). This resulted in the corresponding lease expense being reclassified from interest expense and ROU amortization into operating lease expense, which decreased interest expense by £238,985 for the year ended December 31, 2022. Additionally due to the change in the expense recognition method, the total resulting decrease in lease related expense from the transition from IFRS to GAAP was £76,105 for the year ended December 31, 2022. The expense for 2023 was recognized under GAAP and did not require any adjustments.

The following table summarizes the changes for the year ended December 31, 2022:

	IFRS	Adjustments	GAAP
Research and development expenses	£ 7,447,506	£ 144,964	£ 7,592,470
Administrative expenses	7,013,056	17,916	7,030,972
Interest expense	(6,994,423)	(238,985)	(6,755,438)
Total Conversion Adjustments		**(76,105)**	
Net loss	£ (1,389,706)	£ (76,105)	£ (1,313,601)
Weighted-average common shares outstanding, basic and diluted	687,199	-	687,199
Basic and diluted net loss per share	£ (2.02)	£ 0.08	£ (1.91)

The following table summarizes the changes as of December 31, 2022:

	IFRS	Adjustments	GAAP
ASSETS			
Current assets:			

Operating lease right of use assets	£	1,188,947	£	341,327	£	1,530,274
Total Conversion Adjustments			£	341,327		
LIABILITIES AND STOCKHOLDERS' (DEFICIT)						
Non-current operating lease liability	£	1,812,450	£	(15,615)	£	1,796,835
Accumulated deficit		(33,731,738)		356,942		(33,374,796)
Total Conversion Adjustments			£	341,327		

NOTE 4. REVENUE

The Company earned revenue from collaboration agreements and contracts with customers. Revenue is recognized on upfront collaboration payments on a straight-line basis over the estimated term over which the services promised will be provided. Collaboration agreement revenue for the years ended December 31, 2023 and 2022 is as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenue from collaboration agreements	£ —	£ 3,844,532

The terms of business for payment on satisfaction of a performance obligation are typically 30-60 days. Collaboration agreements entered into by the Company provide for the entity to work with a partner to carry out collaborative research and development work. Performance obligations around upfront payments are deemed to be satisfied over the estimated life of the services promised to be provided. This estimated life of the services was estimated by management at the inception of each contract and evaluated at each reporting date. During 2022, the contract with the collaboration partner was terminated. As such, the Company re-classed any remaining deferred revenue (from the upfront payment) to revenue as 1) no additional goods or services were required to be provided to the collaboration partner and 2) the upfront payment was non-refundable.

Revenue from reimbursement of research and development costs by collaboration partners is recognized as the costs are incurred.

NOTE 5. PROPERTY, PLANT AND EQUIPMENT

The Company's property, plant and equipment balances consist of the following:

	Facilities & Scientific Equipment	Computer Equipment	Office Equipment	Total
Cost				
At January 1, 2022	£ 4,889,662	£ 333,148	£ 86,331	£ 5,309,141
Additions	225,666	15,046	-	240,712
Disposals	(228,026)	-	-	(228,026)
At December 31, 2022	4,887,302	348,194	86,331	5,321,827
Additions	91,724	18,629	-	110,353
Disposals	-			-
At December 31, 2023	£ 4,979,026	£ 366,823	£ 86,331	£ 5,432,180
Depreciation				
At January 1, 2022	£ 2,636,772	£ 312,718	£ 60,996	£ 3,010,486
Disposals	(164,380)	-	-	(164,380)
Depreciation expense	683,592	15,098	15,860	714,550
At December 31, 2022	3,155,984	327,816	76,856	3,560,656
Depreciation expense	575,233	13,947	7,546	596,726
At December 31, 2023	£ 3,731,217	£ 341,763	£ 84,402	£ 4,157,382
Net book value				
At December 31, 2023	£ 1,247,809	£ 25,060	£ 1,929	£ 1,274,798
At December 31, 2022	£ 1,731,318	£ 20,378	£ 9,475	£ 1,761,171

Depreciation expense on these assets for the years ended December 31, 2023 and 2022, was £596,726 and £714,550, respectively, and is included in research and development and administrative expenses in the accompanying consolidated statements of operations. The Company incurred a loss on disposal of equipment totaling £8,646 for the year ended December 31, 2022.

NOTE 6. INTANGIBLE ASSETS

The Company's intangible assets consist of the following:

	Software	Patents and Licenses	Total
Cost			
At January 1, 2022	£ 49,613	£ 588,072	£ 637,685
Additions	-	124,485	124,485
At December 31, 2022	49,613	712,557	762,170
Additions	-	98,436	98,436
At December 31, 2023	49,613	810,993	860,606
Amortization			
At January 1, 2022	39,536	114,572	154,108
Amortization expense	7,125	47,921	55,046
At December 31, 2022	46,661	162,493	209,154
Amortization expense	2,952	33,330	36,282
At December 31, 2023	49,613	195,823	245,436

Net book value					
At December 31, 2023	£	-	£	615,170	£ 615,170
At December 31, 2022	£	2,952	£	550,064	£ 553,016

Amortization expense on these assets for the years ended December 31, 2023 and 2022, was £6,282 and £55,046, respectively, and is included in research and development expenses in the accompanying consolidated statements of operations.

NOTE 7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

The Company's prepaid expenses and other current assets consist of the following:

	December 31, 2023	December 31, 2022
Other receivables	£ 51,584	£ 56,264
VAT owed to the Company	135,642	27,055
Prepaid clinical trial costs	307,519	307,519
Deferred clinical trial testing costs	1,177,500	-
Other prepayments	522,480	528,618
	£ 2,194,725	£ 919,456

The fair value of trade and other receivables are not materially different to the book value.

NOTE 8. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

The Company's accounts payable and accrued liabilities consist of the following:

	December 31, 2023	December 31, 2022
Trade payables	£ 1,847,279	£ 882,364
Other tax and social security	139,029	293,467
Accruals	1,229,419	944,904
Amounts accrued in respect to clinical trial testing	1,177,500	-
Other payables	38,613	38,323
	£ 4,431,840	£ 2,159,058

The fair value of accounts payable and accrued expenses are not materially different to the book value.

NOTE 9. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm business.

In accordance with the terms of a Convertible Loan Note ('Note') on August 9, 2022 (the Conversion Date) the Company issued183,820 Ordinary Shares and 367,640 listed warrants to the Note holder in full satisfaction of the Note in the aggregate amount of $781,233. The holder filed a claim in the English courts on June 19, 2023 asserting that notice was provided such that the Company should have paid it the value of the Note in cash, rather than by settling it through the issuance of Ordinary Shares and listed warrants. The holder is demanding payment of the face value of the Note, together with interest, (approximately $860,000). The litigation process is in its early stages and is not expected to conclude until late 2024 or later. The Company has retained English solicitors and is contesting the claim in its entirety. The Company believes that it acted correctly under the terms of the Note and has accounted for the transaction on that basis, and that no further amounts are payable to the holder.

