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

FORM 10-K

(Mark One)

☒ **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**

Commission file number: 001-40367

BARINTHUS BIOTHERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

England and Wales	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

Unit 6-10, Zeus Building
Rutherford Avenue
Harwell,
Didcot, OX11 0DF, United Kingdom
(Address of principle executive offices) (Zip Code)

Registrant's telephone number, including area code: +44 (0) 1865 818 808

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*	BRNS	The Nasdaq Global Market
Ordinary shares, nominal value £0.000025 per share**		

* American Depositary Shares may be evidenced by American Depositary Receipts. Each American Depositary Share represents one (1) ordinary share.
** Not for trading, but only in connection with the listing of American Depositary Shares on The Nasdaq Global Market.

Securities registered pursuant to Section 12(g) of the Act: None

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 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the 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	☐	Accelerated filer	☐	Non-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. ☐

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 12b-2 of the Act). Yes ☐ No ☒

As of the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's ordinary shares, nominal value £0.000025 per share, in the form of American Depositary Shares, held by non-affiliates was approximately $79.4 million.

The number of shares outstanding of the registrant's ordinary shares, nominal value £0.000025 per share, as of March 14, 2024: 38,921,212 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission relative to the registrant's 2024 Annual Meeting of Shareholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

BARINTHUS BIOTHERAPEUTICS PLC

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023

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We own the registered trademark BARINTHUS in the United Kingdom, and we have filed applications at the UK Intellectual Property Office and other intellectual properties to register trademarks for BARINTHUS, SNAP-TI, SNAP-CI and a design logo globally. We also own various trademark registrations and applications, and unregistered trademarks, including the registered trademark VACCITECH, and trademarks relating to the technologies acquired as part of our acquisition of Avidea Technologies, Inc. in December 2021 including the registered trademarks TRAPD, SNAPVAX and SYNTHOLYTIC. All other trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 10-K ("Annual Report") are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

From time to time, we may use our website, our X (formerly known as Twitter) account at @Barinthusbio and our LinkedIn account at linkedin.com/company/barinthus-bio to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.barinthusbio.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our X (formerly known as Twitter) posts and our LinkedIn posts are not incorporated into, and does not form a part of, this Annual Report.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains express or implied forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue,” “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements and opinions contained in this Annual Report are based upon information available to our management as of the date of this Annual Report and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- the timing, scope or likelihood of regulatory filings and approvals, including timing of Investigational New Drug Application ("IND") and Biological License Application filings for our current and future product candidates, and final U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), United Kingdom Medicines and Healthcare products Regulatory Agency ("MHRA") or other foreign regulatory authority approvals relating to our current and future product candidates;
- our ability to develop and advance our current and future product candidates and programs into, and successfully complete, clinical trials;
- our ability to establish future or maintain current collaborations or strategic relationships;
- the rate and degree of market acceptance and clinical utility of our current and future product candidates;
- any expectations surrounding the payments we could potentially receive pursuant to our collaborations and license agreements;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our product candidates;
- our ability to obtain, maintain, defend and enforce our intellectual property protection for our product candidates, and the scope of such protection;
- our manufacturing, commercialization and marketing capabilities and strategy;
- future agreements with third parties in connection with the commercialization of our product candidates, if approved, and any other approved products;
- regulatory developments in the United States and foreign countries;
- competitive companies, technologies and our industry and the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the accuracy of our estimates of our annual total addressable markets, future revenue, expenses, capital requirements and needs for additional financing;
- our expectations about market trends;
- our ability to anticipate and overcome challenges posed to the conduct of our business in the event of a global pandemic, such as COVID-19, or similar event;

- the impact of global economic and political developments on our business, including rising or sustained high inflation and capital market disruptions, the conflict in Ukraine, the conflict in Israel and Gaza, disruptions in the banking industry, economic sanctions and economic slowdowns or recessions that may result from such developments; and

- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended ("JOBS Act").

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

This Annual Report contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Unless the context otherwise requires, reference in this Annual Report to the terms “Barinthus Bio,” “the Company,” “we,” “us,” “our,” and similar designations refer to Barinthus Biotherapeutics plc and, where appropriate, our wholly-owned subsidiaries. As used herein, all references before November 7, 2023 to (i) Barinthus Biotherapeutics plc shall refer to Vaccitech plc, (ii) Barinthus Biotherapeutics (UK) Limited shall refer to Vaccitech (UK) Limited, (iii) Barinthus Biotherapeutics North America, Inc. ("Barinthus Bio NA") shall refer to Vaccitech North America, Inc., (iv) Barinthus Biotherapeutics Switzerland GmbH shall refer to Vaccitech Switzerland GmbH, (v) Barinthus Biotherapeutics S.R.L. shall refer to Vaccitech Italia S.R.L. and (vi) Barinthus Biotherapeutics Pty Limited shall refer to Vaccitech Australia Pty Limited, after which the name change described herein shall have taken effect.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

- We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.
- We have not yet generated any material revenue from our product candidates.
- If we engage in further acquisitions or future strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.
- We may require substantial additional funding in the future. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.
- Actual payments we may receive in connection with certain milestones or net sales under the AstraZeneca License Agreement may differ from those described in this Annual Report, and there can be no assurance that we will receive any such payments at all.
- If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval or reimbursement and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support marketing authorization of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.
- Interim, “topline,” and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.
- Our product candidates may cause serious adverse events, serious side effects or have other properties that could halt their clinical development, prevent their marketing authorization, require expansion of the trial size, limit their commercial potential or result in significant negative consequences.
- If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- The market opportunities for certain of our oncology product candidates may be relatively small as it may be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

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

- The marketing authorization processes of the FDA, the EMA, MHRA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing authorizations for our product candidates, or the marketing authorization is for a narrower indication than we seek, our business will be substantially harmed.

- Even if we receive marketing authorization for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

- If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected.

- Our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others and if we fail to comply with our current or future obligations in any agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

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

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

- We previously identified material weaknesses in connection with our internal control over financial reporting. Although we have taken steps to remediate these material weaknesses, we may identify other material weaknesses in the future, which could have a significant adverse effect on our business and the trading price of our ADSs.

- If we were classified as a passive foreign investment company, it would result in adverse U.S. federal income tax consequences to U.S. Holders (as defined below).

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

- The United Kingdom’s withdrawal from the EU could increase the regulatory burden of product development and authorization in the United Kingdom and European Union.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity and cancer. Helping patients and their families is the guiding principle at the heart of Barinthus Bio. We stand apart through our broad pipeline, built around four proprietary platform technologies; two viral vector platforms, ChAdOx and MVA; and two versions of the synthetic SNAP platform, SNAP-TI (SNAP-Tolerance Immunotherapy) and SNAP-CI (SNAP-Cancer Immunotherapy), previously referred to collectively as SNAPvax™. These platforms are enabling us to develop antigen-specific immunotherapeutic candidates designed to optimize the disease-fighting capabilities of T cells and guide them towards a healthy balance. Our immunotherapeutic candidates are designed to work by increasing disease-specific CD8+ T cell activity in the case of chronic infectious diseases and cancers, or by dampening autoreactive CD4+ and CD8+ T cells, and increasing regulatory T cells in autoimmunity.

Harnessing our range of proprietary platform technologies, we are advancing a pipeline of four product candidates across a diverse range of therapeutic areas, including: VTP-300, a Phase 2 immunotherapeutic candidate designed as a potential component of a functional cure for chronic hepatitis B viral ("HBV") infection; VTP-200, a Phase 2 non-surgical product candidate for persistent high-risk human papillomavirus ("HPV") with near term clinical read-outs; VTP-1000, our first preclinical autoimmune candidate designed to utilize the SNAP-TI platform to treat patients with celiac disease; and VTP-850, a second-generation Phase 2 immunotherapeutic candidate designed to treat recurrent prostate cancer.

Alongside these proprietary programs, we have partnerships in place to advance three additional prophylactic and therapeutic product candidates in Middle East Respiratory Syndrome ("MERS"), Zoster and Non-Small Cell Lung Cancer (NSCLC). We also co-invented Vaxzevria, a COVID-19 vaccine with the University of Oxford, which has been exclusively licensed worldwide to AstraZeneca UK Limited ("AstraZeneca"). The co-invention of the COVID-19 vaccine demonstrated our ability to navigate a changing environment with speed and efficiency and lead the way in responding to urgent medical needs, as well as providing a strong proof-of-concept for the ChAdOx platform.

We believe our proven scientific expertise, diverse portfolio and focus on product candidate development uniquely positions us to navigate towards delivering treatments for patients with infectious diseases, autoimmune disorders and cancers that have a significant impact on their everyday lives.

Scientists have successfully harnessed the strengths of the immune system to prevent and treat diseases using a wide range of approaches over hundreds of years. The most widely known application of such approaches is prophylactic vaccines, which aim to create long-lasting immunity largely via the generation of protective antibodies. More recently, approaches targeting the immune system to treat diseases have emerged with many immunotherapeutics aiming to balance the body’s immune response. These immunotherapeutic approaches can broadly fit into two categories: those that are designed to strengthen the immune system to enable clearance of pathogens and infected or cancerous cells, or those that are designed to dampen the immune system to limit inflammation and tissue damage due to autoimmune hyperactivity or uncontrolled inflammation. A key element of the immune system is specialized white blood cells, also called lymphocytes. B cells and T cells are the two main types of lymphocytes. B cells are responsible for generating antibodies while T cells assist in the clearance of acute and chronic infections, such as HBV and HPV, and are involved in killing cells that become cancerous. Although designed to be protective, these immune cells can also be hyperactive and, when targeted against self, they are responsible for tissue-specific damage in many autoimmune conditions.

Over the past three decades, hundreds of trials have examined a wide variety of approaches that induce the production of cytotoxic CD8+ T cells against infected and cancerous cells. These trials have demonstrated that different approaches induce different breadths and magnitudes of immune response. While there have been many successes, certain diseases requiring a robust CD8+ T cell response have remained resistant to existing approaches. Infected or cancerous cells are recognized as a “danger” by the immune system through their expression of specific antigens, which elicit a targeted immune response, largely led by T cells, to eliminate the “danger.” Our platforms are designed to stimulate the production of very high levels of functional T cells, in addition to antibodies, against such antigens.

Our approach for the treatment of a disease with known target antigens is to attempt to elicit a strong and specific immune response against these antigens using a combination of two proprietary platforms encoded with the target antigens, each administered one month apart. We employ unique antigen design strategies designed to optimize antigen presentation to the

immune system and maximize the desired type of immune response we are seeking to induce. This specific combination approach has been shown to provide a very high magnitude and durable CD8+ T cell response induced in humans to date. Our platforms are further differentiated by their flexibility, applicability across diseases, favorable tolerability profile and proven rapid production on a large scale.

Autoimmunity develops when the tolerance checkpoints meant to maintain a state of unresponsiveness of our immune system towards self-antigens are lost. It results in abnormal immune reaction against our own tissues, causing tissue damage and disease. Although the past two decades have seen incredible progress in the treatment of chronic inflammatory and autoimmune diseases, current therapies still rely heavily on the use of non-specific immunosuppressive agents and supportive therapies. These may efficiently dampen inflammation and compensate organ dysfunction to some degree, but they require lifelong treatment and their lack of specificity for the pathogenic mechanism only can lead to several, sometimes life-threatening, side effects. A far less aggressive approach is to restore immune tolerance to self-antigens, in an antigen-specific manner, enabling to selectively blunt autoinflammation and control the disease without impairing protective immunity to pathogens and cancer. Our SNAP-TI platform is designed to exactly do that: restore immune tolerance to self. The platform is comprised of several self-antigens involved in the target disease associated with a tolerizing immunomodulator, enabling presentation of the disease antigens in a tolerizing context, which will potentially lead to dampening T cell hyperactivity and/or inducing self-antigen-specific regulatory T cells, whose main function is to control immune responses. We believe SNAP-TI is further differentiated from its competitors by its high antigen loading capacity, controlled size, and self-assembling nature for ease of manufacturing.

In 2023, we achieved a number of strategic, operational, and financial objectives, which we believe positions us to deliver on our long-term plans:

- In January, we announced the appointment of Nadège Pelletier, Ph.D., as Chief Scientific Officer.
- In March, we announced favorable topline interim data from the HPV001 Phase 1b/2 clinical trial of VTP-200 in high risk HPV ("hrHPV") infection, and positive topline final data from the HBV002 Phase 1b/2 clinical trial for VTP-300 in chronic HBV.
- In April, we presented interim data from the VTP-200 APOLLO (HPV001) Phase 1b/2 clinical trial in hrHPV infection at the 35th Annual International Papillomavirus Conference ("IPVC"). The interim data showed VTP-200 induced high T cell responses to HPV antigens. VTP-200 was generally well-tolerated with no product-related grade 3 unsolicited events and no product-related SAEs.
- In June, we announced the dosing of the first patient in the Phase 1/2 PCA001 clinical trial for VTP-850 in prostate cancer.
- In June, we presented positive final data from the Phase 1b/2a HBV002 clinical trial for VTP-300 in chronic Hepatitis B (CHB) at the European Association for the Study of the Liver ("EASL") Congress 2023 – The International Liver Congress™. The data showed meaningful, durable reductions of Hepatitis B Surface Antigen (HBsAg) in all participants with a >0.5 log10 reduction in HBsAg who received VTP-300 alone (Group 2) or in combination with a single administration of low-dose PD-1 inhibitor, nivolumab (Group 3). Two of five patients with baseline HBsAg below 100 IU/mL in Group 3, developed a non-detectable HBsAg level, which continued eight months after last dose.
- In June, we completed the move of our U.S. facility to Germantown, Maryland, which houses a state-of-the art wet laboratory and office space.
- In November, we announced our renaming as Barinthus Biotherapeutics plc to represent the evolution and expansion of its focus beyond vaccines. As part of the renaming, we announced the ticker on Nasdaq was changed to "BRNS," which became effective on November 7, 2023.
- In November, we conducted an oral presentation of interim data from the Phase 2b HBV003 clinical trial for VTP-300 in CHB at the American Association for the Study of Liver Diseases ("AASLD") – The Liver Meeting® 2023, which indicated that VTP-300 in combination with nivolumab continued to show sustained HBsAg reductions, particularly in patients with HBsAg levels below or equal to 200 IU/mL at screening.
- In November, interim data from the Phase 2a AB-729-202 clinical trial in collaboration with Arbutus Biopharma Corporation in CHB patients were presented via poster presentation at AASLD, showing that imdusiran in combination with VTP-300 demonstrated meaningful and sustained declines in HBsAg levels.
- In December, we announced we signed an agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI") and the University of Oxford, aiming to fast-track the development of a vaccine candidate known as

VTP-500 for the prevention of MERS. This agreement includes CEPI investing funding of up to $34.8 million with Barinthus Biotherapeutics (UK) Limited in addition to funds previously committed to the University of Oxford to develop and stockpile a ready reserve of emergency MERS vaccine candidate, VTP-500.

- In December 2023, we submitted an Australian ethics submission and regulatory notification to the Alfred Research Review Committee for the Phase 1 GLU001 study in Celiac disease.

The Key Elements of Our Antigen-Delivery Platforms

Our proprietary platforms are comprised of several components that are designed to be either immunostimulatory or tolerizing. When combined, our immunomodulatory platforms (ChAdOx, MVA and SNAP-CI) allow us to develop product candidates designed to induce high and durable levels of antigen-specific polyfunctional T cells and B cells to prevent and treat infectious diseases and cancer. Our tolerizing platform (SNAP-TI) is designed to restore immune tolerance by a mechanism of action that includes the induction of regulatory T cells and/or decrease of T cell activation to specifically restore a beneficial T regulatory to T effector ratio and control autoreactive immune cell hyperactivity, while maintaining the desired tolerability profile.

The key elements of our viral vector platforms, which include ChAdOx and MVA, are:

- **Proprietary simian vectors**: ChAdOx1 and ChAdOx2 are modified simian adenoviral vectors which deliver target antigens into cells to generate a specific immune response. These viruses were originally isolated from chimpanzees to avoid pre-existing immunity issues affecting the use of human adenovirus vectors. Researchers at the Jenner Institute modified the ChAdOx viruses to be non-replicating and to have an increased antigen-carrying capacity. To date, we have developed several candidates with the ChAdOx vectors, each carrying antigens that are specific to the targeted pathogens and diseases. Adenoviral vectors have demonstrable safety profiles and have induced the desired immune responses in all age groups evaluated to date.

- **Well-validated follow-up vector**: MVA is a highly attenuated vaccinia virus used to deliver target antigens into cells to generate de novo or amplify an existing immune response. MVA has a large antigen-carrying capacity and generates a particularly strong immune response when used secondarily, in sequential combination, to an alternative viral vector carrying the same antigen load (ChAdOx in this case). MVA is replication-deficient and has a well-documented safety profile in hundreds of thousands of people, and is licensed as a smallpox vaccine in both Europe and the US.