NOTE 10. LEASES

The Company leases certain office space under operating leases for use in operations. The Company recognizes operating lease expense on a straight-line basis over the lease term. Management determines if an arrangement is a lease at contract inception. Lease and non-lease components are accounted for as a single component for all leases. Operating lease right to use (ROU) assets and liabilities are recognized at the lease commencement date based on the present value of the future lease payments over the expected lease term, which includes optional renewal periods if we determine it is reasonably certain that the option will be exercised. As our leases do not provide an implicit rate, the discount rate used in the present value calculation represents our incremental borrowing rate determined using information available at the commencement date. Operating lease expense is included as a component of research and development and administrative expenses in the consolidated statements of operations. For the years ended December 31, 2023 and 2022, the Company recorded operating lease expense of £402,314 and £402,314, respectively. Cash payments on lease liabilities during the years ended December 31, 2023 and 2022 totaled £447,015 and £763,487, respectively. At December 31, 2023 and 2022, weighted-average remaining lease term and discount rate were as follows:

	December 31,	
	2023	2022
Weighted-average remaining lease term	5.11 years	8.2 years
Weighted-average discount rate	8.6%	8.6%

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of December 31, 2023:

Years Ended December 31,	
2024	£ 447,015
2025	447,015
2026	447,015
2027	447,015
2028	447,015

Less imputed interest	(433,919)
Total	£ 1,801,156

NOTE 11. CONVERTIBLE LOAN

The Company entered into a $20 million convertible loan note instrument in April 2021. The note has a5% annual interest rate. During the years ended December 31, 2023 and 2022, the Company converted loan notes totaling $809,692 and $14,228,245, respectively, into ordinary shares and warrants and repaid $0 and $3,195,765, respectively, of the convertible loan note. The convertible loan was recognized as a hybrid financial instrument and accounted for as two separate components: (i) a loan and (ii) an embedded conversion option derivative. As of December 31 2023, the convertible loan had either been fully paid down or converted. As such, the balance of both the convertible loan and corresponding embedded derivative was $0 as of December 31, 2023.

(i) The convertible loan's initial fair value was the residual amount of the consideration received, net of attributable costs, after separating out the fair value of the embedded conversion option derivative. The loan is subsequently measured at its amortized cost.

(ii) The embedded conversion option derivative was initially measured at fair value and is subsequently remeasured to fair value at each reporting date. The embedded derivative could have been classified as a component of equity only if in all cases the contract would be settled by the Company delivering a fixed number of its own equity instruments in exchange for a fixed amount of cash or debt redemption. That is, had the embedded instrument satisfied the "fixed-for-fixed" criteria outlined in ASC 815-40. However, the convertible instrument included a conversion feature resulting in settlement in a variable number of shares and consequently, was not considered indexed to the company's shares (i.e. it did not qualify for the scope exception to derivative accounting outlined in ASC 815-40). As a result, the derivative is presented in the consolidated balance sheet as a liability in accordance with ASC 815-15, *Derivatives and Hedging-Embedded Derivatives*. Changes in the fair value (gains or losses) of the derivative at the end of each period are recorded in the consolidated statements of operations.

On August 9, 2022, the Company agreed with one of the loan note holders not to exercise the right to require the loan notes to be repaid in cash in accordance with the terms of the loan notes and to amend certain other aspects of the loan notes ("2022 amended loan note"). As additional consideration, the Company has issued warrants to subscribe for 11,678 ordinary shares in the share capital of the Company.

In accordance with ASC 470-50, the modifications to the 2022 amended loan notes represent a substantial modification as the amended debt instrument was considered substantially different (as compared to the original instrument) due to the following changes:

(i) Removing the exercise of the right to require the loan in cash as of August 9, 2022.

(ii) Extending the repayment date to January 31, 2023 and modifying the structure to be repaid in shares if not redeemed before in cash.

(iii) Revising the conversion price for the conversion of the loan notes in shares. The revised conversion price would be $0.50 and would be based on the the 5-day trailing VWAP of the Company's ADS if it is trading above that amount. Further, the conversion option would have a $0.20 as a floor.

(iv) Giving the option to the holder for redemption in cash, which will occur no later than February 10, 2023 and to the Company for an early redemption at any moment but having the Holder an option to convert into shares using the revised conversion price at that moment.

On April 3, 2023, the Company agreed with the loan note holder not to exercise the right to require the loan notes to be repaid in cash in accordance with the terms of the loan notes and to amend certain other aspects of the loan notes ("2023 amended loan note"). As additional consideration, the Company has issued warrants to subscribe for 200,000 ordinary shares in the share capital of the Company. This warrant contained a condition whereby if a registration statement, to be filed by the Company, registering all of the securities underlying the note holder's amended convertible loan note, was not declared effective by July 31, 2023, the note holder will be entitled to receive 0.30 Ordinary Shares for each share it was originally entitled to purchase under these warrants without the payment of any additional consideration. No such registration statement was filed. The related fair value of the issue of any additional securities is approximately £29,000 ($37,000) and is not considered material to the financial statements.

The modifications to the 2023 amended loan notes represent as substantial amendment as the modifications are related to:

(i) A waiver to any defaults arising in connection with the 2022 amended loan notes.

(ii) Extending the repayment date to January 15, 2024; and

(iii) Amend the Conversion Price (as defined in the Loan Note) of the outstanding loan notes to be the lesser of $1.00 or the lowest closing price of the Ordinary Shares during the ten (10) day period prior to the date the Noteholder delivers a notice of conversion to the Company, not to be lower than $0.20

The following table summarizes the changes in the convertible debt instrument during the year ended December 31, 2023:

	Residual loan	Embedded Derivative	Total
Balance at December 31, 2022	£ 653,484	£ 2,439	£ 655,923
Accrued interest	71,568	-	71,568
Repayment	(639,336)	(2,439)	(641,775)
Modification of loan notes	(53,619)	-	(53,619)
Currency adjustment	(32,097)	-	(32,097)
Balance at December 31, 2023	£ -	£ -	£ -

The value of the embedded derivative was remeasured to fair value at each reporting date, based on the Black-Scholes valuation model, with recognition of the changes in fair value in the consolidated statements of operations. The inputs associated with calculating the fair value of the embedded derivative are considered to be Level 2. The following inputs were used to determine the conversion option:

	December 31, 2022
Exercise price in USD	$ 100.00
Share price in USD	$ 77.00
Time to maturity	0.8 years
Expected volatility	90%
Risk free interest rate (US treasury bond)	4.1%
Dividend yield	-

The following inputs were used in the Black-Scholes valuation model to determine the related share purchase warrants:

	December 31, 2023
Exercise price in USD	$ 100.00
Share price in USD	$ 3.17
Time to maturity	4.3 years
Expected volatility	90%
Risk free interest rate (US treasury bond)	4.5%
Dividend yield	-

NOTE 12. SHAREHOLDERS' EQUITY

Ordinary shares

The Ordinary shares have no specific rights, preferences or restrictions attached to them.

Deferred shares

Deferred shares have the following properties:

a. do not entitle their holders to receive any dividend or other distribution;
b. do not entitle their holders to receive a share certificate in respect of the relevant shareholding;
c. do not entitle their holders to receive notice of, nor to attend, speak or vote at, any general meeting of the Company;
d. entitles their holders on a return of capital on a winding up of the Company (but not otherwise) only to the repayment of the amount paid up on that share after payment of the capital paid up on each Ordinary Share in the share capital of the Company and the further payment of £100,000,000 on each ordinary share;
e. do not entitle their holders to any further participation in the capital, profits or assets of the Company. The Deferred Shares shall not be capable of transfer at any time other than with the prior written consent of the directors of the Company.

A Ordinary shares

The A Ordinary shares ranked equally with all other shares in issue in that on a vote every member has one vote for each share held. The A ordinary shares contain preferential economic rights such that, in the event of a share or asset sale (as defined in the Articles of Association), they provide a return to the holders of the A Ordinary Shares of an amount greater than or equal to 1.5x the price paid by the investors for A Ordinary Shares. The A Ordinary shares have an anti-dilution provision where shares are subsequently issued at a price below £215.00 per share, whereby the existing A Ordinary shareholders receive additional compensation shares in line with the formula set out in the Articles of Association. The A Ordinary shares rank equally with all other shares in issue with respect to dividends.