- **Proprietary promoters and enhancers:** Promoters and molecular enhancers are genetic codes that influence antigen expression. For our adenoviral vectors, we use a proprietary promoter that is modified from cytomegalovirus. The use of this modified promoter has been shown to increase both antigen expression and the associated immune response. For our MVA vector, we use a proprietary promoter to control expression of recombinant antigens and thereby further enhance T cell induction levels. We may use molecular adjuvants to enhance the CD8+ T cell response.

- **Rapid vector generation and manufacturing**: We employ manipulation of adenovirus genomes to enable rapid generation of recombinant adenoviral vectors to meet GMP standards. We believe our sequencing techniques have the potential to result in safer, more stable, product candidates. We believe that our adenovirus product candidates can be manufactured quickly and to significant scale, as demonstrated by Vaxzevria, a prophylactic vaccine for the prevention of COVID-19 infection. Vaxzevria, which is based on the ChAdOx1 vector, was designed, constructed and manufactured for human use within three months. Normal GMP production processes typically take six to ten months each for adenovirus and for MVA.

The key elements of our synthetic platforms, which include SNAP-TI and SNAP-CI, are:

- **Synthetic nanoparticle technology:** SNAP is a modular immunotherapy platform that is designed to co-deliver multiple targeted peptide antigens and immunomodulators in self-assembling nanoparticles to key immune cell populations for promoting the appropriate T cell immunity. SNAP's unique design allows for trafficking to lymphoid organs and local tissues to engage with local immunity. The large antigen loading capacity is designed to allow for subcutaneous or intramuscular administration. It can be administered as a monotherapy or in combination with the viral vectors. Its synthetic nature allows for repeated administration.

- SNAP-TI: has shown promising data on protection from disease in a mouse model of autoimmunity. We are advancing assets based on the SNAP-TI platform designed to treat autoimmune diseases with known autoantigens. SNAP-TI contains autoantigens and immunomodulators (*e.g.*, mTOR inhibitors). Its putative mechanism of action includes both dampening of pathogenic T effector activity and induction of regulatory T cells, crucial to restore immune tolerance to self-antigens and maximize therapeutic benefit.

- SNAP-CI: An article in Nature Biotechnology described SNAP as among the most efficient immunotherapy platforms for inducing T cell immunity reported to date. Another article in Nature Biotechnology reported that SNAP enabled repeated intravenous ("IV") administration to maximize clinical effect. SNAP-CI has been observed to induce high magnitude, functional CD8+ T cells, especially when given sequentially with ChAdOx1 in preclinical studies in mice and non-human primates. It contains cancer-specific antigens and immunomodulator (*e.g.*, Toll-like receptor agonists).

Antigen selection and design across all platforms: We select full-length and/or subunit antigen sequences involved in or associated with targeted infectious diseases, autoimmune diseases, or cancer. We employ unique antigen design strategies to optimize *in vivo* antigen presentation and maximize the desired type of immune responses while maintaining the desired tolerability profile. For example, some targeted diseases may require a greater CD8+ T cell-mediated response, whereas others may require a more balanced T and B cell response, and others require the induction of regulatory T cells. We use cutting-edge bioinformatics methods to design and optimize our antigen load. For example, to select antigen targets for pathogens, we use databases to rank options based on factors including global distribution of genetic strains, evolutionary competitive advantage, known pathogenicity and sequence upload bias; and design our final antigens to achieve maximal antigen presenting cell processing to elicit CD8+ T cells.

We have several product candidates in our pipeline focusing on infectious diseases, oncology and immune tolerance.

Our Proprietary Pipeline:

The chart below provides key information about our programs.

We have worldwide rights for all product candidates.
These are estimated timelines only and are subject to change.

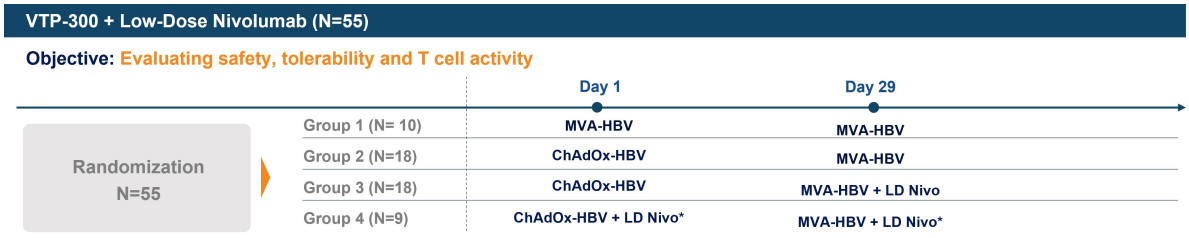
Our Partnered Pipeline:

VTP-300: An Immunotherapeutic Targeting Chronic HBV Infection

VTP-300 is composed of two viral vectors (ChAdOx and MVA), both encoding the same antigen sequence based on HBV genotype C antigen sequences that are administered intramuscularly one month apart, with the potential for additional administrations subsequently, depending upon outcome.

HBV002 – Completed Phase 1b/2a

In March 2023, we announced topline results from the Phase 1b/2a clinical trial, HBV002, to evaluate the safety and reactogenicity of VTP-300 with or without a low-dose (0.3 mg/kg) anti-PD-1 (nivolumab) in CHB patients whose infection has been suppressed with oral antiviral medication. In the HBV002 trial, we enrolled CHB patients in four treatment groups as described in the table below.



Since the participants were already infected with HBV, we thought it was possible that natural exposure could eliminate the need for the an initial ChAdOx1 dose. Hence, Group 1 of the HBV002 trial was designed to compare MVA-HBV given twice with the ChAdOx1-HBV plus MVA-HBV combination approach used in Group 2. We expected that the regimen given to Group 2 would be more potent and planned to further explore this specific regimen in Groups 3 and 4 with the addition of PD1 blockade.

In the cancer field, the timing of PD-1 blockade has been reported to be critical as its administration prior to immune stimulation has been observed to result in diminished T cell responses as compared to later administration. Hence, Groups 3 and 4 evaluated the impact of the timing of PD1 blockade, administered either with the MVA dose (Group 3) or with both the ChAdOx1 and the MVA doses (Group 4). Nivolumab has been used in earlier immunotherapy trials at 1/10 the licensed dose for oncology indications and has been shown to give full peripheral blood T cell receptor occupancy for up to over one month.

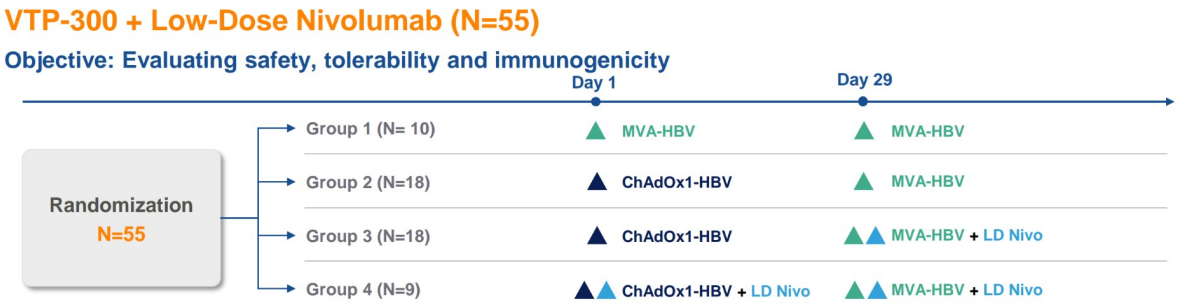
The secondary objectives of this study were to evaluate the HBV-specific T cell response and the effect on the levels of hepatitis B markers, including HBsAg, hepatitis B surface antibody seroconversion, HBV DNA and HBeAg. The majority

of the patients were recruited in Taiwan and South Korea and these territories were selected due to the high prevalence of HBV genotype C virus in Asia. Patients were also enrolled in the United Kingdom.

An interim analysis of HBV002 was conducted in November 2021, after which the protocol was amended to stop enrollment in cohorts 1 and 4 as no meaningful T cell responses nor meaningful reduction of HBsAg were observed with these regimen. Enrollment continued in the cohort receiving VTP-300 as a monotherapy (Group 2) and the cohort receiving VTP-300 with a single low dose of nivolumab administered with the MVA dose (Group 3).

EASL Poster to Present Final Analysis of Safety and Efficacy Data from the HBV002 Study

In June 2023, we announced final safety and efficacy data from the HBV002 study (NCT04778904), which was presented as a poster at the EASL Congress 2023 – The International Liver Congress™. In the HBV002 study, 55 participants were randomized into four groups to receive combinations of VTP-300 and low-dose nivolumab, with follow-up for eight months post-final dose.



VTP-300 as monotherapy and in combination with low-dose nivolumab was administered with no treatment-related serious adverse events. As reported previously, two out of 55 participants experienced transient transaminase flares. Both incidents occurred in participants with HBsAg declines, but not in any of the participants who cleared HBsAg (<0.05 IU/mL).

Group 2
Meaningful, durable reductions of HBsAg were seen in Group 2 (receiving VTP-300 monotherapy, N=18). Three participants had 0.7, 0.7, and 1.4 log10 declines two months post-final dose, with durable responses continuing eight months post-final dose. These participants all had baseline HBsAg <50 IU/mL. A robust T cell response was generated and was highest in this group and there was a relation demonstrated between ELISpot response and HBsAg decline.

Group 3
Those in Group 3 received VTP-300 followed by a single low dose of nivolumab together with Modified Vaccinia Ankara (MVA)-HBV (N=18). Two months post-final dose, the mean reduction in HBsAg was 0.76 log10 ($p<0.001$). This effect persisted with a mean decline of 0.98 log10 at eight months ($p<0.001$) after the last dose and was most prominent with starting values HBsAg <1,000 IU/mL. Two participants developed non-detectable HBsAg levels, which continued eight months after last dose. Pre-genomic RNA levels were observed to decrease significantly in the majority of participants in this group only, consistent with the decline in HBsAg levels.

Groups 1 and 4
No meaningful reductions in HBsAg were observed in Group 1, in which participants received two doses of MVA-HBV without ChAdOx1-HBV, or in Group 4, in which participants received low-dose nivolumab with both doses of VTP-300. These groups were discontinued following interim analysis, as previously announced in June 2022.

Importantly, VTP-300, based on HBV genotype C sequences, was observed to lead to a decline in HBsAg in both genotype B- and C-infected CHB patients. Additionally, T cell responses to HBV core protein induced by VTP-300 in healthy subjects were shown to cross-react with other prevalent genotypes (A to E). Together, these results highlighted that T cell responses induced by VTP-300, based on genotype C, were cross-reactive to other common HBV genotypes.

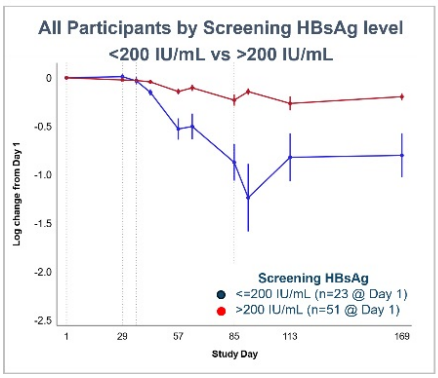
HBV003 – Ongoing Phase 2b

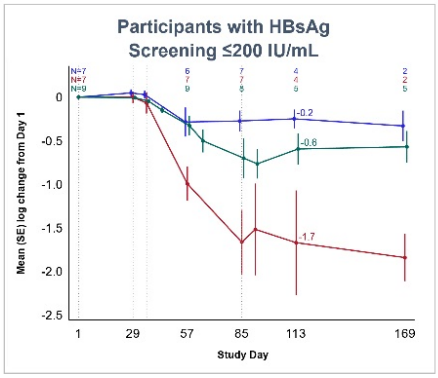
HBV003 is designed to obtain critical information on treatment dosing regimen with patients receiving VTP-300 and low-dose nivolumab. Our first patient was dosed in October 2022. In the HBV003 trial, we are enrolling CHB patients in three treatment groups as described in the table below. The study design directly builds from HBV002 to evaluate PD-1 inhibition timing, and includes criteria for discontinuation of standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NUC) to obtain information on the durability of the response in the absence of treatment.

AASLD Oral Presentation on Interim Data from the HBV003 Study

In November 2023, we announced interim data from HBV003 (NCT05343481) as of October 10, 2023, which was presented as an oral presentation at The AASLD – The Liver Meeting® 2023. Seventy-four out of a planned 120 virally suppressed CHB patients on stable NUC therapy had been enrolled in the trial and 57 had reached Day 113. VTP-300 in combination with nivolumab led to HBsAg declines in all treatment groups, particularly in participants with screening HBsAg levels ≤200 IU/mL.

>0.5 and >1 log drops were observed in all groups at Day 113 in 23% and 9% of participants, respectively. Participants with an HBsAg level of ≤200 IU/mL at screening were more likely to have >1 log HBsAg reductions (31%) compared to those with HBsAg levels >200 IU/mL at Day 1 (2%). Greater mean HBsAg log reductions were observed in Group 2 (ChAdOx-HBV Day 1; MVA-HBV and nivolumab Day 29 and Day 85) but insufficient data were available for a definitive conclusion. Seven participants had met the criteria for NUC discontinuation; three had discontinued and two had restarted NUC therapy. One remained off NUC therapy at the time of analysis, retaining undetectable HBsAg 16 weeks post-NUC discontinuation.





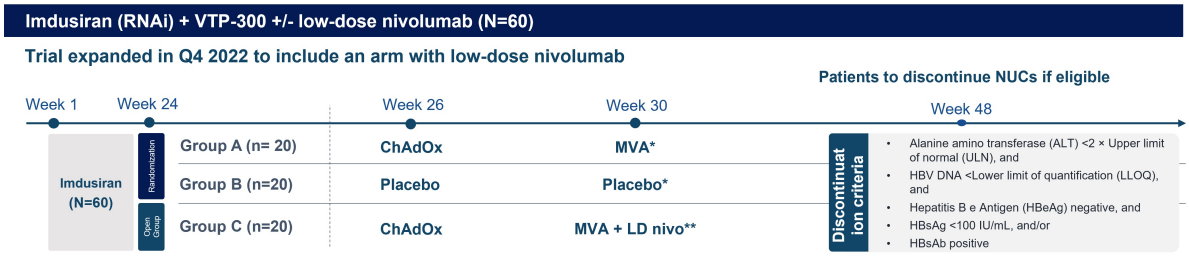
Day 113: 4 weeks after last MVA dose
Day 169: NUC discontinuation data
*Participants with screening HBsAg <200 IU/mL account for ~30% of those currently on the study.
Group 1
Group 2
Group 3

Preliminary safety data suggested that VTP-300 in combination with nivolumab was generally well tolerated, with no treatment-related SAEs observed or reported. Thyroid dysfunction was reported in seven participants attributed to nivolumab administration which had returned to normal in four patients.

We observed the highest rate of response in participants with screening HBsAg ≤200 IU/mL in the preliminary data. The HBV003 trial protocol has since been amended to include only participants with screening HBsAg ≤200 IU/mL and people with thyroid autoantibodies, family history of autoimmune thyroiditis, or abnormal thyroid levels have been excluded from trial eligibility to minimize the risk of thyroiditis and improve the overall risk/benefit ratio.

AB-729-202 – Ongoing Phase 2a in collaboration with Arbutus Biopharma Corporation

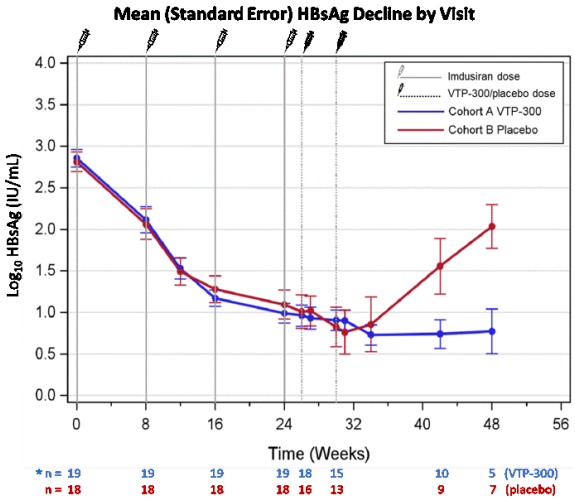
AB-729-202 is an ongoing Phase 2a clinical trial in collaboration with Arbutus Biopharma Corporation (NASDAQ: ABUS) to evaluate Arbutus' RNAi therapeutic candidate, imdusiran or AB-729, in combination with VTP-300 for the treatment of patients with chronic HBV infection. The clinical trial is designed to evaluate whether decreasing HBsAg levels with imdusiran prior to VTP-300 treatment, leads to a more sustained HBsAg reduction over treatment with imdusiran alone for CHB patients. Primary endpoints are evaluating the safety, antiviral activity and immunogenicity of VTP-300 administered after AB-729. The trial is designed to enroll 60 CHB patients as shown in the table below. All patients receive imdusiran (60mg every 8 weeks) plus NUC therapy for 24 weeks. At week 24, treatment with AB-729 stops and patients are randomized to receive either placebo (Group B) or VTP-300 (Groups A & C) at week 26 and 30 (and conditionally at week 38 if they experienced a >0.5log10 decline in HBsAg between week 26 and 34). Group C receives in addition low dose nivolumab together with their MVA dose. At week 48 all participants are evaluated for eligibility to either discontinue or remain on NUC therapy.



AASLD Poster Presentation on Interim Data from the AB-729-202 Study

On November 9, 2023, we announced interim data from the AB-729-202 trial (ACTRN12622000317796) as of October 13, 2023, which was presented as a late-breaking poster presentation at AASLD. The preliminary data included a subset of patients from groups A and B (28/40 patients) and available follow-up data to week 48 (12/40 patients) and showed that robust reductions of HBsAg were observed during the imdusiran treatment period (-1.86 log10 mean reduction from baseline after 24 weeks of treatment). This decline in HBsAg was comparable to the declines seen with imdusiran in other clinical trials conducted to date. 97% of the imdusiran treated patients (33/34) had HBsAg <100 IU/mL at the time of the first VTP-300/placebo dose. VTP-300 treatment appeared to contribute to the maintenance of low HBsAg levels in the early post-treatment period, as the mean HBsAg levels in the placebo group began to increase starting approximately 12 weeks after the last dose of imdusiran.

All VTP-300 treated patients, with available follow-up data to week 48, maintained HBsAg <100 IU/mL through week 48, 60% have maintained HBsAg <10 IU/mL, and all qualified to stop NUC therapy. Preliminary immunology data for those patients through to week 48 for which samples met the quality threshold and were available to be analyzed, suggested HBV-specific T cell IFN-γ production was enhanced in patients receiving imdusiran plus VTP-300 compared to placebo. The preliminary safety data from this trial demonstrated that imdusiran and VTP-300 were both generally well-tolerated. As of October 12, 2023, there were no serious adverse events, Grade 3 or 4 adverse events or treatment discontinuations.



We believe that the interim analysis from the HBV003 Phase 2b and the AB-729-202 Phase 2a studies suggest that VTP-300 could become part of a regimen that can attain a functional cure.

Future Development

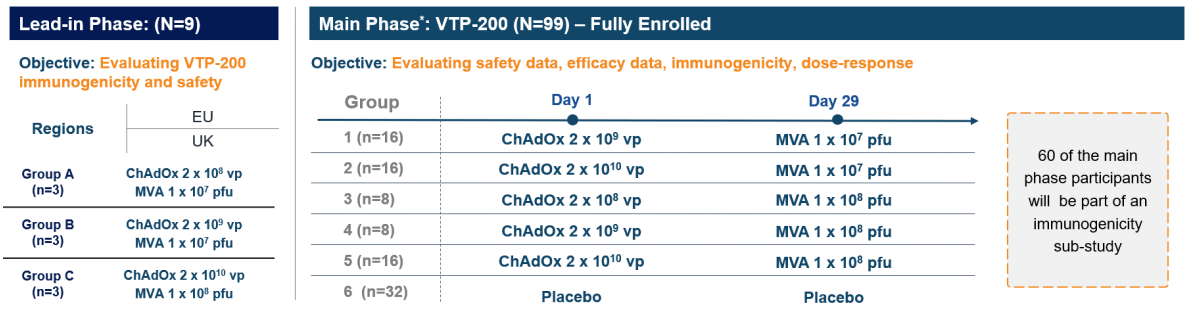
We expect to announce interim efficacy data from both the HBV003 study and the AB-729-202 combination study with Arbutus in the second quarter of 2024.

VTP-200: Developing a Potential Non-Invasive Treatment for Persistent High-Risk HPV

We are developing VTP-200 as a potential curative treatment for persistent hrHPV infection and associated pre-cancerous lesions. An estimated 291 million women worldwide are carriers of HPV DNA, which can progress to pre-cancerous cervical lesions if untreated. Enrollment in our Phase 1b/2 APOLLO (HPV001) clinical trial of VTP-200, (NCT04607850), was completed in December 2022 and the last visit of the final patient to the clinic was in January 2024. VTP-200 is composed of two viral vectors (ChAdOx1 and MVA), both encoding the same HPV antigens (*i.e.*,: E1, E2, E4, E5, E6, E7), designed to elicit an antigen-specific T cell immune response to HPV. Both vectors are administered intramuscularly and sequentially, one month apart.

Clinical Development

Our Phase 1b/2 APOLLO trial is designed to assess the safety and efficacy of VTP-200 and determine the optimal dosing regimen. We have enrolled a total of 108 healthy women with low grade lesions who had persistent hrHPV for at least six months. Patients with high-grade squamous intraepithelial lesions ("HSIL") or early cancer were excluded. The trial was run in the United Kingdom and the European Union. The diagram below provides an overview of the Phase 1b/2 clinical trial design.

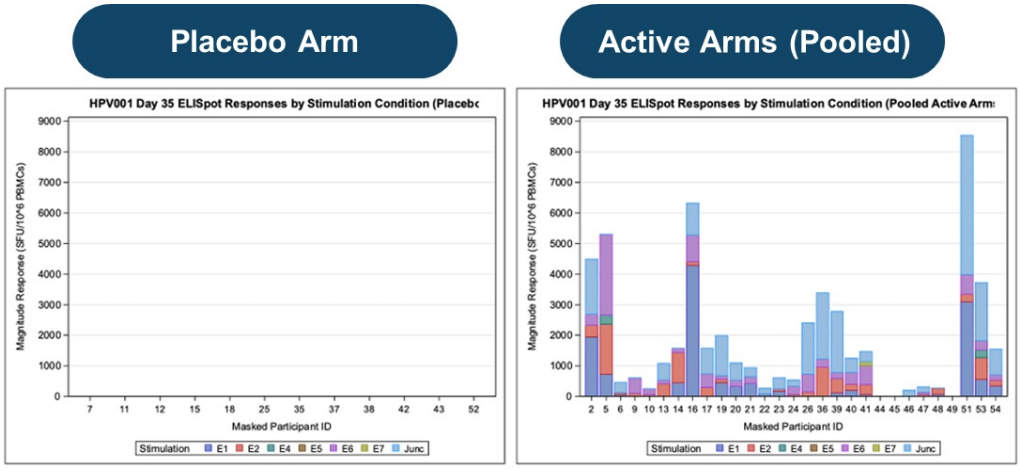


The primary objective of the trial is to evaluate the safety and tolerability of VTP-200. The secondary objectives of the trial are to determine the optimal dose and to evaluate the efficacy of HPV001 on the clearance of hrHPV infection and on the cervical intraepithelial neoplasia ("CIN").

We announced the topline initial interim safety and immunogenicity data of 58 patients in the main phase of the trial that reached their six-month evaluation timepoint in April 2023, and presented a poster at the 35th IPVC.

IPVC Poster Presentation on Interim Data from the APOLLO (HPV001) Trial

The poster presentation in April 2023 showed interim data for 42 women at Day 35, 7 days after the MVA dose of VTP-200, split by active treatment versus placebo. VTP-200 was generally well-tolerated and was administered with no product-related grade 3 unsolicited adverse events and no product-related SAEs. While the placebo group showed no antigen-specific T cell responses as measured by IFNg ELISpot, 26 of 29 women receiving varying doses of VTP-200 showed a response. The pooled active groups showed meaningful responses, with the average being greater than 1,000 spot-forming units per million peripheral blood mononuclear cells. Responses were strongest to the E1, E2 and E6 antigens. In addition, intracellular cytokine staining data from the active groups showed both CD4+ and CD8+ responses.



Future Development

We expect to announce full data from the APOLLO trial at the beginning of the second quarter of 2024. Following the HPV001 Phase 1b/2 clinical trial, if successful, we intend to review options to initiate further clinical trials of VTP-200, whether that is directly funded by the company or through external parties via partnerships, collaborations or grant funding. Our next trials would potentially be a Phase 2/3 trial in healthy women with early grade CIN (squamous intraepithelial lesions ("LSIL")) and additional trials in patients with more advanced CIN, vulval intraepithelial neoplasia, or VIN, and anal intraepithelial neoplasia ("AIN").

VTP-850: Our Next-Generation Immunotherapeutic Candidate for Prostate Cancer

We are developing VTP-850, our next-generation prostate cancer product candidate, to improve upon VTP-800. Both VTP-800 and VTP-850 are composed of two viral vectors (ChAdOx1 and MVA, both encoding the same antigen sequences); however, VTP-800 encodes only one antigen, 5T4, while VTP-850 encodes four antigens, PSA, PAP, STEAP1 and 5T4. We designed VTP-850 to induce a broader immune response by encoding multiple antigens to reduce the ability of cancer cells to evade the immune response by mutating or losing expression of any one antigen. The antigens we encode in VTP-850 are expressed in most prostate cancers but have little or no expression on healthy tissues other than prostate.

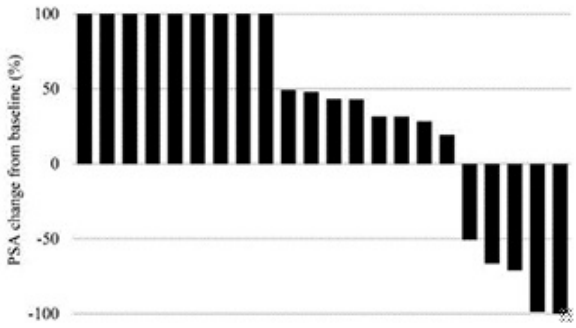
Clinical Development

Phase 1 (VANCE) and Phase 2 (ADVANCE) clinical trials of VTP-800 were sponsored and conducted by the University of Oxford in the United Kingdom. VTP-800 was generally well tolerated in both studies, with no treatment-related serious adverse events reported in VANCE or ADVANCE. One grade 3 adverse event was reported in ADVANCE (chest infection), which was deemed not related to study drug. There were no grade 4 or 5 treatment-related adverse events.

VANCE was a first-in-human, open label, randomized, Phase 1 clinical trial designed to evaluate the safety and immunological response of VTP-800 with and without low dose cyclophosphamide in localized prostate cancer. Thirty-nine patients with early stage localized, castration-sensitive prostate cancer were treated. Thirty-three patients received sequential administration of ChAdOx1-5T4 and MVA-5T4, one month apart, while six patients received MVA-5T4 alone. Patients received both regimens alone or with cyclophosphamide preconditioning. VTP-800 was generally well tolerated, with side effects of local injection site pain, fatigue, feverishness, and myalgia, which are consistent with those observed for these vectors in other clinical trials. There were no reported treatment-related serious adverse events. Data showed that 59% of participants had no detectable T cell response at baseline and developed a 5T4-specific T cell response de novo. Two patients had a baseline response, and the frequency of 5T4-specific T cells was observed to increase following administration. T cell infiltration into the resected prostate was also observed.

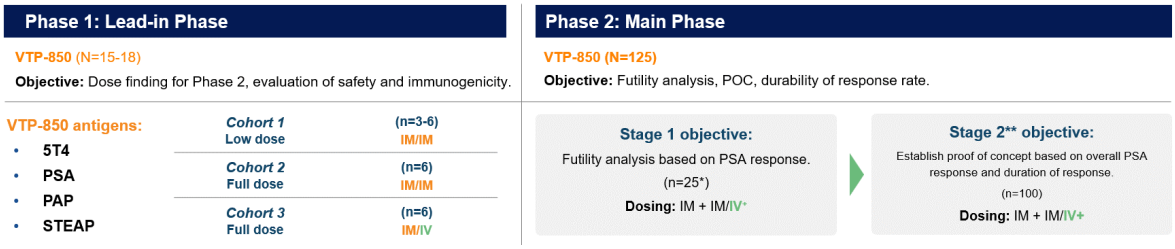
ADVANCE was an open-label, non-randomized Phase 2 clinical trial of VTP-800 in combination with anti-PD-1 checkpoint inhibitor, nivolumab, in 23 patients with metastatic prostate cancer. The primary objectives of the ADVANCE trial were to assess the safety and response rate of VTP-800 when administered in combination with nivolumab. The secondary objectives were to assess the immune responses in peripheral blood and to evaluate radiographic progression-free survival and overall survival. Patients received sequential administration of ChAdOx1-5T4 followed by MVA-5T4 one month later. Nivolumab was administered at months one, two and three. In most patients, VTP-800 was also given at months three and four. All patients received 2.5 x 10^10 vp of ChAdOx1-5T4, 2.0 x 10^10 pfu of MVA-5T4 and 480mg of nivolumab. VTP-800 was generally well tolerated. The most common treatment emergent adverse events were bone pain, injection site pain, muscle pain, stomatitis, and constipation, and most were mild and grade 1 or 2. The only grade 3 adverse event was a chest infection, which was not related to study drug. There were no grade 4 or 5 treatment-related adverse events. Data showed that three of eight patients with measurable disease had partial tumor responses. Five of 23, or 22%, of enrolled patients had greater than 50% reduction of prostate specific antigen ("PSA") at any timepoint.

PSA Reduction in Patients from ADVANCE Phase 2 Clinical Trial



In June 2023, we dosed our first patient with VTP-850 in PCA001, an ongoing Phase 1/2 clinical trial designed to determine the recommended Phase 2 regimen and evaluate the safety, efficacy, as measured by prostate-specific antigen (PSA) response, and induced T cell response of VTP-850 monotherapy in men with rising PSA after definitive local therapy for their disease (i.e., biochemical recurrence). PCA001 builds on the previous promising data from the University of Oxford Phase 1 VANCE and Phase 1/2 ADVANCE clinical trials of VTP-800.

The trial involves a Phase 1 lead-in dose finding stage testing 2 doses of ChAdOx-PCA with follow-up MVA-PCA dose administered either intramuscularly or intravenously to determine the Phase 2 recommended dose and route of administration, followed by a two-stage expansion Phase 2 to evaluate immunogenicity and anti-tumor activity of VTP-850. The diagram below provides an overview of the Phase 1/2 clinical trial design for PCA001.



The first phase of the trial is enrolling participants in the US.

Future Development

We expect to announce futility data from the lead-in phase of PCA001 in 2025, which will allow us to determine how we will progress with the PCA001 trial.

VTP-1000: Antigen-specific Tolerizing Immunotherapy Candidate for Celiac Disease

Patients with celiac disease have an unwanted immune response against gluten proteins and can become severely ill following exposure to gluten found in various cereal grains, especially wheat.

VTP-1000 is a tolerizing immunotherapy candidate that is designed to restore tolerance and suppress the unwanted immune response to gluten by restoring a beneficial T regulatory to T effector ratio. It is based on SNAP-TI and comprises multiple gluten antigens (representing the key antigens linked to celiac disease) and an immunomodulator co-delivered in nanoparticles of precise size and composition that are optimized to target the appropriate immune cells. The immunomodulator is a key component of VTP-1000 and is intended to drive Treg expansion and prevent proinflammatory responses.

Status and Future Development

VTP-1000 is currently in preclinical development. We submitted a filing to an Australian Research Ethics Committee and received approval for the study to proceed in the first quarter of 2024. This application process will now be completed with a Clinical Trial Notification to the Australian Regulatory Authorities. We also intend to file an IND with the FDA, and initiate the Phase 1 clinical trial in the second quarter of 2024. We intend for the trials to be run in Australia and/or the U.S.

We plan to include pharmacodynamic analysis as part of the Phase 1 study to provide an indication that the immunotherapy is inducing Tregs and/or decreasing Teffectors. Importantly, we also intend to include a controlled gluten challenge in the Phase 1 study to assess as an early signal whether VTP-1000 suppresses pathological response to gluten ingestion.

As VTP-1000 is our first product candidate directed towards the treatment of an inflammatory disease, we believe demonstration of Treg induction and/or suppression of unwanted immune responses to gluten would pave the way for other therapeutic candidates based on SNAP-TI, including those for alternative autoimmune indications.

VTP-600: Our Immunotherapeutic Candidate Targeting MAGE-A3 and NY-ESO1 Antigens

We are developing VTP-600, our immunotherapy candidate encoding the tumor-associated antigens MAGE-A3 and NY-ESO1, initially as a potential first line treatment of NSCLC in combination with standard of care treatment, chemotherapy and pembrolizumab. Lung cancer is the most common cancer diagnosis and cause of cancer death worldwide, with 85% of cases classified as NSCLC. About 25% to 30% of NSCLC patients have squamous histology and the remainder have non-squamous histology. MAGE-A3 is expressed in 48% of squamous NSCLC and 24% of non- squamous NSCLC. NY-ESO1 has been shown to have an expression rate of 27% across all NSCLC types. We initiated a first-in-human Phase 1/2a trial in the first quarter of 2022, in collaboration with Cancer Research UK ("CRUK"), which is sponsoring and funding this study.

VTP-500: A Prophylactic Vaccine Candidate to Prevent MERS

We are developing VTP-500 as a vaccine product candidate to prevent infection and subsequent disease caused by the MERS coronavirus. Although human-to-human transmission appears to be rare, MERS coronavirus has the potential to cause epidemics, infecting hundreds of thousands of people and causing significant morbidity and mortality in 34% of infected individuals. Clinical efficacy trials to prevent MERS are challenging to execute due to the sporadic nature of infection, however studies have demonstrated positive Phase 1 safety and immunogenicity data. In November 2021, VTP-500 results from the Saudi Arabia Phase 1 study were published in The Lancet Microbe. The Phase 1 data showed that VTP-500 was generally well tolerated in patients, and further development of the product candidate is planned by our non-exclusive licensee, the University of Oxford.