Immediately prior to the completion of the IPO, 493,860 ordinary shares were issued, under the terms of the Articles of Association to certain shareholders who, prior to the IPO, owned A Ordinary shares which carried the right, to subscribe at nominal value for a certain number of additional shares, calculated by reference to the pre-money valuation of the IPO. As part of the IPO share issue, the Company re-organized its share capital whereby all of the outstanding series A ordinary shares were re-designated as ordinary shares of the Company on a one for one basis and as such no anti-dilution provisions are included within the issued shares.

Reorganization and IPO

Immediately prior to completion of the IPO, the Company re-organized its share capital whereby all of the outstanding series A ordinary shares were re-designated as ordinary shares of TC BioPharm (Holdings) plc on a one for one basis. Immediately prior to the completion of the offering, a further 493,860 ordinary shares were issued, under the terms of the Articles of Association to certain shareholders who, prior to the IPO, owned A ordinary shares which carried the right, to subscribe at nominal value for a certain number of additional shares, calculated by reference to the pre-money valuation of the IPO. The fair value of the shares issued was £3.8 million.

On February 10, 2022, the Company issued 3,164 ADSs representing 63,280 ordinary shares with nominal value of £31,640 and warrants to buy 6,278 ADSs on conversion of loan notes totaling $13.4 million (£9.9 million).

On February 10, 2022, the Company completed the IPO, listing on Nasdaq, issuing 4,117 ADSs representing 82,353 ordinary shares with nominal value of £41,176 and warrants to buy 9,470 ADSs for proceeds before expenses of $17.5 million (£12.8 million). Funding costs of $3.0 million (£2.2 million) including underwriter fees were incurred.

Share Issuances

Between June 7, 2022 and June 8, 2022, the Company issued and sold 11,500 ADSs representing 230,000 ordinary shares generating proceeds of $4.6 million (£3.7 million) before deductions for offering expenses of approximately $0.8 million (£0.6 million).

On August 9, 2022, Convertible Loan Noteholders with loan notes with a face value of $0.8 million (£0.6 million) agreed to not exercise their right to be repaid and in consideration for this agreement received warrants over 233,560 ordinary shares. In addition, the conversion price of the loan notes was amended to be the lower of (i) the 5-day trailing VWAP of the Company's ADS calculated as at 31 January 2023 and (ii) $25.00, subject to not being below $10.00.

On August 9, 2022, the Company issued 183 ADSs representing 3,676 ordinary shares and warrants to buy 366 ADSs on conversion of loan notes totaling $0.8 million (£0.7 million).

On November 15, 2022, the Company issued 21 Ordinary shares (number stated prior to the reverse split) for a consideration of $7.565 (£6.362) per share.

On November 24, 2022, the Company issued 3 Ordinary shares for a consideration of $6.51 (£5.41) per share.

On November 27, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "Investors") as purchasers. Pursuant to the Purchase Agreement, the Company sold, and the Investors purchased in a private placement an aggregate of 7,750 American Depositary Shares (the "ADSs"), pre-funded warrants to purchase up to 65,750 ADS (the "Pre-Funded Warrants"), Series A purchase warrants to purchase up to 73,500 ADSs (the "Series A Ordinary Warrants") and Series B purchase warrants to purchase up to 73,500 ADSs (the "Series B Ordinary Warrants" and together with the Series A Ordinary Warrants, the "Ordinary Warrants") for aggregate gross proceeds of $7.4 million (£6.1 million), excluding any proceeds that may be received upon exercise of the Ordinary Warrants. The purchase price for each ADS and associated Ordinary Warrants is $100 and the purchase price per each Pre-Funded Warrant and associated Ordinary Warrants is $99.98.

On March 27, 2023, the Company, entered into a Second Securities Purchase Agreement with Investors, pursuant to which the Company agreed to issue and sell an aggregate of 10,750 ADSs, pre-funded warrants to purchase up to 161,125 ADSs, and Series C purchase warrants to purchase up to 171,875 ADSs Securities. In addition, the Company also issued placement agent warrants to purchase 12,891 ADSs. The purchase price for each ADS and associated Ordinary Warrants was $32 (on a post-split basis) and the purchase price per each Pre-Funded Warrant and associated Ordinary Warrants was $31.98 (on a post-split basis). The Ordinary Warrants were immediately exercisable, expire five (5) years from the date of issuance and the Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The total net proceeds from this offering were approximately $4.6 million, after deducting estimated offering expenses of approximately $0.9 million.

On March 27, 2023, the Company also agreed that certain existing warrants to purchase up to an aggregate of 140,000 ADSs of the Company that were previously issued on November 30, 2022, at an exercise price of $100 (on a post-split basis) per ADS and expiration dates of May 30, 2025 and May 30, 2028, were amended effective upon the closing of the Offering so that the amended warrants will have a reduced exercise price of $35 (on a post-split basis) per ADS. To account for the modification, the Company recognized the increase in fair value of the modified warrants (measured as the difference between the fair value immediately before and after the modification) a as a charge against the gross proceeds of the offering.

On August 30, 2023, the Company entered into an agreement with its Series A and B warrant holders whereby it induced 70,000 and 70,000 of the outstanding warrants, respectively. In addition, the Company also entered into an agreement with its Series C warrant holders to induce all of the outstanding warrants (171,875). The inducement resulted in gross proceeds to the Company of approximately $2.8 million. In order to incentivize the inducement, the Company issued 623,750 Series D warrants to the Series, A, B and C warrant holders. In addition, the Company also issued placement agent warrants to purchase 23,391 ADSs. The Ordinary Warrants were immediately exercisable and expire five 5.5 years from the date of issuance. The Company received aggregate gross proceeds of approximately £2.2 million (approximately $2.8 million) from the exercise of the Existing Warrants by the Holders, before deducting placement agent fees payable by the Company. The Company accounted for the inducement in accordance with modification and exchange guidance in ASC 815-40 and recognized the fair value of the issued Series D warrants as an equity issuance cost.

On December 18, 2023, the Company entered into a Third Securities Purchase Agreement with a certain institutional Investor pursuant to which the Company agreed to issue and sell to the Investor in a best-efforts public offering 75,000 ADSs representing 1,500,000 ordinary shares, pre-funded warrants to purchase up to 1,675,000 ADS representing 33,500,000 Ordinary Shares (the "Pre-Funded Warrants"), and Series E purchase warrants to purchase up to 1,750,000 ADSs representing 35,000,000 Ordinary Shares (the "Warrants" and together with the Pre-Funded Warrants and the ADSs, the "Securities"). In addition, the Company issued placement agent warrants to purchase 131,250 ADSs representing 2,625,000 ordinary shares. The purchase price for each ADS and associated Warrant was $2.00 and the purchase price per each Pre-Funded Warrant and associated Warrant was $1.999. The Warrants are immediately exercisable, will expire five years from the date of issuance and have an exercise price of £1.5814. Further, pursuant to ASC 815-40, we concluded that the warrants were indexed to the company's stock and should therefore be equity classified. The relative fair value of the warrants upon issuance were approximately $1.5 million. The Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full at an exercise price of $0.001 per ADS. Additionally, the Company agreed that the Series E warrants to purchase up to an aggregate of 623,750 ADSs of the Company that were previously issued on September 5, 2023, at an exercise price of £7.00 per ADS and an expiration date of March 5, 2029, were amended effective upon the closing of the offering so that the amended warrant will have a reduced exercise price of £1.5814 (or $2.00, as translated for illustration to U.S. dollars at the rate of £1.00 to $1.264 as of December 18, 2023) per ADS. To account for the modification, the Company recognized the increase in fair value of the modified warrants (measured as the difference between the fair value immediately before and after the modification) as a charge against the gross proceeds of the offering.

Reverse share split

On November 18, 2022, the Company completed a reverse stock split of one (1) new share for every fifty (50) existing shares effective November 21, 2022. As a result, the depositary bank, BNY Mellon effected a reverse stock split on the Company's American Depositary Receipt ("ADR") program. Following the reverse split, a sub-division of every Ordinary share into one new Ordinary Share with a nominal value of £0.0001 and one deferred share with a nominal value of £0.4999 was enacted.