On December 21, 2023, we announced a project with the CEPI and the University of Oxford, aiming to fast-track the development of VTP-500 for the prevention of MERS. The project includes CEPI contributing funding of up to $34.8 million to Barinthus Bio, in addition to funds previously committed to the University of Oxford to develop and stockpile a ready reserve of emergency MERS vaccine candidate, VTP-500.

Due to VTP-500's potential in significantly addressing the unmet need for MERS, the EMA confirmed support for the program through PRIME designation in December 2023. The EMA's PRIME designation enhances support for the development of medicines that target an unmet medical need, offering early and proactive support to medicine developers to optimize the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications.

VTP-400: A Prophylactic Vaccine Candidate for Shingles

VTP-400 is our vaccine candidate in development to prevent shingles in adults aged 50 years and older. There are an estimated 140 million cases globally of shingles each year, which can result in significant post-infection pain, known as post-herpetic neuralgia, or even death. Our regional partner in China and Southeast Asia, CanSino, initiated a Phase 1 clinical trial of VTP-400 in Canada in November 2023 to evaluate both T cell-mediated and B cell-mediated immune responses resulting from VTP-400.

Vaxzevria: A Prophylactic Vaccine for the Prevention of COVID-19 Infection

The speed of the development of Vaxzevria (formerly VTP-900 and AZD1222) for the prevention of COVID-19, which entered the clinic within three months from initial antigen design, demonstrated that our ChAdOx platform positions us well to develop future products, if approved, rapidly. We co-invented VTP-900 in partnership with the University of Oxford's Jenner Institute, which we assigned to Oxford University Innovation (OUI) to facilitate the licensing of those rights by OUI to AstraZeneca. As of November 2022, more than 3 billion doses of Vaxzevria have been supplied across 180 countries globally. It has been estimated that over 6 million lives have been saved worldwide, and between 37.7 and 122.4 million hospitalizations were prevented. We are eligible to receive a share of royalties and other revenue received by OUI pursuant to its agreement with AstraZeneca for Vaxzevria. There is no guarantee that further payments will be received pursuant to the agreement in the future and, if such payments are made, that we will be notified of such payments in a timely manner.

Our History and Team

We were founded in May 2016 as a spin-out from a leading institution in the United Kingdom, the Jenner Institute at the University of Oxford, with the aim of developing and commercializing innovative immunotherapeutics and vaccines to treat and prevent infectious diseases and cancer. The ChAdOx1 and MVA platforms use technologies that were developed at the Jenner Institute over 15 years and through clinical trials involving thousands of participants. Our scientific founders, Professor Adrian Hill KBE, FRCP, FRS and Professor Dame Sarah Gilbert DBE, are leaders in the fields of infectious diseases, immunology, vaccine development and viral vectors. Professor Hill is the founding Director of the Jenner Institute at the University of Oxford and is also the Lakshmi Mittal and Family Professor of Vaccinology at the University of Oxford. Professor Gilbert is Professor of Vaccinology at the University of Oxford and leads programs on the development of vaccines against multiple emerging viral pathogens as well as research into vaccine manufacturing. She was the Oxford Project Lead for the Oxford/AstraZeneca COVID-19 vaccine project. Our strategic trajectory has grown with the acquisition of Avidea Technologies, Inc. ("Avidea") and the SNAP platform in 2021, expanding our product candidate pipeline and strengthening our scientific leadership in immunotherapies and the autoimmune space.

We have assembled a management team with extensive expertise in building and operating biopharmaceutical organizations that have discovered, developed and delivered innovative medicines to patients. Our management team has broad experience and successful track records in biopharmaceutical drug discovery, clinical development, regulatory affairs, manufacturing and commercialization, as well as in business, operations, and finance. Our management team's experience was gained at leading institutions that include Agalimmune, Altimmune, Ernst & Young, GenVec, Merck-Serono, Novartis and Roche.

Our board of directors has extensive expertise in the fields of science, business, and finance. Our scientific advisory board ("SAB") works with our management team in the planning and development of scientific, clinical, and research and development initiatives and strategies. The SAB is composed of scientific and clinical thought leaders in the fields of immunotherapy, vaccine development, immunology, infectious diseases, immunotolerance and oncology.

Our Collaboration and License Agreements

2016 License Agreement with OUI

In March 2016, we entered into a license agreement ("the 2016 OUI License Agreement") (as amended in January 2019 and April 2020), with OUI (previously known as Isis Innovation Limited) for the development and commercialization of vaccines for influenza, cancer (including therapeutic and prophylactic vaccines and including cancer associated with viral infections), varicella zoster and MERS. We refer to these areas together as the "Field."

Pursuant to the 2016 OUI License Agreement, OUI granted us a worldwide license under certain patent rights of OUI, including rights related to the use of ChAdOx1, ChAdOx2, adenoviral and MVA promoters and influenza product candidates, among other rights (the "2016 Licensed Technology") to develop, manufacture, use and commercialize licensed products. The rights are exclusive in certain fields and non-exclusive in others. Our license to certain patents and applications relating to certain adenoviral vectors encoding a pathogen or tumor antigen and certain pox virus expression systems is exclusive within the Field, non- exclusive in all other fields, and excludes veterinary applications. Our license to certain patents and applications relating to certain compositions and methods is exclusive in all fields and excludes veterinary applications. Our license for the use of the ChAdOx1 vector under certain patents and applications relating to certain simian adenovirus and hybrid adenoviral vectors is exclusive in the Field, non-exclusive in all other fields, and excludes veterinary applications (apart from MERS) and certain specified indications. Furthermore, our license with respect to the use of the ChAdOx2 vector under certain patents and applications relating to certain adenoviral vectors is exclusive in certain vaccine-related fields, non- exclusive in all other fields, and excludes all veterinary applications (apart from MERS) and certain other specified indications. In addition, we also obtained a license to certain clinical data generated from OUI projects and related confidential know-how to develop, manufacture, use and commercialize licensed products, and such license is exclusive in the Field, other than with respect to know-how related to ChAdOx2, which is licensed non-exclusively. The 2016 Licensed Technology is sublicensable subject to obtaining OUI's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) and inclusion in any sublicense agreement of restrictions on further sub-licensing, among other terms and conditions.

Pursuant to the 2016 OUI License Agreement, all intellectual property rights resulting from improvements made prior to the second anniversary of the agreement (i) to the licensed patent rights by the inventor belong to OUI, and (ii) to the 2016 Licensed Technology by us belong to us. OUI retains the right for the University of Oxford and any person who works or has worked on the 2016 Licensed Technology to use the 2016 Licensed Technology, as well as any improvements that we made to that technology during the first two years of the license, for education, research and limited clinical patient care. Furthermore, the University of Oxford may publish the 2016 Licensed Technology and those improvements without our consent provided that they have first given us advance notice and delayed the publication if necessary for us to obtain patent protection. In addition, OUI retains the right to grant academic and research licenses to any third parties under the 2016 Licensed Technology to encourage basic research for education and limited clinical patient care but may not grant licenses for commercialization of the 2016 Licensed Technology that is exclusively licensed to us, nor for development or marketing or products or services that are produced or supplied using the 2016 Licensed Technology.

Upon execution of the 2016 OUI License Agreement, we paid OUI a one-time upfront fee of £100,000. We are obligated to pay OUI a low single-digit royalty (that varies based on the indication) on net sales of any product or process produced by or using the 2016 Licensed Technology. If we sublicense the 2016 Licensed Technology, we will be required to pay OUI a mid-single-digit royalty on any royalties paid to us by the sublicensee and a high single-digit royalty on non-royalty sublicensing income (excluding milestone payment income overlapping with milestone payments paid to OUI and income used to fund research and development). In the event that the royalties (excluding the royalty on sublicensing income) owed to OUI do not amount to a specified minimum ranging from the mid five figures to low six figures based on the

license year in each year following March 2020, we must also pay OUI the difference between the royalty paid and the applicable minimum sum payable. In addition, we are required to pay OUI milestone payments of up to an aggregate of £14.8 million upon the achievement of specified development, regulatory and commercial milestones.

Unless earlier terminated, the 2016 OUI License Agreement will continue until the later of the expiration of the last claim of a licensed patent or 20 years from the date of the agreement. The last patent under the 2016 OUI License Agreement, if granted, is expected to expire in November 2039, without giving effect to any potential patent term extensions or patent term adjustments. Either party may terminate for the uncured breach of the other party. We may terminate the agreement at any time upon three months' prior written notice. OUI may terminate the agreement upon us filing for bankruptcy or in the event of liquidation or receivership proceedings, or upon 30 days' prior written notice upon the occurrence of certain other events. Upon termination of the 2016 OUI License Agreement, we are required to, among other things, grant to OUI an irrevocable, transferable, non-exclusive license to develop, make and use any improvements to the 2016 Licensed Technology which we made prior to the second anniversary of the date of the agreement.

2017 License Agreement with OUI (Barinthus Biotherapeutics (UK) Limited)

In September 2017, we entered into a further license agreement with OUI (the "2017 OUI License Agreement") for the development and commercialization of immunotherapies for HBV and HPV.

Pursuant to the 2017 OUI License Agreement, we acquired a worldwide license under certain additional patent rights of OUI, including rights related to the use of HBV immunotherapy product candidates, HPV immunotherapy product candidates and shark invariant chain polypeptides, among other rights (the "2017 Licensed Technology"), to develop, manufacture, use and commercialize licensed products. The rights are exclusive in some fields and non-exclusive in others. Our license to certain patents and applications relating to certain HBV and HPV vaccines is exclusive in all fields. Our license to certain patents and applications relating to molecular adjuvants is non-exclusive in the field of HBV. Our license to certain patents and applications relating to certain simian and hybrid adenoviral vectors is exclusive in the fields of HPV associated diseases and HBV. Further, our license to certain patents and applications relating to certain other vectors is exclusive in the field of HBV.

Pursuant to the 2017 OUI License Agreement, we also obtained a non-exclusive license under related know- how to develop, manufacture, use and commercialize licensed products in all fields. The 2017 Licensed Technology is sublicensable subject to obtaining OUI's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) and inclusion in any sublicense agreement of restrictions on further sub-licensing, among other terms.

Pursuant to the 2017 OUI License Agreement, all intellectual property rights resulting from improvements made prior to the second anniversary of the agreement (i) to the licensed patent rights by the inventor belong to OUI, and (ii) to the 2017 Licensed Technology by us belong to us. OUI retains the right for the University of Oxford and any person who works or has worked on the 2017 Licensed Technology to use the 2017 Licensed Technology, as well as any improvements that we made to that technology during the first two years of the license, for education, research and limited clinical patient care. Furthermore, the University of Oxford may publish the 2017 Licensed Technology and those improvements without our consent provided that they have first given us advance notice and delayed the publication if necessary for us to obtain patent protection. In addition, OUI retains the right to grant academic and research licenses to any third parties under the 2017 Licensed Technology to encourage basic research for education and limited clinical patient care but may not grant licenses for commercialization of the 2017 Licensed Technology that is exclusively licensed to us, nor for development or marketing or products or services that are produced or supplied using the 2017 Licensed Technology.

Upon execution of the 2017 OUI License Agreement, we paid OUI a one-time upfront fee of £50,000. We are obligated to pay OUI a low single-digit royalty (that varies based on the indication) on net sales made by us or our sublicensees of any product or process produced by or using the 2017 Licensed Technology. In the event that such sales royalties owed to OUI do not amount to a specified minimum ranging from the mid five figures to low six figures based on the license year in each year following September 2020, we must also pay OUI the difference between the royalty paid and the applicable minimum sum payable. If we sublicense the 2017 Licensed Technology, we will be required to pay OUI a mid-single-digit royalty on non- royalty sublicensing income (excluding milestone payment income overlapping with milestone payments paid to OUI and income used to fund research and development). In addition, we are required to pay OUI milestone payments of up to an aggregate of £9.85 million upon the achievement of specified development, regulatory and commercial milestones.

Unless earlier terminated, the 2017 OUI License Agreement will continue until the later of the expiration of the last claim of a licensed patent or 20 years from the date of the agreement. The last patent under the 2017 OUI License Agreement, if

granted, is expected to expire in August 2038, without giving effect to any potential patent term extensions or patent term adjustments. Either party may terminate for the uncured breach of the other party. We may terminate the agreement at any time upon three months' prior written notice. OUI may terminate the agreement upon us filing for bankruptcy or in the event of liquidation or receivership proceedings, or upon 30 days' prior written notice upon the occurrence of certain other events. Upon termination of the 2017 OUI License Agreement, we are required to, among other things, grant to OUI an irrevocable, transferable, non-exclusive license to develop, make and use any improvements to the 2017 Licensed Technology which we made prior to the second anniversary of the date of the agreement.

2017 License Agreement with OUI (Barinthus Biotherapeutics North America, Inc.)

In March 2017, Avidea entered into a license agreement with OUI (the "March 2017 OUI License Agreement") for the development and commercialization of products comprising thermo-responsive adjuvant scaffolds for use in all indications. All of Avidea's rights, duties and obligations under this March 2017 OUI License Agreement were assumed by Barinthus Bio NA following the acquisition of Avidea by Barinthus Biotherapeutics plc on December 10, 2021.

Pursuant to the March 2017 OUI License Agreement, OUI granted us a worldwide license under certain patent rights of OUI related to the use of thermo-responsive adjuvant scaffolds, among other rights (the "March 2017 Licensed Technology"), to develop, manufacture, use and commercialize licensed products. The license to patent rights are exclusive in all fields, and the license to know how is non-exclusive. The March 2017 Licensed Technology is sublicensable subject to obtaining OUI's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) and inclusion in any sublicense agreement of restrictions on further sub-licensing, among other terms and conditions.

Pursuant to the March 2017 OUI License Agreement, all intellectual property rights resulting from improvements made by us belong to us. OUI retains the right for the University of Oxford, the U.S. National Institutes of Allergy and Infectious Diseases ("NIAID"), the Institute of Macromolecular Chemistry of the Czech Republic ("IMC") and any person who works or has worked on the March 2017 Licensed Technology to use the March 2017 Licensed Technology and any licensee improvements for non-commercial use. Furthermore, the University of Oxford, NIAID or IMC may publish the March 2017 Licensed Technology and those improvements without our consent provided that they have first given us advance notice and delayed the publication if necessary for us to obtain patent protection. In addition, OUI retains the right to grant academic and research licenses to any third parties under the March 2017 Licensed Technology to encourage basic research for education and limited clinical patient care but may not grant licenses for commercialization of the March 2017 Licensed Technology that is exclusively licensed to us, nor for development or marketing or products or services that are produced or supplied using the March 2017 Licensed Technology.

Upon execution of the March 2017 OUI License Agreement, we paid OUI a one-time upfront fee of £3,000. We are obligated to pay OUI a low single-digit royalty on net sales of any product or process produced by or using the March 2017 Licensed Technology. If we sublicense the March 2017 Licensed Technology, we will be required to pay OUI a mid-single-digit royalty on any non-royalty sublicensing income. As of March 14, 2024, OUI has not been paid any royalties under the 2017 OUI License Agreement. In the event that the royalties (excluding the royalty on sublicensing income) owed to OUI do not amount to a specified minimum ranging from the low to mid five figures based on the license year in each year following March 2020, the licensee must also pay OUI the difference between the royalty paid and the applicable minimum sum payable. For 2023, £55 thousand was paid to OUI, being the difference between royalties paid and the minimum sum payable. In addition, we are required to pay OUI milestone payments of up to an aggregate of £2.43 million upon the achievement of specified development, regulatory and commercial milestones.

Unless earlier terminated, the 2017 OUI License Agreement will continue for as long as anything within the definition of the licensed patent remains in effect or 20 years from the date of the agreement. The patent licensed under the March 2017 OUI License Agreement, if granted, is expected to expire in October 2035, without giving effect to any potential patent term extensions or patent term adjustments. Either party may terminate for the uncured breach of the other party. We may terminate the agreement at any time upon six months' prior written notice. OUI may terminate the agreement upon us filing for bankruptcy or in the event of liquidation or receivership proceedings, or upon 30 days' prior written notice upon the occurrence of certain other events. Upon termination of the March 2017 OUI License Agreement, we are required to, among other things, grant to OUI an irrevocable, transferable, non-exclusive license to develop, make and use any improvements to the March 2017 Licensed Technology which we made prior to the second anniversary of the date of the agreement.

2017 Cooperative Research and Development Agreement with NIH (Barinthus Biotherapeutics NA)

In February 2017, Avidea entered into a Cooperative Research and Development Agreement ("CRADA") with the U.S. National Institutes of Health ("NIH") to carry out collaborative research for the evaluation of Avidea's synthetic, polymer-based vaccine technology, "Immunotherapeutic Nanoscaffolds" (IMNs) for infectious disease prevention and cancer treatment in animal models. Under this CRADA Avidea committed to providing scientific staff together with materials for use in experiments to evaluate their performance in various animal models of infectious disease and cancer. Under this CRADA NIH committed to evaluating Avidea materials in animal models and to perform comprehensive immune analysis. No funding was exchanged under this CRADA.

In October 2019, the CRADA was amended ("1st CRADA Amendment") to expand the scope of the collaborative research to evaluate the therapeutic potential of Avidea's polymer-based vaccine technology, "Immunotherapeutic Nanoscaffolds" (IMNs), including Star polymers and self-assembling nanoparticles based on amphiphilic polymers (SNAP), in preclinical animal models for cancer, infectious and inflammatory diseases. Under this 1st CRADA Amendment Avidea committed to increase its scientific staffing contribution and to provide funding of $22,500 by October 15, 2019 and a further $62,500 by October 15, 2020.

In October 2020, the CRADA was further amended ("2nd CRADA Amendment") to defer payment of Avidea's October 2020 funding contribution of the 1st CRADA Amendment to April 15, 2021.

In May 2021, the CRADA was further amended ("3rd CRADA Amendment") to extend the term of the CRADA by 2 additional years and to defer payment of Avidea's April 2021 funding contribution of the 2nd CRADA Amendment to October 31, 2021.

In November 2021, the CRADA was further amended ("4th CRADA Amendment") to expand the scope of the collaborative research to evaluate the therapeutic potential of Avidea's polymer-based vaccine technology, "Immunotherapeutic Nanoscaffolds" (IMNs), including Star polymers and self-assembling nanoparticles based on amphiphilic polymers (SNAP), in preclinical animal models for cancer, infectious and inflammatory diseases (e.g., induction of suppression and/or tolerance for treating or preventing allergies, autoimmunity, and transplant rejection).

In October 2022, the CRADA was further amended ("5th CRADA Amendment") to acknowledge that all of Avidea's rights, duties and obligations under the CRADA were assumed by Barinthus Bio NA following the acquisition of Avidea by Barinthus Biotherapeutics plc on December 10, 2021.

Under the CRADA as amended we own inventions made solely by our staff, and we have an option to enter an exclusive or nonexclusive license to any inventions made solely by NIH staff or made jointly by our staff and NIH under the CRADA (the "CRADA Licensed Technology"). NIH retains rights on behalf of the U.S. Government in the CRADA Licensed Technology as required by statute and NIH policy. We have an option to exclusively license any further inventions made under the CRADA.

Unless earlier terminated, the CRADA will expire on February 23, 2025. The parties may terminate the CRADA by mutual consent, or either party may unilaterally terminate the CRADA at any time upon 60 days' prior written notice.

2019 License Agreement with NIH (Barinthus Bio NA)

In September 2019, Avidea entered into a license agreement with the NIH for the commercial development of products and processes for the prevention and/or treatment of cancer and infectious diseases within the scope of Licensed Patent rights that had been developed under a CRADA entered into by NIH and Avidea in February 2017 and amended in March 2019, December 2020, May 2021, November 2021 and October 2022. We are co-owners of all the Licensed Patents under this agreement, and we have an option to exclusively license NIH rights in all inventions made under this CRADA.

All of Avidea's rights, duties and obligations under the 2019 License Agreement with NIH were assumed by Barinthus Bio NA following the acquisition of Avidea by Barinthus Biotherapeutics plc on December 10, 2021. The 2019 License Agreement with NIH was amended in September 2022 to note Barinthus Bio NA's rights, duties and obligations and also to include newly filed patents developed under the 2017 CRADA as amended.

Pursuant to the 2019 License Agreement with NIH, NIH granted us a worldwide exclusive license under certain patent rights co-owned by us and NIH related to the use of the SNAP platform, among other rights (the "2019 Licensed Technology"), to develop, manufacture, use and commercialize licensed products. The license to patent rights are exclusive in all fields. The 2019 Licensed Technology is sublicensable subject to obtaining NIH's prior written consent (such consent not to be unreasonably withheld) and inclusion of other customary provisions. NIH retains rights on behalf of the U.S. Government in the 2019 Licensed Technology as required by statute and NIH policy.

Upon execution of the 2019 License Agreement with NIH, we paid NIH a one-time upfront fee of $20,000. We are obligated to pay NIH a low single-digit royalty on net sales of any product or process produced by or using the 2019 Licensed Technology. If we sublicense the 2019 Licensed Technology, we will be required to pay NIH a low-single-digit royalty on any non-royalty sublicensing income. As of March 23, 2023, NIH has not been paid any royalties under the 2019 License Agreement with NIH. In the event that the royalties (excluding the royalty on sublicensing income) owed to NIH do not amount to a specified minimum ranging from the low to mid five figures based on the license year in each year following September 2019, the licensee must also pay NIH the difference between the royalty paid and the applicable minimum royalty payment. For 2023, $10 thousand was paid to NIH, being the difference between royalties paid and the minimum sum payable. In addition, we are required to pay NIH milestone payments of up to an aggregate of $3.24 million upon the achievement of specified development, regulatory and commercial milestones for each Licensed Product.

Unless earlier terminated, the 2019 License Agreement with NIH will continue until expiry of the last to expire Licensed Patent. 5 patent families licensed under the 2019 License Agreement with NIH that cover the SNAP platform, if granted, are expected to expire in April 2038, in May 2039, in October 2039, in February 2042 and in June 2042, without giving effect to any potential patent term extensions or patent term adjustments. Two patent families licensed under the 2019 License Agreement with NIH that cover the syntholytic platform, if granted, are expected to expire in April 2040 and in October 2041, without giving effect to any potential patent term extensions or patent term adjustments. Either party may terminate for the uncured breach of the other party. We may terminate the agreement at any time upon 60 days' prior written notice. NIH may terminate the agreement upon the occurrence of certain events.

2017 Research Collaboration Agreement ("RCA") with Institute of Macromolecular Chemistry, Prague (Barinthus Biotherapeutics NA)

In September 2017, Avidea entered into a RCA with the IMC to carry out collaborative research for the development of polymer-based immunotherapies for cancer treatment, HIV prevention and recombinant protein delivery. Under this RCA Avidea committed to providing bioactive molecules and to developing and deploying animal models for evaluating immunotherapies. Under this RCA IMC committed to synthesizing various polymers and bioactive molecules and to linking such polymers and bioactive molecules for use in experiments to characterize their physicochemical properties. No funding was exchanged under this RCA. All of Avidea's rights, duties and obligations under the 2017 RCA with IMC were assumed by Barinthus Bio NA following the acquisition of Avidea by Barinthus Biotherapeutics plc on December 10, 2021.

Under the RCA we own inventions made solely by our staff, and we have an exclusive option to enter an exclusive or nonexclusive license to any inventions made solely by IMC staff or made jointly by our staff and IMC under the RCA. We have secured exclusive rights in two patent families that we co-own with IMC under the 2022 License Agreement with IMC as described below. We have an exclusive option to exclusively license any further inventions made under the RCA. The RCA expired on September 18, 2022. Our rights in inventions made under the RCA survive expiry of the RCA.

2022 License Agreement with IMC (Barinthus Bio NA)

In April 2022, we entered into an exclusive license agreement with the IMC for the exploitation, development and commercialization of technologies and products within the scope of Licensed Patent rights that had been developed under a RCA entered into by IMC and Avidea in September 2017. We are co-owners of all the Licensed Patents under this agreement, and we have an option to exclusively license IMC rights in all inventions made under this RCA.

Pursuant to the 2022 License Agreement with IMC, IMC granted us a worldwide, exclusive license under certain patent rights co-owned by us and IMC related to the use of polymer-based immunotherapies, among other rights (the "2022 Licensed Technology"), to develop, manufacture, use and commercialize licensed products. The license to patent rights is exclusive in all fields. The 2022 Licensed Technology is sublicensable.

We are obligated to pay IMC a low single-digit royalty on net sales of any product or process produced by or using the 2022 Licensed Technology. If we sublicense the 2022 Licensed Technology, we will be required to pay IMC a low-single-digit royalty on any non-royalty sublicensing income. As of March 14, 2024, IMC has not been paid any royalties under the 2022 License Agreement with IMC. In addition, we are required to pay IMC milestone payments of up to an aggregate of $820,000 upon the achievement of specified development, regulatory and commercial milestones for each Licensed Product.

Unless earlier terminated, the 2022 License Agreement with IMC will continue until expiry of the last valid claim of the Licensed Patents. One patent family licensed under the 2022 License Agreement with IMC that covers the SNAP platform, if granted, is expected to expire in September 2041, without giving effect to any potential patent term extensions or patent term adjustments. One patent family licensed under the 2022 License Agreement with IMC that covers the syntholytic platform, if granted, is expected to expire in April 2040, without giving effect to any potential patent term extensions or patent term adjustments. Either party may terminate for the uncured breach or insolvency of the other party. We may terminate the agreement at any time upon 3 months' prior written notice.

2019 License Agreement with OUI

In January 2019, we entered into an additional license agreement with OUI (the "2019 OUI License Agreement"). Pursuant to the 2019 OUI License Agreement, OUI granted us a worldwide, license under an additional patent application of OUI related to the rapid production of recombinant adenovirus constructs, to be used as personalized cancer vaccines or emerging pathogen vaccines, and related confidential know-how (the "2019 OUI Licensed Technology") to develop, manufacture, use and commercialize licensed products. The license is exclusive in the field of personalized cancer vaccines for therapeutic use in humans, non- exclusive in in all other fields and excludes veterinary applications (apart from MERS) and certain other specified indications. The license is sublicensable subject to obtaining OUI's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) and inclusion in any sublicense agreement of restrictions on further sub-licensing, among other terms.

Pursuant to the 2019 OUI License Agreement, all intellectual property rights resulting from improvements made prior to the second anniversary of the agreement (i) to the licensed patent rights by the inventor belong to OUI, and (ii) to the 2019 OUI Licensed Technology by us belong to us. OUI retains the right for the University of Oxford and any person who works or has worked on the 2019 OUI Licensed Technology to use the 2019 OUI Licensed Technology, as well as any improvements that we make to that technology during the first two years of the license, for education, research and limited clinical patient care. Furthermore, the University of Oxford may publish the 2019 OUI Licensed Technology and those improvements without our consent provided that they have first given us advance notice and delayed the publication if necessary for us to obtain patent protection. In addition, OUI retains the right to grant academic and research licenses to any third parties under the 2019 OUI Licensed Technology to encourage basic research for education and limited clinical patient care but may not grant licenses for commercialization of the 2019 OUI Licensed Technology that is exclusively licensed to us, nor for development or marketing or products or services that are produced or supplied using the 2019 OUI Licensed Technology.

Upon execution of the 2019 OUI License Agreement, we paid OUI a nominal upfront fee. We are required to pay OUI a variable low single-digit royalty on net sales of products we develop using the 2019 OUI Licensed Technology, which varies depending on whether the sales are within or outside of the field of personalized cancer vaccines for therapeutic use in humans. While we are continuing to develop the 2019 OUI Licensed Technology, no product candidate that we are currently developing incorporates this technology. If we sublicense the 2019 OUI Licensed Technology, we will be required to pay OUI a 15% or 7% royalty (for licensed products within the field and outside the field respectively) on any royalties paid to us by the sublicensee and 15% or 7.5% of non-royalty sublicensing income (for sublicenses granted before or after three years after the date of the agreement respectively). In the event that the aforementioned royalties (excluding the royalty on non-royalty sublicensing income) owed to OUI do not amount to a specified minimum ranging from the mid five figures to low six figures based on the license year in each year following January 2022, we must also pay to OUI the difference between the royalty paid and the applicable minimum sum payable. In addition, if we develop at least two products in the Field, we are required to pay OUI milestone payments of up to an aggregate of £1.9 million upon the achievement of specified development, regulatory and commercial milestones.

Subject to earlier termination, the 2019 OUI License Agreement will continue until the later of the expiration of the last claim of a licensed patent or 20 years from the date of the agreement. The last patent under the 2019 OUI License Agreement, if granted, is expected to expire in August 2039, without giving effect to any potential patent term extensions or patent term adjustments. Either party may terminate for the uncured breach of the other party. At any time after the third anniversary of the agreement, we may terminate the agreement at any time upon three months' prior written notice. OUI

may terminate the agreement upon us filing for bankruptcy or in the event of liquidation or receivership proceedings, or upon 30 days' prior written notice upon the occurrence of certain other events. Upon termination of the 2019 OUI License Agreement, we are required to, among other things, grant to OUI an irrevocable, transferable, non- exclusive license to develop, make and use any improvements (to the technology embodied by the relevant licensed patent and know-how) which we made prior to the second anniversary of the date of the agreement.

2018 License Agreement with OUI and Oxford

In September 2018, we entered into a license agreement (the "2018 License Agreement") with The Chancellor, Masters and Scholars of the University of Oxford, or Oxford, and OUI. Pursuant to the 2016 OUI License Agreement, OUI had granted us certain exclusive rights related to the Licensed Technology, as defined in the 2016 OUI License Agreement, in the field of diagnosis, prevention and treatment of MERS. The 2018 License Agreement enables Oxford to grant a further sublicense to CEPI in the field of MERS (the "Field") and to enable Oxford to conduct related activities.

Pursuant to the 2018 License Agreement, we agreed to grant to Oxford a fully-paid-up, worldwide, non- exclusive license under the Licensed Technology, as defined in the 2016 OUI License Agreement, and developments and improvements to such technology controlled by us during the term of the 2016 OUI License Agreement (the "MERS Technology") in the Field solely for the purpose of enabling Oxford to develop any product or process which uses or is within the scope of the MERS Technology ("Licensed Product"). This license includes the right to generate investigational stockpiles, but excludes any commercial use or sale of Licensed Products and is sublicensable by Oxford solely to its collaborators under the framework agreement entered into on or about the same date as the 2018 License Agreement between Oxford, CEPI and Janssen Vaccines & Prevention B.V. Furthermore, we agreed that the rights retained by OUI under the 2016 OUI License Agreement include the right to allow Oxford to use the MERS Technology to carry out research activities (including in collaboration with other parties) up to and including the performance of Phase 1/2 clinical trials and related activities, and the generation of Licensed Product for research use (but excluding any commercial use or sale of such Licensed Product). We have been informed by Oxford that Janssen Vaccines & Prevention B.V. is no longer a party to that framework agreement.

In addition, we agreed to grant to Oxford a fully-paid-up, worldwide, non-exclusive license under the MERS Technology in the Field solely for the purpose of enabling Oxford to grant a sublicense to CEPI in order to address (i) circumstances in which CEPI determines there to be a heightened need for the Licensed Product and that steps should be taken to prepare for such need; and/or (ii) material increases in the number of cases of people infected with MERS in particular geographical areas that are declared a public health emergency. Oxford is permitted to grant CEPI a fully-paid-up, worldwide, non-exclusive sublicense under the MERS Technology to develop, manufacture and commercialize the Licensed Product in the Field anywhere in the world, provided that all end users (i) are in a relevant affected territory, or (ii) are healthcare workers going to an affected territory under the direction of one or more governments or recognized not-for-profit organizations, or Public Sector Agencies, in order to help address a public healthcare issue. However, the sublicense must exclude the right for CEPI to (i) apply for or obtain any marketing approval or conduct any post-marketing activities, (ii) sell Licensed Product other than to Public Sector Agencies on a "cost plus" basis, where "cost plus" means the cost of manufacturing and supply plus a margin of 10% percent on such cost, or (iii) further sublicense its rights other than to its affiliates and/or to Public Sector Agencies and their appointees for the sole purpose of accelerating epidemic preparedness for public health applications.

Pursuant to the 2018 License Agreement, OUI agreed that, notwithstanding our payment obligations under the 2016 OUI License Agreement, we are not obligated to make any payment to OUI in connection with the 2018 License Agreement.

On February 2, 2024, following the entry by Barinthus Biotherapeutics (UK) Limited and Oxford into a funding agreement with CEPI (described below), Oxford, OUI and Barinthus Biotherapeutics (UK) Limited entered into a termination agreement, pursuant to which the 2018 License Agreement was terminated other than obligations that have accrued prior to the termination or were expressly intended to survive, including certain confidentiality obligations.

OUI License Agreement Amendment

In April 2020, we entered into an amendment, assignment and revenue share agreement (the "OUI License Agreement Amendment") with OUI to amend the 2016 OUI License Agreement. Pursuant to the 2016 OUI License Agreement and among other rights and obligations, OUI granted to us a non-exclusive license to certain patent applications relating to its ChAdOx1 and ChAdOx2 vaccine vectors and the adenovirus long promoter for use in certain fields, or the Field, including

SARS-CoV2, which is the virus known to cause COVID 19. The OUI License Agreement Amendment was entered into to enable a single exclusive license agreement for a COVID 19 vaccine co-developed by us and the University of Oxford's Jenner Institute to be negotiated with a suitable pharmaceutical partner.