As a result of the share split, all references in these consolidated financial statements and accompanying notes to units of ordinary shares or per share amounts are reflective of the reverse share split for all periods presented. In addition, the exercise prices and the numbers of ordinary shares issuable upon the exercise of any outstanding options to purchase ordinary shares were proportionally adjusted pursuant to the respective anti-dilution terms of the share-based payment plans.

ADS Ratio Change

On December 15, 2023, the Company changed its ratio of ADSs ordinary shares from one ADS representing one ordinary share to one ADS representing 20 ordinary shares. As a result of the ratio change, all references in these consolidated financial statements and accompanying notes to units of ordinary shares underlying ADSs are reflective of the ratio change for all periods presented. In addition, the exercise prices and the numbers of ordinary shares issuable upon the exercise of any outstanding options to purchase ordinary shares were proportionally adjusted pursuant to the respective anti-dilution terms of the share-based payment plans.

NOTE 13. SHARE-BASED COMPENSATION

Enterprise Management Incentive (EMI) share option scheme

The Company operates an HMRC Approved Enterprise Management Incentive ("EMI") share option scheme for employees. Effective December 16, 2014, the Company approved a share option scheme under which the Board of Directors of the Company can award options to directors, officers, employees and consulting personnel of the Company. The Board of Directors will determine the terms, limitations, restrictions and conditions of the options granted under the plan.

The Company has granted options over ADSs to certain employees.

	Number of share options	Weighted average exercise price per ADS £
Outstanding at December 31, 2022	5,329	£ 460
Granted during the period	-	-
Exercised during the period	-	-
Forfeited during the period	-	-
Outstanding at December 31, 2023	5,329	£ 460
Exercisable at December 31, 2023	5,329	£ 460
Unexercisable at December 31, 2023	-	£ -

The estimated fair value of the options outstanding in the period was calculated by applying a Monte Carlo Simulation for those options issued in 2020 and 2019 and a Black Scholes Model for those options issued in prior periods. The most appropriate approach is selected with reference to the share capital structure at the time of grant. The expense recognized for share-based payments in respect of employee services received during the year ended December 31, 2023 was £0 as all options were fully vested as of December 31, 2023.

2021 Share Option Scheme

Effective immediately prior to completion of the IPO on February 10, 2022, the Company adopted a new share option scheme, or the 2021 Share Option Scheme, for the purpose granting share options to incentivize the Company's directors, employees and consultants. The 2021 Share Option Scheme incorporates a sub-plan for option holders subject to taxation in the United States, or the 2021 U.S. Sub-Plan, to provide for the grant of U.S. qualified incentive options.

The Company has granted options over ADSs to certain employees and directors.

	Number of share options	Weighted average exercise price per ADS $
Outstanding at December 31, 2022	2,615	$ 4,240
Granted during the period	35,125	8
Exercised during the period	-	-
Forfeited during the period	(674)	4,240
Outstanding at December 31, 2023	37,066	$ 230
Exercisable at December 31, 2023	36,782	$ 8
Unexercisable at December 31, 2023	284	$ 4,240

The totals of options and related exercise price are for options over ADSs and reflect the ratio change on December 15, 2023.

The estimated fair value of the options outstanding in the period was calculated by applying a Black Scholes Model. The most appropriate approach is selected with reference to the share capital structure at the time of grant. The weighted average fair value of the options as of December 31, 2023 and 2022 was $62.12 and $1,068, respectively. The expense recognized for share-based payments in respect of employee services received during the years ended December 31, 2023 and 2022 was £444,459 and £1,123,250, respectively.

The options granted under the 2021 share option scheme will typically vest over three years after the date of grant. In some cases, options granted to senior management vested immediately. As of December 31, 2023 the unvested options would, under the agreed terms, vest evenly over the remaining period in either six month or annual installments.

Additional Right to Subscribe for Shares

On August 25, 2020, the Company issued Ordinary shares, which included an additional right to subscribe for a fixed number (15,891) of shares at £215.00 per share at a future date based on certain clinical and commercial milestones. The estimated fair value of the right to subscribe was calculated by applying a Black Scholes Model. This was deemed the most appropriate approach due to the future liquidity event being date-uncertain and could take one of many forms.

NOTE 14. FAIR VALUE MEASUREMENTS

The fair value of the Company's financial assets and liabilities reflects management's estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

Level 1: Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2: Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3: Unobservable inputs based on the Company's assessment of the assumptions that market participants would use in pricing the asset or liability.

The Company had cash and cash equivalents of £2.5m as of December 31, 2023. The cash and cash equivalents are carried at fair value due to the liquid nature of the instruments and are measured in Level 1.

In addition, the Company also had numerous outstanding warrants that were classified in Level 2 due to our use of implied volatility in determining the expected volatility input for purposes of determining the instruments fair value via the Black-Scholes valuation model. The details of the issued warrants were as follows:

On February 10, 2022, the Company completed its IPO and issued ADSs and listed warrants to buy ADSs. The ADSs and warrants are considered two freestanding financial instruments because each can be traded separately. The exercise price of the Warrants is $4,250 per ADS (on a post-split basis) and will expire on the sixth anniversary of the date of issuance. The exercise price is subject to standard anti-dilutive adjustments in the event of certain stock splits, stock combinations, stock dividends or recapitalizations, and it is also subject to adjustment in certain events specified in the warrant agreement.

On November 27, 2022, the Company entered into the First Purchase Agreement with Investors as purchasers. Pursuant to the First Purchase Agreement, the Company sold, and the Investors purchased in a private placement an aggregate of 7,750 ADSs, pre-funded warrants to purchase up to 65,750 ADS (the "Pre-Funded Warrants"), Series A purchase warrants to purchase up to 73,500 ADSs (the "Series A Ordinary Warrants") and Series B purchase warrants to purchase up to 73,500 ADSs (the "Series B Ordinary Warrants" and together with the Series A Ordinary Warrants, the "Ordinary Warrants") for aggregate gross proceeds of $ 7,350,000, excluding any proceeds that may be received upon exercise of the Ordinary Warrants. In addition, the Company also issued placement agent warrants to purchase 5,513 ADSs. The purchase price for each ADS and associated Ordinary Warrants is $100 (on a post-split basis) and the purchase price per each Pre-Funded Warrant and associated Ordinary Warrants is $99.98 (on a post-split basis).

On March 27, 2023, the Company, entered into a Second Securities Purchase Agreement with Investors, pursuant to which the Company agreed to issue and sell an

aggregate of 10,750 ADSs, pre-funded warrants to purchase up to 161,125 Pre-Funded Warrants, and Series C purchase warrants to purchase up to 171,875 ADSs Securities. In addition, the Company also issued placement agent warrants to purchase 12,891 ADSs. The purchase price for each ADS and associated Ordinary Warrants was $32 (on a post-split basis) and the purchase price per each Pre-Funded Warrant and associated Ordinary Warrants was $31.98 (on a post-split basis). The Ordinary Warrants were immediately exercisable, expire five (5) years from the date of issuance and the Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.