Under the OUI License Agreement Amendment, we agreed to exclude SARS-CoV2 from the Field and to cease use of the ChAdOx1 vector, ChAdOx2 vector and the adenovirus long promoter in SARS-CoV2. In addition, we assigned to OUI our rights to a jointly owned U.K. patent application relating to the composition of matter related to a ChAdOx1 vector-based or a ChAdOx2 vector-based vaccine to prevent COVID 19 (the "Assigned Patent Application"), as well as certain other intellectual property rights related to any ChAdOx1 vector-based or ChAdOx2 vector-based COVID 19 vaccine covered by the Assigned Patent Application and its manufacture, including rights to the variations, improvements and modifications thereof, whether existing at or arising after the date of the OUI License Agreement Amendment. In consideration of the rights granted by us, OUI agreed to pay us approximately 24% of payments, including royalties and milestones, received by OUI in connection with the commercialization of any ChAdOx1 vector-based or ChAdOx2 vector-based vaccine in the field of SARS-CoV2 covered by or disclosed in the Assigned Patent Application. The last patent under the OUI License Agreement Amendment, which is owned by OUI, if granted, is expected to expire in March 2041, without giving effect to any potential patent term extensions or patent term adjustments.

Impact of OUI's Agreement with AstraZeneca

OUI has entered into an exclusive research collaboration and worldwide license agreement (the "AstraZeneca License Agreement") with AstraZeneca. The following description of the impact of AstraZeneca License Agreement with respect to our rights under the OUI License Agreement Amendment is based solely on an extract of the AstraZeneca License Agreement provided by the parties to that agreement. We are not a party to the AstraZeneca License Agreement and do not have access to a copy of that agreement to verify the accuracy of such extract. In addition, no party to the AstraZeneca License Agreement has confirmed that there are no material terms in that agreement that are not included in the description below that could adversely impact the economic and other terms of the AstraZeneca License Agreement described below. Moreover, there can be no assurance that the AstraZeneca License Agreement is an enforceable agreement, that the parties thereto will comply with their obligations under that agreement (including any obligations of AstraZeneca to make milestone or royalty payments to OUI), or that the terms of that agreement (including royalty rates and other economic terms) will not be modified by the parties in the future.

The AstraZeneca License Agreement allows AstraZeneca to pursue, among other things, the commercialization of a vaccine product candidate for the prevention of COVID 19 containing one or more of the ChAdOx1 or ChAdOx2 vectors or their derivatives. AstraZeneca announced that as of January 13, 2022, the vaccine had been granted a conditional marketing authorization or emergency use in more than 90 countries. It also has Emergency Use Listing from the World Health Organization, which accelerates the pathway to access in up to 144 countries through the COVAX Facility.

Pursuant to the OUI License Agreement Amendment, we received $2.4 million in July 2020 as our share of the upfront fee paid by AstraZeneca. We are also entitled to receive a share of certain regulatory and sales milestones and royalties on net sales of Vaxzevria, as well as a portion of any sublicensing income payable by AstraZeneca. Our share of the royalties on net sales of Vaxzevria is approximately 1.4%.

Our understanding is that we were not entitled to receive any royalties or payments from sub-licensees from the commercialization of Vaxzevria until after the pandemic period, which was defined as a period that would end on July 1, 2021 (or such later date when AstraZeneca, in good faith, determines that the COVID-19 pandemic is over). However, our understanding is that we would be entitled to receive our share of any regulatory milestone payments during the pandemic period.

The royalty term for net sales of Vaxzevria commenced in 2022 and will continue, on a country-by-country basis, until the later of (i) the date upon which the vaccine is no longer subject to patent protection in such country, (ii) expiration of regulatory exclusivity for the vaccine in such country or (iii) ten years from the first commercial sale of the vaccine in such country.

Master Collaboration Agreement with CanSino Biologics Inc.

In September 2018, we entered into a master collaboration agreement (the "CanSino Agreement") with CanSino Biologics Inc. ("CanSino"). The CanSino Agreement provides a framework under which we can agree with CanSino (in separate project agreements) the details of one or more collaborative projects for the development and commercialization of certain

products, and carry out those projects under the terms of the CanSino Agreement and the respective project agreements in our respective territories. Under the CanSino Agreement, the CanSino Territory includes China (including Taiwan, Hong Kong and Macao), Malaysia, Thailand, Myanmar, Indonesia, Laos, Vietnam, and the Philippines, while our territory (the "Barinthus Bio Territory") includes the rest of the world.

Under the CanSino Agreement, each party grants to the other party a royalty-free, non-exclusive license to use its relevant background intellectual property rights ("Background IPR") solely to perform the project in the other party's territory, together with a right to sub-license to any agreed-upon subcontractor performing services for and on behalf of the other party. For any collaborative project, each party is obliged to provide to the other party all applicable materials specified in that project agreement and to grant to the other party a non-exclusive license to use such materials solely for the purpose of that project. In addition, each party grants to the other party a non-exclusive license to use its Background IPR and an exclusive license to any new intellectual property created in the course of activities performed by such party in relation to a project or otherwise under the CanSino Agreement ("New IPR") to the extent necessary to commercialize and exploit collaboration products in the other party's territory. Such commercialization licenses are sublicensable (without further right to sub-license) and subject to the payment of royalties and milestones as set out in the relevant project agreement. CanSino is permitted to commercialize such products only in the CanSino Territory and we are entitled to commercialize such products in the Barinthus Bio Territory. Both parties are under obligations to use commercially reasonable efforts to maximize sales of products that are the subject of collaboration.

During the term of any project agreement entered into as contemplated by the CanSino Agreement and for three months thereafter, neither party is permitted to enter into discussions, collaborations or similar arrangements with any third parties regarding matters or products which are materially the same as set forth in the project agreement or related to the project that is the subject of the project agreement, unless such party reasonably believes such an arrangement with such third party would not be detrimental to the relevant project or project arrangement. Furthermore, unless agreed otherwise in a project agreement, for any product which we collaboratively develop, CanSino has the exclusive and sub-licensable right to manufacture and supply all master virus seed and clinical adenoviral material necessary for the development and sale of any products by either party in their respective territories. CanSino will supply any such material to be used by us for the manufacture of products to be sold by us (or our sub-licensees) at the price of 15% to 30% over cost of goods sold ("COGS"). COGS is equal to the reasonable COGS for equivalent material manufactured by CanSino or its subcontractors for sale by CanSino or its sub-licensees.

Unless agreed otherwise in a project agreement: (i) any improvements of a party's Background IPR will be owned by the party with rights to such Background IPR, and will be treated as Background IPR; and (ii) New IPR will be owned by one or both parties in accordance with the respective inventive contribution of each party as determined by the principles of United Kingdom patent law. Where any New IPR is wholly owned by a party, that party is obliged to endeavor to file patent applications to the extent required to provide reasonable protection for the relevant product. Where any New IPR is jointly owned by the parties, we are obliged to endeavor to file patent applications to the extent required to provide reasonable protection for the relevant product, in consultation with CanSino, with costs shared between the parties. Before we abandon a jointly-owned patent claiming any New IPR, we must give CanSino at least three months' notice, and CanSino can request assignment of our rights on terms to be agreed. We are obliged to discuss with CanSino the enforcement of jointly owned patent rights but are entitled to enforce such patent rights outside the CanSino Territory.

Unless earlier terminated, the CanSino Agreement will continue for ten years from the date of the agreement. Either party can terminate by written notice for the uncured material breach or persistent breaches of the other party. Either party may terminate by written notice if the other party cannot pay its debts, takes any step in connection with entering administration, liquidation, or other arrangement with creditors (other than a solvent arrangement), or suspends all or part of its business; or suffers a force majeure event that continues for 60 days. Furthermore, a project agreement entered into pursuant to the CanSino Agreement shall automatically terminate if the 2016 OUI License Agreement or the 2017 OUI License Agreement terminates or expires, Background IPR licensed from OUI is necessary under such project agreement and the parties are unable to agree to a modification of the project or relevant collaboration product that would not require use of such Background IPR.

2018 ChAdOx Zoster Project Agreement (under the CanSino Agreement)

Pursuant to the CanSino Agreement, we entered into a project agreement in September 2018 with CanSino (the "ChAdOx Zoster Project Agreement") with the goal of developing a Zoster vaccine to become a competitor to Shingrix. Under the ChAdOx Zoster Project Agreement, we are responsible for funding and undertaking various development tasks, including

(subject to availability of funding) conducting a Phase 1 clinical trial in the UK. CanSino was responsible for funding and undertaking various development tasks, including conducting a Phase 1 clinical trial in China. The ChAdOx Zoster Project Agreement was amended on August 31, 2023 following the parties' agreement that the Phase 1 clinical trial to be conducted by CanSino as Sponsor should be carried out in Canada (rather than China). It was also agreed that the parties would each be responsible for 50% of the budgeted cost of the Phase 1 clinical trial (rather than each being responsible for funding or securing funding for any Phase 1 clinical trial in its respective country). The amendment further expanded the scope of the ChAdOx Zoster Project Agreement to cover potential administration of the product by inhalation.

The parties' rights and responsibilities in relation to Phase 2 and 3 clinical trials are pending, subject to further negotiation. In addition, the parties agreed to use all reasonable efforts to enter into a separate supply agreement pursuant to which CanSino will manufacture all product necessary for clinical trials and commercialization under the project agreement. If the parties cannot agree upon such supply agreement, they must follow a specified dispute resolution process set forth in the CanSino Agreement. For all products manufactured by CanSino under a supply agreement that we wish to sell in the Barinthus Bio Territory, we have agreed to pay the costs incurred by CanSino to manufacture the products plus 20% of such costs.

We received an upfront payment of £50,000 under this project agreement. We will also receive milestone payments of up to an aggregate of £1.125 million based on successful conduct of clinical trials and commercialization of the product. We will receive mid-single-digit royalties on the net sales of the product by or on behalf of CanSino or its sub-licensees in the CanSino Territory. If CanSino sublicense their rights in the product to a non-affiliate third party, we are also entitled to receive a mid-teens royalty on the transaction value (excluding royalties). We must pay to CanSino mid-single-digit royalties on the net sales of the product by or on behalf of us or our sub-licensees in the Barinthus Bio Territory. A party will benefit from a reduction of its royalties (in the low single digits) where it requires a license from a third party to sell the product in its territory.

Unless earlier terminated, the term of the ChAdOx Zoster Project Agreement will expire upon the later of expiry of all registered patents in the New IP developed under the project, or ten years from first commercial sale of the product. The last patent under the ChAdOx Zoster Project Agreement, if granted, is expected to expire in November 2039, without giving effect to any potential patent term extensions or patent term adjustments. A party may terminate the ChAdOx Zoster Project Agreement by written notice if the other party unreasonably delays the performance of its obligations. Upon the expiration of the term, we agreed to grant CanSino a royalty-free, perpetual, sub-licensable, non-exclusive license to use our Background IPR and our New IPR used to develop, incorporated in, or referenced in any products that are the subject of the project agreement to the extent necessary for CanSino to undertake research, develop, manufacture and commercialize such products in the CanSino Territory. Pursuant to the CanSino Agreement, upon the expiration or earlier termination of the project agreement, except for termination by CanSino for our breach, CanSino agreed to grant us a royalty-free, perpetual, sub-licensable, non-exclusive license to use their Background IPR and New IPR used to develop, incorporated in, or referenced in any products that are the subject of the project agreement to the extent necessary for us to undertake research, develop, manufacture and commercialize such products in the Barinthus Bio Territory. Unless we terminate the project agreement early for CanSino's breach, upon early termination after completion of a Phase 1 trial, we will continue to pay CanSino a low single-digit royalty on net sales of the product by us or our sub-licensees in the Barinthus Bio Territory, for the remainder of the Term. If such early termination is after completion of a Phase 2 trial, the royalty we must pay rises to mid-single digit.

Clinical Trial and Option Agreement with CRUK

In December 2019, Vaccitech Oncology Limited ("VOLT"), entered into a clinical trial and option agreement (the "Clinical Trial Agreement") with CRUK and CRUK's subsidiary, Cancer Research Technology Limited ("CRT"), relating to the conduct of a Phase 1/2a clinical trial of VOLT's VTP 600 immunotherapy product in patients with non-small cell lung cancer, or the Clinical Trial. The trial opened in the first quarter of 2022 across multiple clinical sites in the UK.

VOLT is our oncology focused strategic collaboration with the Ludwig Institute for Cancer Research, an international non-profit organization that conducts innovative cancer research and is looking to enable the clinical development of new treatments that induce and harness CD8+ T cells of the immune system to fight cancer. VOLT has a license to our proprietary CD8+ T cell induction platform and research by Benoit Van den Eynde's group at the Ludwig Oxford Branch.

Pursuant to the Clinical Trial Agreement, CRUK is responsible for, among other things, designing, preparing, carrying out and sponsoring the Clinical Trial, at its cost, and VOLT has granted to CRUK a license under its intellectual property to enable CRUK to perform such activities. VOLT is responsible for supplying agreed quantities of its VTP 600

immunotherapy product. VOLT retains the right to continue the development of the product during the Clinical Trial, provided that the parties have first agreed appropriate terms for sharing of safety data. CRUK owns all results, including all intellectual property therein, generated in the performance of the Clinical Trial. Upon the completion of the Clinical Trial, VOLT has the option to obtain a license to use such results (the "VTP 600 License"). The terms of the VTP 600 License have been pre-agreed and are set out in the Clinical Trial Agreement.

If VOLT exercises the option to take the VTP 600 License, CRT agrees to grant VOLT an exclusive license under the results of the Clinical Trial that exclusively relate to the VTP 600 immunotherapy product (the "Exclusive Results") and a non-exclusive license under any results that are not Exclusive Results, in each case, to develop and commercialize any product which makes use of the results of the Clinical Trial in an application for regulatory authorization, contains the relevant active ingredients, or is covered by the patent application PCT/EP2019/070555 (the "Product"). The rights under the VTP 600 License are sublicensable (except to a tobacco company). The exclusive rights granted under the VTP 600 License are subject to the right of certain third-party contributors associated with the Clinical Trial, CRUK and scientists funded or employed by CRUK to use the Exclusive Results for non-commercial scientific or clinical research purposes and to publish the Exclusive Results and the results of non-commercial research performed using the Exclusive Results (subject to the publication process set out in the Clinical Trial Agreement). Upon exercise of the option, VOLT is required to pay a one-time upfront fee of an amount in pounds Sterling in the high six-digits. VOLT is also obligated to make future milestone payments upon the achievement of development, regulatory and commercial milestones, with an aggregate total value of £40.8 million. VOLT is required to pay to CRT a low single-digit royalty on net sales of Products sold by VOLT or its sublicensees. If VOLT sublicenses the right to sell Products, VOLT will also be required to pay to CRT a royalty of between 5% and 20% on non-royalty amounts due to VOLT from a sublicensee, with the precise rate depending on the stage in development at which such sublicense was granted. VOLT is obligated to use commercially reasonable efforts to meet certain development, regulatory and commercialization obligations, including commencement of a Phase 2 clinical trial of a Product in an oncology indication before the second anniversary of the date of the VTP 600 License. CRT may terminate the VTP 600 License in respect of any given Product if VOLT is not actively developing it or fails to launch it after receiving marketing authorization. CRT may also terminate the VTP 600 License as a whole if no Product is being actively developed or commercialized.

If VOLT does not exercise the option to take the VTP 600 License, or if the VTP 600 License or Clinical Trial Agreement is subsequently terminated by CRUK (as described below) VOLT will enter into a step-in agreement with CRT (the "Step-In Agreement"). Pursuant to the Step-In Agreement, the terms of which have been pre-agreed and are set out in the Clinical Trial Agreement, VOLT will assign to CRT certain know- how and materials owned or controlled by VOLT. In addition, we agreed to grant to CRT an exclusive sub-license to a third-party patent family relating to viral vectors and methods for the prevention or treatment of cancer and non-exclusive sub-licenses to the HEK293 TetR Cell Line as well as certain third party patents and patent applications relating to certain adenovirus vectors and poxvirus expression systems, in each case, to develop and commercialize the Products on a revenue sharing basis. VOLT will receive a share of between 55% and 80% of the net revenue received by CRT for commercialization of the Product, with the precise share depending on the stage in development at which such Step-In Agreement is entered into.

The term of the Clinical Trial Agreement continues until it is otherwise terminated by the parties or, if the option is not exercised, upon the execution of the Step-In Agreement. The Clinical Trial Agreement can be terminated by either party upon an insolvency event in respect of the other party, for material breach of the other party, or upon a change of control of the other party (if the new controlling entity generates its revenue from the sale of tobacco products). If the Clinical Trial Agreement is terminated by CRUK for such causes prior to VOLT’s exercise of its option, VOLT will reimburse CRUK for all costs incurred or committed in connection with the Clinical Trial. In addition, CRUK may terminate the Clinical Trial Agreement at any time before the last cycle of treatment under the Clinical Trial is complete, in which case, upon VOLT’s request, CRT will grant the VTP 600 License to VOLT with appropriately reduced payments, to reflect the stage of the Clinical Trial at the date of termination. If the Clinical Trial Agreement is terminated for any reason after VOLT’s exercise of its option, VOLT may for three months following such termination continue to manufacture Products to the extent necessary to satisfy orders for Products accepted before such termination, and sell, use or otherwise dispose of Product inventory.