On July 10, 2023, the Company entered into a warrant amendment with an existing investor pursuant to which the Company and the investor agreed that certain Series A and Series B warrants to purchase 140,000 ADSs of the Company that were previously issued on November 30, 2022 (the "November 2022 Warrants") and certain Series C warrants to purchase 171,875 ADSs of the Company that were previously issued on March 30, 2023 (the "March 2023 Warrants," and together with the November 2022 Warrants, the "Existing Warrants") would be amended as follows: (i) amend the current exercise price on all Existing Warrants so that it is now equal to £7.00, (ii) extend the termination date on 50% of the November 2022 Warrants and all of the March 2023 Warrants until May 30, 2028 and (iii) amend to the definition of "Black Scholes Value" included in Section 3(e) of the Existing Warrants. As a result of the amendments to the related warrants (Series A, Series B and Series C) they were reclassified to equity as they no longer contained a strike price denominated in a foreign currency. Further, the Series A, B and C warrants were also re-measured to a fair value of $6.40 per warrant as of the modification date using the Black-Scholes model with the following inputs:

	July 10, 2023
Exercise price	$ 9.00
Share price	$ 9.00
Time to maturity	4.8 years
Expected volatility	90%
Risk free interest rate (US treasury bond)	4.0%
Dividend yield	-

On August 30, 2023, the Company entered into an agreement with its Series A and B warrant holders whereby it induced 70,000 and 70,000 of the outstanding warrants, respectively. In addition, the Company also entered into an agreement with its Series C warrant holders to induce all of the outstanding warrants (171,875). The inducement resulted in gross proceeds to the Company of approximately $2.8 million. In order to incentivize the inducement, the Company issued 623,750 Series D warrants to the Series, A, B and C warrant holders. In addition, the Company also issued placement agent warrants to purchase 23,391 ADSs. The Ordinary Warrants were immediately exercisable and expire five 5.5 years from the date of issuance.

On December 18, 2023, the Company, entered into a Securities Purchase Agreement with Investors, pursuant to which the Company agreed to issue and sell an aggregate of 75,000 ADSs, pre-funded warrants to purchase up to 1,675,000 Pre-Funded Warrants, and Series C purchase warrants to purchase up to 1,750,000 ADSs Securities. The offering resulted in gross proceeds of $3.5 million. In addition, the Company also issued placement agent warrants to purchase 131,250 ADSs. The purchase price for each ADS and associated Ordinary Warrants was $2.00 and the purchase price per each Pre-Funded Warrant and associated Ordinary Warrants was $1.99. The Ordinary Warrants were immediately exercisable, expire five (5) years from the date of issuance and the Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.

While the Series D and Series E warrants are equity classified, there are remaining IPO, Series A and Series B warrants that are still liability classified. However, as a result of being significantly out of the money, the fair value of the liability classified warrants was not material as of December 31, 2023.

Unlisted warrants in issue

Series A warrants

The fair value of each of the warrants was approximately $0.37 and $51.60 as of December 31, 2023 and 2022, respectively.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

	December 31, 2023	December 31, 2022
Exercise price	$ 100.00	$ 100.00
Share price	$ 3.17	$ 77.00
Time to maturity	4.4 years	5.4 years
Expected volatility	90%	85%
Risk free interest rate (US treasury bond)	4.0%	3.9%
Dividend yield	-	-

Series B warrants

The fair value of each of the warrants was approximately $0.01 and $36.80 as of December 31, 2023 and 2022, respectively.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

	December 31, 2023	December 31, 2022
Exercise price	$ 100.00	$ 100.00
Share price	$ 3.17	$ 77.00
Time to maturity	1.4 years	2.4 years
Expected volatility	90%	90%
Risk free interest rate (US treasury bond)	4.0%	4.3%
Dividend yield	-	-

Series A-B placement agent warrants

The fair value of each of the warrants was $0.31 and $51.20 as of December 31, 2023 and 2022, respectively.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

	December 31, 2023	December 31, 2022
Exercise price	$ 125.00	$ 125.00

Share price	$	3.17	$	77.00
Time to maturity		4.4 years		5.4 years
Expected volatility		90%		90%
Risk free interest rate (US treasury bond)		4.0%		4.0%
		-		-

Series C warrants

The fair value of each of the warrants was $21.63 as of March 30, 2023 (issuance date). The warrants were induced during August of 2023 (further information is included in Note 12).

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

		March 30, 2023
Exercise price	$	35.00
Share price	$	31.00
Time to maturity		5.0 years
Expected volatility		90%
Risk free interest rate (US treasury bond)		4.0%
Dividend yield		-

Series C placement agent warrants

The fair value of each of the warrants was $0.69 as of December 31, 2023 and $21.09 as of March 30, 2023 (issuance date), respectively.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

		December 31, 2023		**March 30, 2023**
Exercise price	$	40.00	$	40.00
Share price	$	3.17	$	31.00
Time to maturity		4.2 years		5.0 years
Expected volatility		90%		90%
Risk free interest rate (US treasury bond)		4.0%		4.49%
Dividend yield		-		-

Series D warrants

The fair value of each of the warrants was $8.46 as of the August 30, 2023 issuance date. As the warrants were equity classified, they were not re-measured to fair value as of December 31, 2023.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

		August 30, 2023
Exercise price	$	8.80
Share price	$	11.00
Time to maturity		5.5 years
Expected volatility		90%
Risk free interest rate (US treasury bond)		4.0%

Series D placement agent warrants

The fair value of each of the warrants was $8.20 as of the August 30, 2023 issuance date. As the warrants were equity classified, they were not re-measured to fair value as of December 31, 2023.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

		August 30, 2023
Exercise price	$	11.00
Share price	$	11.00
Time to maturity		5.5 years
Expected volatility		90%
Risk free interest rate (US treasury bond)		4.0%
Dividend yield		-

Series E warrants

The fair value of each of the warrants was $1.97 as of the December 18, 2023 issuance date. As the warrants were equity classified, they were not re-measured to fair value as of December 31, 2023.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

		December 18, 2023
Exercise price	$	2.00
Share price	$	2.61
Time to maturity		5.0 years
Expected volatility		90%
Risk free interest rate (US treasury bond)		4.0%

Series E placement agent warrants

The fair value of each of the warrants was $1.89 as of the December 18, 2023 issuance date. As the warrants were equity classified, they were not re-measured to fair value as of December 31, 2023.

The inputs associated with calculating the fair value of the warrants are considered to be Level 2 and were valued using a Black-Scholes valuation model. The inputs were as follows:

	December 18, 2023
Exercise price	$ 2.50
Share price	$ 2.61
Time to maturity	5.0 years
Expected volatility	90%
Risk free interest rate (US treasury bond)	4.0%
Dividend yield	-

NOTE 15. INCOME TAXES

	Year Ended December 31, 2023 £	Year Ended December 31, 2022 £
Current tax		
Corporation tax credit	1,088,729	1,720,000
Total current tax credit	1,088,729	1,720,000
Reconciliation of loss before tax to the tax credit for the year		
Loss before tax	6,995,682	3,033,601
Loss on ordinary activities multiplied by the standard rate of tax of 23.5% (2022: 19%)	1,643,985	576,384
Adjustments in respect of prior years	45,136	154,422
Non-deductible expenses	(1,497,764)	(1,834,581)
Super deductions	-	13,178
Change in deferred tax asset	-	(186,879)
Change in valuation allowance	357,897	(671,566)
Foreign rate differential	(29,318)	-
Other	(233,096)	-
Additional allowance in respect of enhanced R&D relief	-	4,198,115
Surrender of tax losses for R&D tax credit refund	-	(2,109,111)
Adjustments relating to GAAP	(241,704)	14,460
R&D tax credits generated	1,043,593	1,565,578
Current tax credit	1,088,729	1,720,000

As of December 31, 2023, the Company's net operating loss carryforwards in the United Kingdom totaled £16.4 million. U.K. tax credit carryforwards can be carried forward indefinitely to be offset against future tax liabilities of the Company. As of December 31, 2023, the Company's net operating loss carryforwards in the United States of America totaled £1.2 million. U.S. tax credit carryforwards can be carried forward indefinitely to be offset against future tax liabilities of the TC BioPharm (North America) Inc.

Significant components of the Company's deferred tax assets as of December 31, 2023 and 2022 are summarized below.

	2023	2022
Deferred tax assets:		
Net operation losses	£ 4,357,668	£ 4,433,305
Fixed asset	79,338	71,426
Other	17,946	308,118
Total deferred tax assets	4,454,952	4,812,849
Valuation allowance	(4,454,952)	(4,812,849)
Net deferred tax asset, net of valuation allowance	£ –	£ –

After weighing all available positive and negative evidence for the periods ended December 31, 2023 and 2022, the Company has recorded a valuation allowance of £4,454,952 and £4,812,849, respectively.

The Company continuously monitors its current and prior filing positions in order to determine if any unrecognized tax positions should be recorded. The analysis involves considerable judgement and is based on the best information available. For the periods ended December 31, 2023 and 2022, the Company is not aware of any positions which require an uncertain tax position liability.

NOTE 16. SUBSEQUENT EVENTS

Management evaluated subsequent events and transactions that occurred after the balance sheet date, up to the date that the financial statements were issued. Based upon this review, other than as set forth below, management did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

Exercise of Pre-funded Warrants

During January 2024, pre-funded warrants representing 1,398,000 ADSs were exercised in three separate tranches.

Issuances of ADSs and grants of options to purchase ADSs

On February 29, 2024, the Renumeration Committee of the Board of Directors approved a grant of options to purchase ADSs to the Company's executive officers and non-employee directors under the Company's 2021 Shares Option Scheme (the "Plan") and agreed to cancel all shares options previously issued to such persons. Each non-employee director received an option to purchase 41,760 ADSs, or ADSs representing 835,200 Ordinary Shares at an exercise price of $1.09 per ADS, which is equal to the closing price of the Company's ADSs on the Nasdaq Capital Market on January 31, 2024. Martin Thorp, the Company's Chief Financial Officer, received an option to purchase 177,122 ADSs, or ADSs representing 3,542,440 Ordinary Shares at an exercise price of $1.09 per ADS, which is equal to the closing price of the Company's ADSs on the Nasdaq Capital Market on January 31, 2024. Bryan Kobel, the Company's Chief Executive Officer received an option to purchase 381,606 ADSs, or ADSs representing 7,632,120 Ordinary Shares at an exercise price of $1.09 per ADS, which is equal to the closing price of the Company's ADSs on the Nasdaq Capital Market on January 31, 2024. All share options that were issued vest immediately upon issuance.

On March 8, 2024, Bryan Kobel, the Chief Executive Officer of the Company agreed to (a) defer the payment of accrued but unpaid contractual pension benefits owed to him in the amount of $66,000 for a period of 9 months and (b) convert an aggregate amount of $24,760 of accrued but unpaid contractual pension benefits owed to him into 476,153 ordinary shares, par value £0.0001 per share of Company, based on a price per share equal to the closing price of the Company's ADSs on the Nasdaq Capital Market on March 7, 2024 divided by twenty (20), or the ADS ratio.

In addition, the board of directors approved a grant of options to Mr. Kobel purchase 153,000 ADSs, or ADSs representing 3,060,000 Ordinary Shares at an exercise price of $2.00 per ADS, which is a premium to the closing price of the Company's ADSs on the Nasdaq Capital Market on March 7, 2024. The options granted to Mr. Kobel were issued under the Company's 2021 Plan. All share options that were issued vested immediately.

Exercise of Series D Warrants

On March 12, 2024, the Company issued 623,750 ADS representing 12,475,000 ordinary shares of the Company upon exercise of outstanding Series D warrants resulting in gross cash proceeds to the Company of £986,398 (approximately $1,263,000).

Item 9. Changes and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective at a reasonable assurance level due to the material weaknesses in internal control over financial reporting described below. The Company's disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officer and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K under the Securities Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies. Additionally, this Report does not contain an attestation report of our registered public accounting firm regarding internal control over financial reporting since the Company, as a smaller reporting company and non-accelerated filer, is not required to provide such report.

Material Weaknesses in Internal Control over Financial Reporting

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the framework established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that our internal control over financial reporting as of December 31, 2023 was not effective.

We identified a material weakness in our internal control over accounting for complex financial instruments (including in determining the appropriate valuation basis in areas requiring significant judgement) during the years ended December 31, 2022 and December 31, 2023, and in the accounting for our property leases on conversion from IFRS to GAAP, which remained unremediated as of December 31, 2023, prior to processing corrective adjustments to the financial information which is included in the financial statements that are included in this Form 10K. After identifying the material weaknesses, we implemented measures designed to improve our financial control in the aforementioned areas through early engagement with third party technical accounting experts and those measures are now in operation.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fiscal year ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this item will be filed by amendment to the 10-K not later than 30 days after the applicable due date or be incorporated by reference to our Proxy Statement for our 2024 Annual General Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, or Code of Ethics, applicable to our employees, senior management, and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the Code of Ethics is posted on our website, which is located at www.tcbiopharm.com. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report and is not incorporated by reference herein.

Item 11. Executive Compensation

The information required by this item will be filed by amendment to the 10-K not later than 30 days after the applicable due date or be incorporated by reference to our Proxy Statement for our 2024 Annual General Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be filed by amendment to the 10-K not later than 30 days after the applicable due date or be incorporated by reference to our Proxy Statement for our 2024 Annual General Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

Item 13. Certain Relationships and Related Party Transactions and Director Independence

The information required by this item will be filed by amendment to the 10-K not later than 30 days after the applicable due date or be incorporated by reference to our Proxy Statement for our 2024 Annual General Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

Item 14. Principal Accountant Fees and Services

The information required by this item will be filed by amendment to the 10-K not later than 30 days after the applicable due date or be incorporated by reference to our Proxy Statement for our 2024 Annual General Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. *Financial Statements*

For a list of the financial statements included herein, see Index to the Financial Statements on page 83 of this Annual Report, incorporated into this Item by reference.

2. *Financial Statement Schedules*

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the financial statements or the notes thereto.

3. *Exhibits*

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Exhibit	Description	Schedule/ Form	File Number	Exhibit	File Date
3.1	Articles of Association of TC BioPharm (Holdings) plc	F-1	333-260492	3.2	03/08/2022
3.2	Amendment to Articles of Association	6-K	001-41231	99.1	10/06/2022
4.1	Deposit Agreement – Bank of New York Mellon for American Depositary Shares	F-1	333-260492	4.1	01/14/2022
4.2	Form of American Depositary Share (included in Exhibit 2.1)	F-1	333-260492	4.2	01/14/2022
4.3	Warrant Agent Agreement with Computershare Inc.	F-1	333-260492	4.4	01/14/2022
4.4	Form of Warrant Certificate (included in Exhibit 2.3)	F-1	333-260492	4.5	01/14/2022
4.5	Form of Ordinary Share Certificate	F-1	333-260492	4.6	01/14/2022
4.6	Form of Representative Warrant	F-1	333-260492	4.3	01/14/2022
4.7	Description of Securities of Registrant	20-F	001-41231	4.11	05/13/2022
4.8	Form of Pre-Funded Warrant	6-K	001-41231	10.1	11/30/2022
4.9	Form of Series A and Series B Ordinary Warrant	6-K	001-41231	10.2	11/30/2022
4.10	Form of Placement Agent Warrant	6-K	001-41231	10.3	11/30/2022
4.11	Form of Pre-Funded Warrant	6-K	001-41231	10.1	03/23/2023
4.12	Form of Placement Agent Warrant	6-K	001-41231	10.2	03/23/2023
4.13	Form of Series C Ordinary Warrant	6-K	001-41231	10.3	03/23/2023
4.14	Form of Series D Warrant	6-K	001-41231	4.1	08/31/2023
4.15	Form of Pre-Funded Warrant	6-K	001-41231	10.1	12/21/2023
4.16	Form of Placement Agent Warrant	6-K	001-41231	10.3	12/21/2023
4.17	Form of Series E Warrant	6-K	001-41231	10.2	12/21/2023
10.1	Form of 2014 Share Option Scheme of Registrant	F-1	333-260492	10.1	01/14/2022
10.2	Form of 2021 Share Option Scheme (including sub-plan for U.S. based persons) of Registrant	F-1	333-260492	10.2	01/14/2022