VOLT License Agreement

In November 2018, we entered into a license agreement (the "VOLT License Agreement") with VOLT. Pursuant to the VOLT License Agreement, we granted to VOLT a non-exclusive worldwide license under certain patent rights, know-how and materials related to the use of ChAdOx1, ChAdOx2, adenoviral and MVA promoters, and the TR293 Tet-Repressed Cell Line (the "VOLT Licensed Technology"), to manufacture, use and commercialize any product which uses or is within

the scope of the VOLT Licensed Technology (the "VOLT Licensed Product"). In part, the rights granted are a sublicense of rights granted to us by OUI under the 2016 OUI License Agreement. The license is sublicensable subject to obtaining OUI's prior consent with respect to sublicensing of any of the VOLT Licensed Technology licensed to us by OUI (with such consent not to be unreasonably withheld).

Pursuant to the VOLT License Agreement, we are required to make available to VOLT such further know- how relating to the manufacture of VOLT Licensed Products as we consider to be reasonably necessary or useful. We are also required to notify VOLT on a confidential basis of any improvements to the VOLT Licensed Technology that we develop or acquire rights in, and such improvements will be included within the scope of the license.

Unless earlier terminated, the VOLT License Agreement will continue until the later of the expiration of all patents included in the VOLT Licensed Technology or the know-how included in the VOLT Licensed Technology ceasing to be secret and substantial. The last patent under the VOLT License Agreement, if granted, is expected to expire in July 2039, without giving effect to any potential patent term extensions or patent term adjustments. Either party may terminate for the uncured material breach or insolvency of the other party. In the event of termination of the 2016 OUI License Agreement, we may terminate the VOLT License Agreement in respect of any of the VOLT Licensed Technology that is licensed to us by OUI, and VOLT and OUI shall enter into a direct license containing the same obligations and liabilities as set forth in the VOLT License Agreement.

The VOLT License Agreement was subsequently amended in July 2019 by two separate agreements for the research, development, and commercialization of cancer immunotherapy targeting MAGE-A3 and NY-ESO-1 for the treatment of various forms of cancer under the VOLT Licensed Technology. Such amendments further elaborated on the parties' respective rights and obligations, including with respect to VOLT's payment obligations to us.

2023 CEPI Funding Agreement

On December 20, 2023, we, the Chancellors, Masters and Scholars of the University of Oxford ("Oxford," together with us, the "Partners") and the CEPI entered into a Funding Agreement (the "Funding Agreement") pursuant to which CEPI will provide funding of up to $34.8 million to us to advance the development of VTP-500, our vaccine candidate against MERS (such development activities, the "Project"). In December 2023, VTP-500 received PRIority MEdicines ("PRIME") designation by the EMA. Under the Funding Agreement, the Partners have agreed to use reasonable endeavors to achieve the deliverables, milestones and timelines for the vaccine development activities under discrete "Work Packages" mutually agreed to by the parties from time to time.

Under the initial Work Package, we have agreed, subject to the achievement of certain milestones, including a successful Phase 2 clinical trial of VTP-500, that it will manufacture or have manufactured an investigational ready reserve of 100,000 doses of VTP-500 to be rapidly deployed for a clinical trial in the event of a substantial outbreak of MERS. During the Term (as defined below), we have also agreed to certain collaboration obligations in the event of a regional or national public health emergency or preparation need for an impending outbreak of MERS.

Pursuant to the Funding Agreement, we will retain ownership of its intellectual property owned or controlled throughout the term of the Funding Agreement, subject to the rights of CEPI under the Funding Agreement. We will also own any intellectual property invented by or on behalf of us in connection with the activities contemplated by the Funding Agreement, as well as all tangible materials and results made or developed by or on behalf of us in connection with the Funding Agreement.

Any amounts funded by CEPI to the Partners under the Funding Agreement in accordance with each Work Package will be paid in tranches covering six-month periods based on mutually agreed project-based budgets and subject to certain conditions as set forth in the Funding Agreement including the achievement of identified milestones.

Pursuant to the Funding Agreement, we have agreed to pay CEPI on a country-by-country basis increasing mid-single digit percentage royalties of net sales and net income with respect to future cash sales of VTP-500, less certain deductions, for a period starting on December 20, 2023 ("Effective Date") and ending the later of: (i) the expiration of the last valid patent claim included in intellectual property developed under the Project covering VTP-500 in such country, (ii) the expiration of Regulatory Exclusivity (as defined in the Funding Agreement) for VTP-500 in such country, and (iii) the tenth (10th) anniversary of the first commercial sale of VTP-500 (the "Royalty Term"). The Company shall also pay CEPI a mid-double digit percentage of net revenue earned on VTP-500 until CEPI has received payments from us under the Funding Agreement equaling the total amount of funding paid by CEPI to us and a low double-digit percentage of such net revenue thereafter. Sales for the benefit of end users in specified low and middle income countries ("LMICs") and upper and middle

income countries (“UMICs”) are excluded from the calculations of net sales and net revenue. Sales of product for the benefit of end users in LMICs and UMICs are subject to tiered discounted pricing requirements under the Funding Agreement. The Company is further required to pay a mid-double digit percentage of any proceeds earned on any priority review voucher related to VTP-500 during the Royalty Period.

The Funding Agreement will commence on the Effective Date and will continue until the fifth (5th) anniversary of the Effective Date, unless the parties agree to extend the Funding Agreement for a period of up to twenty-four (24) months unless all activities under the Funding Agreement have been completed (“Term”). Either Partner or CEPI can terminate the Funding Agreement following an insolvency event or material breach by the other party that is not cured within forty-five (45) business days, in the event of termination by a Partner, or thirty (30) business days, in the event of termination by CEPI. Pursuant to the Funding Agreement, CEPI also has certain discretionary termination rights, including if CEPI determines that we are involved in material safety, regulatory, scientific misconduct, or ethical issues or is no longer able to fulfill its obligations under the Funding Agreement.

Neither CEPI, us nor Oxford may assign its rights or obligations under the Funding Agreement without the other parties’ consent; provided that CEPI may do so to an organization of equivalent charitable mission and technical capabilities.

Intellectual Property

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

As of March 14, 2024, we own a patent family relating to our novel regimens that includes one pending U.S. patent application, two pending foreign patent applications and one pending Patent Cooperation Treaty ("PCT") patent application together with one pending U.S. provisional patent application relating to our novel products. In addition, we have in-licensed certain patent families relating to our key technology platforms and product candidates, including ten issued U.S. patents, nine pending U.S. patent applications, at least 20 issued foreign patents and at least 70 pending foreign patent applications. Following the acquisition of Avidea in December 2021 we control a further patent portfolio comprising in-licensed and co-owned patent families, including 10 pending U.S. patent applications, six issued foreign patents, 48 pending foreign patent applications and two pending PCT patent applications.

Universal Vector Technology Platforms

ChAdOx 1 Expression Vector

As of March 14, 2024, with regard to our ChAdOx1 expression vector, we in-license from OUI a patent family that includes three issued U.S. patents with claims directed to the composition of matter of the ChAdOx1 adenovirus vector and methods of using such a vector, and 9 issued foreign patents granted in such jurisdictions as Australia, Canada, China, Europe (validated in 12 countries including Denmark, France, Germany, Italy, Spain, and Great Britain), India, Japan, Singapore and South Africa. A second granted European patent with further claims directed to the composition of matter of ChAdOx adenovirus vector is validated in France, Germany and Great Britain. This patent family also includes a pending U.S. patent application. The granted patents and pending applications, if issued, are expected to expire in 2032, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. Patent term extensions have been granted in Australia until February 16, 2036 and in Japan for an additional 1 year, 1 month and 24 days, based on marketing authorisations received by AstraZeneca for Vaxzevria.

Adenoviral Promoter

Certain of our ChAdOx1 vectors incorporate a proprietary adenoviral promoter, which is covered by a patent family that we in-license from OUI. As of March 14, 2024, the patent family includes two issued U.S. patents and one granted patent in Europe (validated in 7 countries including France, Germany, Italy, Spain, and Great Britain). The patents in this family are expected to expire in 2028, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

MVA-poxvirus Promoter

Our MVA vector incorporates a proprietary poxvirus promoter ("MVA-poxvirus promoter") which is covered by a patent family that we in-license from OUI. As of March 14, 2024, the patent family includes two issued U.S. patents and one granted European patent (validated in 9 countries including Denmark, France, Germany, Italy, Spain, and Great Britain) that are expected to expire in 2031, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Synthetic SNAP platform (SNAP-TI™ and SNAP-CI™)

Our proprietary synthetic SNAP platform is covered by a patent portfolio that includes one patent family we own, seven patent families that we co-own and one patent family that we in-license from OUI. As of March 14, 2024, we in-license a patent family from OUI that includes one pending U.S. patent application and one pending European patent application that are expected to expire in 2035, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. As of March 14, 2024, we own a patent family that includes four issued foreign patents that are expected to expire in 2030, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. As of March 14, 2024, we co-own a patent family that includes two issued foreign patents, one pending U.S. patent application, one pending European patent application and a at least 10 pending foreign patent applications that are expected to expire in 2038, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusively licensed rights in this patent family, which resulted from work carried out under a CRADA with the NIH. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further 5 pending foreign patent applications that are expected to expire in 2039, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusively licensed rights in this patent family, which resulted from work carried out under a CRADA with the NIH. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further 2 pending foreign patent applications that are expected to expire in 2039, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA with the NIH. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further nine pending foreign patent applications that are expected to expire in 2042, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA with the NIH. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further three pending foreign patent applications that are expected to expire in 2042, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA with the NIH. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application, one pending foreign patent application and a further two pending foreign patent applications that are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have licensed exclusive rights in this patent family, which resulted from work carried out under a RCA with the IMC. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application and one pending international PCT patent application that are expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA with the NIH. As of March 14, 2024, we co-own a patent family that includes one pending international PCT patent application that is expected to expire in 2043, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity

or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA with the NIH.

Syntholytic

Our proprietary Syntholytic technology is covered by a patent portfolio that includes one patent family we own, 2 patent families that we co-own and one patent family that we in-license from OUI. As of March 14, 2024, we in-license a patent family from OUI that includes one pending U.S. patent application and one pending European patent application that are expected to expire in 2035, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. As of March 14, 2024, we own a patent family that includes four issued foreign patents that are expected to expire in 2030, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further 6 pending foreign patent applications that are expected to expire in 2040, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA with the NIH, and we have licensed exclusive rights in this patent family, which resulted from work carried out under a RCA with the IMC, Prague. As of March 14, 2024, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further two pending foreign patent applications that are expected to expire in 2041, without giving effect to any potential patent term extensions and patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA with the NIH.

Product Candidates

Our VTP-200 product candidate comprises a ChAdOx1HPV vector and a MVA-HPV vector, where each vector incorporates an engineered HPV antigen. We in-license from OUI a patent family directed to the HPV antigen with claims directed to a nucleic acid encoding a polypeptide comprising certain peptide sequences based on certain HPV proteins. As of March 14, 2024, the patent family includes one issued U.S. patent, two issued foreign patents, one pending U.S. patent application and eight foreign patent applications pending in jurisdictions including Europe, Australia, Canada, and Japan. If patents were to issue from such patent applications, they would be expected to expire in 2038, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, we also rely on patent protection afforded by the patent family directed to the ChAdOx1 expression vector, which is expected to expire in 2032, and the patent family directed to our MVA-poxvirus promoter, which is expected to expire in 2031, as discussed above.

Our VTP-300 product candidate comprises a ChAdOx1HBV vector and a MVA-HBV vector, where each vector incorporates an engineered HBV antigen. As of March 14, 2024, we in-license from OUI a patent family with claims directed to a multi-HBV immunogen viral vector vaccine that includes two issued foreign patents, one pending U.S. patent application and 15 foreign patent applications pending in jurisdictions including Europe, Australia, Canada and China. If patents were to issue from such patent applications, they would be expected to expire in 2038, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, we also rely on patent protection afforded by the patent family directed to the ChAdOx1 expression vector, which is expected to expire in 2032, and the patent family directed to our MVA-poxvirus promoter, which is expected to expire in 2031, as discussed above.

Our VTP-600 product candidate comprises a ChAdOx1MAGE-NYESO vector, a MVA-MAGE vector, and a MVA-NYESO vector. We in-license from Ludwig Institute a patent family with claims directed to a chimpanzee adenovirus vector encapsulating a nucleic acid molecule encoding a MAGE antigen, a NY- ESO1 antigen or both a MAGE antigen and a NY-ESO1 antigen. As of March 14, 2024, the patent family includes one pending U.S. patent application and at least 8 foreign patent applications pending in jurisdictions including Europe, Australia, Canada, China, and Japan. If a patent were to issue from a patent application claiming the benefit of this PCT application, such a patent would be expected to expire in 2039, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, we also rely on patent protection afforded by the patent family directed to the ChAdOx1 expression vector, which is expected to expire in 2032,

the patent family directed to our adenoviral promotor, which is expected to expire in 2028, and the patent family directed to our MVA-poxvirus promoter, which is expected to expire in 2031, as discussed above.

Our VTP-800 and VTP-850 product candidates comprise a ChAdOx15T4 vector and a MVA5T4 vector, where each vector incorporates an engineered 5T4 antigen and in VTP-850 the 5T4 antigen is also in combination with additional antigens. We in-license from OUI a patent family with claims directed to a composition for inducing a T Cell response comprising a MVA vector expressing the 5T4 antigen polypeptide. As of March 14, 2024, the patent family includes one pending U.S. patent application and 11 foreign patent applications pending in jurisdictions including Europe, Australia, Canada, China, and Japan. If a patent were to issue from a patent application claiming the benefit of this PCT application, such a patent would be expected to expire in 2039, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, we also rely on patent protection afforded by the patent family directed to the ChAdOx1 expression vector, which is expected to expire in 2032, the patent family directed to our adenoviral promotor, which is expected to expire in 2028, and the patent family directed to our MVA-poxvirus promoter, which is expected to expire in 2031, as discussed above.

Our VTP-500 product candidate comprises a ChAdOx1MERS vector that incorporates an engineered MERS antigen. We rely on patent protection afforded by the patent family directed to the ChAdOx1 expression vector, which is expected to expire in 2032 and the patent family directed to our adenoviral promotor, which is expected to expire in 2028, as discussed above.

Our VTP-400 product candidate comprises a ChAdOx1VZVgE vector that incorporates an engineered VZVgE antigen. We in-license from OUI a patent family with claims directed to an adenoviral vector comprising a nucleic acid encoding the varicella-zoster virus antigen. As of March 14, 2024, the patent family includes one pending U.S. patent application and 13 foreign patent applications pending in jurisdictions including Europe, Australia, Canada, China, and Japan. If a patent were to issue from a patent application claiming the benefit of this PCT application, such a patent would be expected to expire in 2039, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We also rely on patent protection afforded by the patent family directed to the ChAdOx1 expression vector, which is expected to expire in 2032 and the patent family directed to our adenoviral promotor, which is expected to expire in 2028, as discussed above.

Our VTP-1100 product candidate includes SNAP-CI platform technology to target HPV16+ cancers. We co-own a patent family with claims directed to methods of treating cancers using SNAP-CI compositions. As of March 14, 2024, the patent family includes one pending international PCT patent application. If a patent were to issue from a patent application claiming the benefit of this PCT application, such a patent would be expected to expire in 2043, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. We have exclusive rights in this patent family, which resulted from work carried out under a CRADA between Barinthus Bio and the NIH. In addition, we rely on patent protection afforded by the patent families directed to the SNAP technology platforms, which are expected to expire between 2030 and 2042, as discussed above.

Our VTP-1000 product candidate includes SNAP-TI platform technology to provide tolerizing immunotherapy for celiac disease. We co-own a patent family with claims directed to compositions and methods for treating celiac disease. As of March 14, 2024, the patent family includes one pending U.S. patent application and one pending international PCT patent application. If a patent were to issue from either of these pending applications or from a patent application claiming the benefit of either of these applications, such a patent would be expected to expire in 2043, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, we rely on patent protection afforded by the patent families directed to the SNAP technology platforms, which are expected to expire between 2030 and 2042, as discussed above.

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and certain foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product by product basis, from country to country and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent. Our patents

and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information about the risks associated with our efforts to obtain adequate intellectual property protection for our product candidates, and the enforcement of such intellectual property rights, as well as the risks associated with third party intellectual property rights, see the section titled "Risk Factors — Risks Related to Our Intellectual Property." With regard to our VTP-300 and VTP-850 product candidates, we are aware of third-party patents in the United States with claims which may be relevant to these product candidates. See "Risk Factors — Risks Related to Intellectual Property — The intellectual property landscape around immunotherapeutics and viral-vector based vaccines is crowded and dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights and such claims may be costly and time-consuming and may prevent or delay our product discovery and development efforts."