10.3	Form of 2021 Company Share Option Plan (CSOP) of Registrant	F-1	333-260492	10.3	01/14/2022
10.4	Convertible Loan Note, up to $20,000,000 in principal amount	F-1	333-260492	10.6	01/14/2022
10.5	Form of Lock Up Agreement of Pre-IPO Smaller Shareholders	F-1	333-260492	10.8	01/14/2022
10.6	Form of Lock Up Agreement of Pre-IPO Management and Larger Shareholders	F-1	333-260492	10.9	01/14/2022
10.7	Form of Lock Up Agreement of Holders of Convertible Loan Notes	F-1	333-260492	10.10	01/14/2022
10.8	Form of Deed of Indemnity for directors and officer	20-F	001-41231	4.10	05/13/2022
10.9	Form of Securities Purchase Agreement for Nov 2022 Private Placement	6-K	001-41231	10.4	11/30/2022
10.10	Form of Registration Rights Agreement for Nov 2022 Private Placement	6-K	001-41231	10.5	11/30/2022
10.11	Form of Securities Purchase Agreement for March 2023 Offering	6-K	001-41231	10.4	03/30/2023
10.12	Warrant Amendment Agreement, dated March 27, 2023	6-K	001-41231	10.5	03/30/2023
10.13	Form of Warrant Amendment Agreement, dated July 10, 2023	6-K	001-41231	10.1	07/24/2023
10.14	Form of Inducement Letter, dated August 30, 2023	6-K	001-41231	10.1	08/31/2023
10.15	Form of Securities Purchase Agreement for December 2023 Offering	6-K	001-41231	10.4	12/21/2023
10.16	Form of Warrant Amendment Agreement, dated December 19, 2023	6-K	001-41231	10.5	12/21/2023
14.1	Code of Ethics of the Registrant	F-1	333-260492	11.1	01/14/2022
21.1	List of Subsidiaries of Registrant	F-1	333-260492	21.1	01/14/2022
31.1*	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2022				
31.2*	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2022				
32.1*	Certification by Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2022				
97.1*	Clawback Policy				
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				
101.SCH	Inline XBRL Taxonomy Extension Schema 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 in IXBRL, and included in exhibit 101).				

Item 16. Form 10-K Summary

The Company has elected not to include summary information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TC BIOPHARM (HOLDINGS) PLC

By: */s/ Bryan Kobel*
Bryan Kobel
Chief Executive Officer

By: */s/ Martin Thorp*
Martin Thorp
Chief Financial Officer

Date: April 1, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) OR 15D-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Bryan Kobel, certify that:

1. I have reviewed this Annual Report on Form 10-K of TC BioPharm (Holdings) plc for the year ended December 31, 2023.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

April 1, 2024

/s/ Bryan Kobel
Bryan Kobel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) OR 15D-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Martin Thorp, certify that:

1. I have reviewed this Annual Report on Form 10-K of TC BioPharm (Holdings) plc for the year ended December 31, 2023.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

April 1, 2024

/s/ Martin Thorp
Martin Thorp
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION 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 of TC BioPharm (Holdings) plc (the "Company") on Form 10-K, for the year ended December 31, 2023 as filed with the Securities and Exchange Commission, I, Bryan Kobel, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

April 1, 2024

/s/ Bryan Kobel
Bryan Kobel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION 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 of TC BioPharm (Holdings) plc (the "Company") on Form 10-K, for the year ended December 31, 2023 as filed with the Securities and Exchange Commission, I, Martin Thorp, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

April 1, 2024

/s/ Martin Thorp
Martin Thorp
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

TC BIOPHARM (HOLDINGS) PLC

CLAWBACK POLICY

I. Purpose and Scope

The Board of Directors (the "**Board**") of the Company believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board has therefore adopted this Clawback Policy (this "**Policy**"), which provides for the recovery of erroneously awarded Compensation in the event of a Triggering Event (as defined below). Unless otherwise defined herein, the capitalized terms have the meanings set forth under "XIII. Definitions."

II. Administration

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 of the Exchange Act, Nasdaq Listing Rule 5608 and other regulations, rules and guidance of the Securities and Exchange Commission (the "**SEC**") thereunder, and related securities regulations and regulations of the stock exchange or association on which Company's securities are listed (collectively, the "**Listing Standards**"). This Policy shall be administered by the Compensation Committee of the Board (the "**Committee**").

Any determinations made by the Committee shall be final and binding. In addition, the Company shall file all disclosures with respect to this Policy in accordance with the Listing Standards. The Committee hereby has the power and authority to enforce the terms and conditions of this Policy and to use any and all of the Company's resources it deems appropriate to recoup any excess Compensation subject to this Policy.

III. Covered Executives

This Policy applies to the Company's current and former Covered Executives, as determined by the Committee in accordance with the Listing Standards.

IV. Events That Trigger Recoupment Under This Policy

The Board or Committee will be required to recoup any excess Compensation received by any Covered Executive during the three (3) completed fiscal years (together with any interim stub fiscal year period(s) of less than nine (9) months resulting from the Company's transition to different fiscal year measurement dates) immediately preceding the date the Company is deemed (as determined pursuant to the immediately following sentence) to be required to prepare a Covered Accounting Restatement (the "**Three-Year Recovery Period**") irrespective of any fault, misconduct or responsibility of such Covered Executive for the Covered Accounting Restatement. For purposes of the immediately preceding sentence, the Company is deemed to be required to prepare a Covered Accounting Restatement on the earlier of (A) the date upon which the Board or applicable committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Covered Accounting Restatement; or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare a Covered Accounting Restatement (each a "**Triggering Event**").

V. Excess Compensation: Amount Subject to Recovery

The amount of Compensation to be recovered shall be the excess of the Compensation received by the Covered Executive over the amount of Compensation which would have been received by the Covered Executive had the amount of such Compensation been calculated based on the restated amounts, as determined by the Committee. For purposes of this Policy, Compensation shall be deemed "received", either wholly or in part, in the fiscal year during which any applicable Financial Reporting Measure is attained, even if the payment, vesting or grant of such Compensation occurs after the end of such fiscal year. Amounts required to be recouped under this Policy shall be limited to the amounts received by the Executive on a pre-tax basis. The date of receipt of the Compensation depends upon the terms of the award of such Compensation. For example:

a. If the *grant* of an award of Compensation is based, either wholly or in part, on the satisfaction of a Financial Reporting Measure performance goal, then the award would be deemed received in the fiscal period when that measure was *satisfied*;

b. If the *vesting* of an equity award of Compensation occurs *only* upon the satisfaction of a Financial Reporting Measure performance condition, then the award would be deemed received in the fiscal period when it *vests*;
c. If the *earning* of a non-equity incentive plan award of Compensation is based on the satisfaction of the relevant Financial Reporting Measure performance goal, then the non-equity incentive plan award will be deemed received in the fiscal year in which that performance goal is *satisfied*; and
d. If the *earning* of a cash award of Compensation is based on the satisfaction of a Financial Reporting Measure performance goal, then the cash award will be deemed received in the fiscal period when that measure is *satisfied.*

It is specifically understood that, to the extent that the impact of the Covered Accounting Restatement on the amount of Compensation received cannot be calculated directly from the information in the Covered Accounting Restatement (e.g., if such restatement's impact on the Company's share price is not clear), then such excess amount of Compensation shall be determined based on the Committee's reasonable estimate of the effect of the Covered Accounting Restatement on the share price or total shareholder return upon which the Compensation was received. The Company shall maintain documentation for the determination of such excess amount and provide such documentation to the Nasdaq Stock Market ("**Nasdaq**").

VI. Method of Recovery

The Committee shall determine, in its sole discretion, the methods for recovering excess Compensation hereunder, which methods may include, without limitation:

a. requiring reimbursement of cash Compensation previously paid;
b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
c. offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
d. cancelling outstanding vested or unvested equity awards; and/or
e. taking any other remedial and recovery action permitted by law, as determined by the Committee.

Notwithstanding anything in this Section VI, and subject to applicable law, the Committee may cause recoupment under this Policy from any amount of Compensation approved, awarded, granted, paid, or payable to any Covered Executive prior to, on, or following the Effective Date (as defined below).

VII. Impracticability

The Committee shall recover any excess Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Committee in accordance with the Listing Standards. It is specifically understood that recovery shall only be deemed impractical if (A) the direct expense paid to a third party to assist in

enforcing the Policy would exceed the amount to be recovered (before concluding that it would be impracticable to recover any amount of erroneously awarded Compensation based on the expense of enforcement, the Committee shall make a reasonable attempt to recover such erroneously awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to Nasdaq); (B) recovery would violate home country law where that law was adopted prior to the November 28, 2022 (before concluding that it would be impracticable to recover any amount of erroneously awarded Compensation based on violation of home country law, the Committee shall obtain an opinion of home country counsel, acceptable to the applicable national securities exchange or association on which Company's securities are trading, that recovery would result in such a violation, and must provide such opinion to the exchange or association); or (C) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the registrant, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a), and the regulations promulgated thereunder.

VIII. Other Recoupment Rights; Acknowledgement

The Committee may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company. The Company shall provide notice and seek written acknowledgement of this Policy from each Covered Executive; *provided*, that the failure to provide such notice or obtain such acknowledgement shall have no impact on the applicability or enforceability of this Policy to, or against, any Covered Executive, other than as set out in the following paragraph.

For Compensation to be recovered in accordance with this policy the Company must have issued to the Executive, prior to the Compensation being paid or becoming vested, a letter, which shall constitute an amendment to the Executive's employment contract (and shall be executed by a director of the Company, upon the authority of the Remuneration Committee, and the Executive), and which sets out (a) the form and amount of the Compensation which is to be awarded and is covered by this Clawback Policy and (b) the nature and amount of the Financial Reporting Measure(s) upon which the Compensation is awarded, including any linkage of the Compensation to the Financial Reporting Measure.

IX. No Indemnification of Covered Executives

Notwithstanding any right to indemnification under any plan, policy or agreement of the Company or any of its affiliates, the Company shall not indemnify any Covered Executives against the loss of any excess Compensation. In addition, the Company shall be prohibited from paying or reimbursing a Covered Executive for premiums of any third-party insurance purchased to fund any potential recovery obligations.

X. Indemnification

To the extent allowable pursuant to applicable law, each member of the Board or the Committee and any officer or other employee to whom authority to administer any component of this Policy is designated shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to this Policy and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; *provided*, *however*, that he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such individuals may be entitled pursuant to the Company's Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

XI. Effective Date

This Policy shall be effective as of the date the Policy is adopted by the Board (the "**Board Adoption Date**"). This Policy shall apply to any Compensation that is received by Covered Executives on or after December 1, 2023 (the "**Effective Date**"), even if such Compensation was approved, awarded, granted, or paid to Covered Executives prior to the Effective Date or the Board Adoption Date.

XII. Amendment and Termination; Interpretation

The Board may amend this Policy from time to time in its sole discretion, provided always that any revised policy shall only apply to Compensation paid after the time that the policy is emended; and shall amend this Policy as it deems necessary to reflect and comply with further regulations, rules and guidance of the SEC and Listing Standards. The Board may terminate this Policy at any time.

The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. This Policy is designed and intended to be interpreted in a manner that is consistent with the requirements of the Listing Standards. To the extent there is any inconsistency between this Policy and such regulations, rules and guidance, such regulations, rules and guidance shall control, and this Policy shall be deemed amended to incorporate such regulations, rules and guidance until or unless the Board or the Committee expressly determine otherwise.

This Policy shall be applicable, binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives to the fullest extent of the law. For the avoidance of doubt, this Policy shall be in addition to (and not in substitution of) any other clawback policy of the Company in effect from time to time or applicable to any Covered Executive.

XIII. Definitions

For purposes of this Policy, the following terms shall have the following meanings:

1. "**Company**" means TC Biopharm (Holdings) Ltd., a public limited company incorporated in Scotland pursuant to the Companies Act 2006, as amended, and its subsidiaries and their successors.

2. "**Compensation**" means any compensation which was approved, awarded or granted to, or earned by a Covered Executive (A) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (B) on or after the Effective Date (including any award under any short-term or long-term incentive compensation plan of the Company, including any other short-term or long-term cash or equity incentive award or any other payment) that, in each case, is granted, earned, or vested based wholly or in part upon the attainment of any Financial Reporting Measure (i.e., any measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, including share price and total shareholder return). Compensation may include (but is not limited to) any of the following:

    a. Annual bonuses and other short- and long-term cash incentives;

b. Stock options;
c. Stock appreciation rights;
d. Restricted shares;
e. Restricted share units;
f. Performance shares; and
g. Performance units.

3. "**Covered Accounting Restatement**" means any accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws. A Covered Accounting Restatement includes any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (commonly referred to as "Big R" restatements) or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (commonly referred to as "little r" restatements). A Covered Accounting Restatement does not include (A) an out-of-period adjustment when the error is immaterial to the previously issued financial statements, and the correction of the error is also immaterial to the current period; (B) a retrospective application of a change in accounting principle; (C) a retrospective revision to reportable segment information due to a change in the structure of an issuer's internal organization; (D) a retrospective reclassification due to a discontinued operation; (E) a retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; or (F) a retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

4. "**Covered Executive**" means any person who:

   a. Has received applicable Compensation:

      i. During the Three-Year Recovery Period; and
      ii. After beginning service as an Executive Officer; and

   b. Has served as an Executive Officer at any time during the performance period for such Compensation.

5. "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

6. "**Executive Officer(s)**" means an "executive officer" as defined in Exchange Act Rule 10D-1(d) and the Listing Standards and includes any person who is the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice president of the issuer in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company (with any executive officers of the Company's parent(s) or subsidiaries being deemed Covered Executives of the Company if they perform such policy making functions for the Company), and such other senior executives or employees who may from time to time be deemed subject to the Policy by the Board in its sole discretion. All executive officers of the Company identified by the Board pursuant to 17 CFR 229.401(b) shall be deemed "Executive Officers."

7. "**Financial Reporting Measure(s)**" means any measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, including share price and total shareholder return, including, but not limited to, financial reporting measures including "non-GAAP financial measures" for purposes of Exchange Act Regulation G and 17 CFR 229.10, as well other measures, metrics and ratios that are not non-GAAP measures, like same store sales. Financial Reporting Measures may or may not be included in a filing with the SEC and may be presented outside the Company's financial statements, such as in Management's Discussion and Analysis of Financial Conditions and Results of Operations or the performance graph. Financial Reporting Measures include, without limitation, any of the following:

   a. Company share price;
   b. Total shareholder return;
   c. Revenues;
   d. Net income;
   e. Earnings before interest, taxes, depreciation, and amortization (EBITDA);
   f. Funds from operations;
   g. Liquidity measures such as working capital or operating cash flow;
   h. Return measures such as return on invested capital or return on assets; and
   i. Earnings measures such as earnings per share.