Government Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), the Public Health Service Act (the "PHS Act"), and other federal, state, and local statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the research, development, testing, manufacturing, quality control, approval, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, marketing, promotion, export and import, advertising, post-approval monitoring, and post-approval reporting involving biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations, and international guidelines require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

Further, even if we obtain the required regulatory approvals for our products, pharmaceutical companies are subject to myriad federal, state, and foreign healthcare laws, rules, and regulations governing all aspects of our operations, including, but not limited to, our relationships with healthcare professionals, healthcare institutions, distributors of our products, and sales and marketing personnel; governmental and other third-party payor coverage and reimbursement of our products; and data privacy and security. Such laws, rules, and regulations are complex, continuously evolving, and, in many cases, have not been subject to extensive interpretation by applicable regulatory agencies or the courts. We are required to invest significant time and financial resources in policies, procedures, processes, and systems to ensure compliance with these laws, rules, and regulations, and our failure to do so may result in the imposition of substantial monetary or other penalties by federal or state regulatory agencies, give rise to reputational harm, or otherwise have a material adverse effect on our results of operations and financial condition.

U.S. Biological Products Development Process

In the United States, the FDA is responsible for enforcing the laws in place to protect public health by ensuring the safety, efficacy, and security of biological products. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practices (GLPs), regulations and standards;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board ("IRB") or ethics committee representing each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practices ("GCPs"), and other clinical trial-related regulations to establish the safety, purity and potency of the proposed biological product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labeling;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies);
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice requirements ("cGMPs") and to assure that the facilities, methods and controls are adequate to preserve the biological product's

identity, strength, quality and purity, and of selected clinical trial sites that generated the data in support of the BLA to assess compliance with the FDA's GCPs;
- satisfactory completion of an FDA Advisory Committee review, if applicable; and
- FDA review and approval, or licensure, of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Before testing any biological product candidate in humans, the product candidate enters the preclinical development stage. The preclinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the preclinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, as well as other information, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on 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 drug product candidate at any time before or during clinical trials due to safety concerns, non-compliance, or other issues affecting the integrity of the trial. 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 could cause the trial to be suspended or terminated.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators which generally are physicians not employed by, or under the control of, the trial sponsor. Clinical trials are conducted under written trial protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection (inclusion and exclusion criteria) and the parameters and criteria 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 subsequent amendments to the protocol, must be submitted to the FDA as part of the IND.

An IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data (if blinded) or to data available also to the sponsor (unblinded) from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Certain information about certain clinical trials must also be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

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

- Phase 1. The investigational product is initially introduced into healthy human volunteers or patients with the target disease or condition. Phase 1 clinical trials are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, including any side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

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

- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit:risk

ratio of the investigational product and to provide an adequate basis for physician labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

In some cases, the FDA may require, or companies may voluntarily pursue, post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, 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 trial 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 submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human volunteers and 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 seven days of the sponsor's initial receipt of the information of any unexpected fatal or life-threatening suspected adverse reaction. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor, acting on its own or based on a recommendation from the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. 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.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biological product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing high quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, stability, 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.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. 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.

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

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, conducting a benefit-risk assessment based on the information provided as to whether the benefits (with their uncertainties) of the biological product outweigh the risks (with their uncertainties and approaches to managing risks) under the conditions of use described in the proposed product labeling, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and potency. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians, patient representatives, 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 ("REMS") is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control. 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 the protocol and following GCP.
Under the Pediatric Research Equity Act ("PREA") a BLA or supplement to a BLA for a novel product (*e.g.*, new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the drug substance and/or drug product for commercial supply will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, precautions or interactions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing trials. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Orphan Drug Designation

Under section 526 of the FD&C Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biological product for such disease or condition will be recovered from sales of the product in the United States of such drug. Orphan product designation must be requested before submitting a BLA for the orphan indication. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for qualified clinical testing expenses and a waiver of the BLA application user fee.

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

Orphan drug designation may also entitle a party to additional financial incentives such as opportunities for grant funding towards clinical trial costs.

Expedited Development and Review Programs

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions or fulfill an unmet medical need. To be eligible for fast track designation, new drugs and biological product candidates must be intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for that disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. One benefit of fast track designation, for example, is that the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. However, the review of the BLA does not formally start until the full application has been received by the FDA.

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, defined as those that measure an effect on irreversible morbidity or mortality or on symptoms that represent serious consequences of the disease. Breakthrough therapy designation comes with all of the benefits of fast track designation. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program.

A product candidate is eligible for priority review if when approved, it would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application in six months once it is filed, compared to ten months for a standard review. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity or mortality, that is reasonably likely to predict irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA") the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires sponsors, unless otherwise informed by the agency, to request pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or

indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Post-approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. We currently rely, and may continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Manufacturers also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable United States requirements at any time during the product development process, approval process, or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detentions or refusal to permit the import or export of the product, restrictions on the marketing or manufacturing of the product, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with physicians or other stakeholders, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological 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, including applicable tracking and tracing requirements. 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 withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The United States Patent and Trademark Office (the "USPTO") in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond

its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and the FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12 year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

In addition to exclusivity under the BPCIA, a biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity for all formulations, dosage forms, and indications of the biologic. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Additional Regulation

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

Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products as well as authorization and approval of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

In April 2014, the EU adopted the new Clinical Trials Regulation (EU) No 536/2014, which replaced the current Clinical Trials Directive 2001/20/EC on January 31, 2022. The transitory provisions of the new Regulation offer sponsors the possibility to choose between the requirements of the previous Directive and the new Regulation if the request for

authorization of a clinical trial is submitted in the year after the new Regulation became applicable. If the sponsor chooses to submit under the previous Directive, the clinical trial continues to be governed by the Directive until three years after the new Regulation became applicable. If a clinical trial continues for more than three years after the Regulation became applicable, the new Regulation will at that time begin to apply to the clinical trial. The new Regulation, which is directly applicable in all EU Member States and those within the European Economic Area ("EEA") (meaning that no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. The main characteristics of the new Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (Concerned Member States) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Concerned Member State. Strict deadlines have also been established for the assessment of clinical trial applications.

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

European Union Drug Review and Approval

In the European Union, medicinal products, including biological medicinal products, are subject to extensive pre- and post-market regulation by regulatory authorities at both the European Union and national levels.

To obtain regulatory approval of a biological medicinal product under the European Union regulatory system, we must submit a marketing authorization application ("MAA") either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the European Union: the decentralized procedure, national procedure, or mutual recognition procedure. A marketing authorization may be granted only to an applicant established in the EEA.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the entire territory of the EU and the additional Member States of the EEA. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicinal products (gene-therapy, somatic-cell therapy and tissue-engineered medicines) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of viral diseases, autoimmune and other immune dysfunctions and cancer. For those products for which the use of the centralized procedure is not mandatory, applicants may elect to use the centralized procedure where the product contains a new active substance not yet authorized in the European Union, and where the applicant can show that the product constitutes a significant therapeutic, scientific or technical innovation or for which a centralized process is in the interest of public health at a European Union level.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP"), established at the EMA is responsible for conducting an initial assessment of whether a product meets the required quality, safety and efficacy requirements, and whether a product has a positive benefit-risk profile. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days from receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

For products not falling within the mandatory scope of the centralized procedure, national marketing authorizations may be obtained, which are issued by the competent authorities of the European Union Member States and only cover their

respective territory. Where a product has already been authorized for marketing in an European Union Member State, this national marketing authorization can be recognized in another European Union Member State through the mutual recognition procedure. If the product has not received a national marketing authorization in any Member State at the time of application, it can be approved simultaneously in various European Union Member States through the decentralized procedure. As with the centralized procedure, the competent authorities of the European Union Member States assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy before granting the marketing authorization.

The application used to submit the BLA in the United States is similar to that required in the European Union, with certain exceptions. Directive 2001/83/EC and the laws in the Member States transposing this Directive into national law set out the requirements for an MAA. An MAA for a biological medicinal product must contain certain additional requirements to applications for other medicinal products, such as a description of the origin and history of the starting materials used for the product.

Data and Marketing Exclusivity

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

Orphan Designation and Exclusivity

Products with an orphan designation in the European Union can receive ten years of market exclusivity, during which time "no similar medicinal product" for the same indication may be placed on the market. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can also obtain an additional two years of market exclusivity where an agreed pediatric investigation plan for pediatric trials has been complied with. No extension to any supplementary protection certificate ("SPC") can be granted on the basis of pediatric trials for orphan indications. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity.

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

Orphan medicine marketing exclusivity may be revoked only in very select cases, specifically:

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

Pediatric Development

In the European Union, companies developing a new medicinal product must agree upon a pediatric investigation plan, or PIP, with the EMA's Pediatric Committee ("PDCO") and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Products that are granted a marketing authorization with the results of pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a SPC, provided an application for such extension is made at the same time as filing the SPC application for the product or at any point up to 2 years before the SPC expires, even where the trial results are negative. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

PRIME Designation

In March 2016, the EMA, launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage product development in areas of unmet medical need (where there is no satisfactory method of diagnosis, prevention or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and provides accelerated assessment of products representing substantial innovation. The PRIME scheme is open to medicines under development and for which the applicant intends to apply for an initial MAA through under the centralized procedure. Applicants will typically be at the exploratory clinical trial phase of development, and will have preliminary clinical evidence in patients to demonstrate the promising activity of the medicine and its potential to address to a significant extent an unmet medical need. In exceptional cases, products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies, if compelling non-clinical data in a relevant model provide early evidence of promising activity, and first in human trials indicate adequate exposure for the desired pharmacotherapeutic effects and tolerability. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the CHMP or Committee for Advanced Therapies are appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn. VTP-500, under development for the prevention of MERS caused by the MERS coronavirus, was awarded PRIME designation in December 2023 by the EMA.

Post-Approval Controls

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

- The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").
- All new MAAs must include a risk management plan ("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 trials. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

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

The aforementioned EU rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"), and the United Kingdom officially withdrew from the European Union on January 31, 2020. 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 ("Transition Period"), during which European Union rules continued to apply. However, the European Union and the United Kingdom have concluded a trade and cooperation agreement ("TCA"), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of United Kingdom and European Union pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the European Union regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore largely aligns with current European Union regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of United Kingdom and European Union pharmaceutical legislation. For example, the United Kingdom has implemented the now repealed Clinical Trials Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). The extent to which the regulation of clinical trials in the United Kingdom will mirror the new Clinical Trials Regulation now that has come into effect is not yet known, however the MHRA has conducted a consultation on a set of proposals designed to improve and strengthen the United Kingdom clinical trials legislation.

Great Britain is no longer covered by the European Union's procedures for the grant of centralized marketing authorizations, however as a result of the Northern Ireland Protocol, Northern Ireland will be covered by the centralized authorization procedure and can be covered as a Center for Medicare and Medicaid Services ("CMS") under the decentralized or mutual recognition procedures. A separate marketing authorization will therefore be required to market drugs in Great Britain. All medicinal products with a valid centralized marketing authorization on January 1, 2021 were automatically converted into Great Britain marketing authorizations (unless the marketing authorization holder opted out of such a conversion). For two years from 1 January 2021, the United Kingdom's regulator, MHRA may rely on a decision taking by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. This is known as the EC Decision Reliance Procedure. The MHRA also offers a 150 day assessment timeline for all high quality applications for a UK, Great Britain or Northern Ireland marketing authorization. The 150 day timeline does not, however, include a "clock-off" period which may occur if issues arise or points require clarification following an initial assessment of the application. Such issues should be addressed within a 60 day period, although extensions may be granted in exceptional cases.

Since January 1, 2021, a separate process for orphan designation has applied in Great Britain. There is now no pre-marketing authorization orphan designation (as there is in the European Union) in Great Britain and the application for orphan designation will be reviewed by the MHRA at the time of a MAA application for a United Kingdom or Great Britain marketing authorization. The criteria for orphan designation are the same as in the European Union, save that they apply to Great Britain only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain, as opposed to the European Union, and the prevalence of the condition must be no more than 5 in 10,000 person in Great Britain).

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we may seek regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurers, and managed healthcare organizations. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage, and amount of reimbursement to be provided are made on a plan-by-plan

basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor.

Moreover, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations, and financial condition. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization of the product.

In addition, the United States government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services; examining the medical necessity of pharmaceutical or biological products; reviewing the cost-effectiveness of such products; and questioning the safety and efficacy of such products. Adoption of new price controls and cost-containment measures, or adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability of manufacturers to sell products profitably. Decreases in third-party reimbursement for any product or a decision by a third party not to cover a product could reduce physician usage and patient demand for such product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the United States federal Anti-Kickback Statute ("AKS"); the civil False Claims Act ("FCA"); the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"); and similar foreign, federal, and state fraud and abuse, transparency, and privacy laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration to induce, or in return for, either the referral of an individual, or the purchase, lease, ordering, or arranging for or recommending the purchase, lease, or ordering, of any item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value, whether given directly or indirectly, in cash or in kind. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, third-party payors, patients, and others on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but they are drawn narrowly, and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of an applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, a claim submitted to a federal healthcare program that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim that may result in civil liability under the FCA.

Civil and criminal false claims laws, and civil monetary penalty laws, including the FCA, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent. For example, the FCA prohibits any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the United States government. Several pharmaceutical companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product, or for subsidizing copays for patients, including indirectly through charitable patient assistance programs, as an inducement for patients to utilize their products.

HIPAA created additional federal civil and criminal liability for, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA's fraud and abuse provisions without actual knowledge of the statute or specific intent to violate it.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, impose certain requirements on HIPAA covered entities, which include certain healthcare providers, healthcare clearinghouses, and health plans, and individuals and entities that provide services on their behalf that involve individually identifiable health information, known as business associates, relating to the privacy, security, and transmission of individually identifiable health information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of protected health information and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses, and may be complicated by the fact that the applicable rules are subject to changing interpretation. HIPAA mandates the reporting of certain breaches of health information to the United States Department of Health and Human Services ("HHS") affected individuals, and if the breach is large enough, the media. In addition to reputational harm, entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing civil actions.

The U.S. federal Physician Payments Sunshine Act ("Sunshine Act") requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to annually report to the CMSs, information related to payments or other transfers of value made to physicians (currently defined to include doctors of medicine or osteopathy, dentists, optometrists, podiatrists, and chiropractors), other licensed non-physician health care practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Additionally, we may be subject to federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

We are also subject to additional similar U.S. state and foreign equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws which require pharmaceutical companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws which require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we or our officers, directors, employees,

contractors, or agents may be subject to penalties, including, without limitation, significant civil, criminal, and administrative penalties; damages; fines; exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions; entry into a corporate integrity agreement or similar reporting obligations to resolve allegations of non-compliance; disgorgement; imprisonment; contractual damages; reputational harm; diminished profits; and the curtailment or restructuring of our operations.

Data Privacy and Security Laws

We may also be subject to data privacy and security laws in the United States and various jurisdictions around the world in which we operate or process personally identifiable information ("personal information" or "personal data"). In the United States, even when HIPAA does not apply, according to the Federal Trade Commission (the "FTC") failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act (the "FTCA") 15 U.S.C. § 45(a). The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations. In addition, certain states have enacted laws that govern the privacy and security of health information and other personal information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation as well as reputational harm. For example, the California Consumer Privacy Act (the "CCPA") as amended by the California Privacy Rights Act (the "CPRA") went into effect on January 1, 2023. Also, on January 1, 2023, the Virginia Consumer Data Protection Act ("CDPA") became effective. Further, many additional United States state privacy laws will go into effect throughout 2023: the Colorado Privacy Act ("the CPA") (July 1, 2023); the Connecticut Data Privacy Act (the "CTDPA") (July 1, 2023); and the Utah Consumer Privacy Act (the "UCPA") (December 31, 2023). The CDPA, CPA, CTDPA, and UCPA are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and information governed by HIPAA. Any of these laws may broaden their scope in the future, and similar laws have been proposed on both a federal level and in more than half of the states in the United States. In addition, a number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies.

Outside of the United States, we also face stringent privacy and data protection requirements. For example, in Europe, the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data in the EEA and the UK is subject to the EU General Data Protection Regulation ("EU GDPR") (with regards to the EEA) and the UK General Data Protection Regulation ("UK GDPR") (with regards to the UK), as well as applicable data protection laws in effect in the Member States of the EEA and in the UK (including the UK Data Protection Act 2018). In this Annual Report, "GDPR" refers to both the EU GDPR and the UK GDPR, unless specified otherwise. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, 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 (£17.5 million for the UK GDPR) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Data protection authorities from the different EU member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the EU.

In addition, various jurisdictions around the world continue to propose new laws that regulate the privacy and/or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines, penalties, litigation, and reputational harm if we are unable to comply.

Healthcare Reform and Legislative Changes

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of

containing healthcare costs, improving quality, or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biological products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs and expanding enrollment in commercial health plans through new Health Insurance Marketplaces operated by the federal and state governments; a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, Congress has considered legislation that would repeal, or repeal and replace, all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, which started on January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted.

For example:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, absent further legislative action.

- The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers.

- The Inflation Reduction Act of 2022, or IRA, includes several provisions that will impact our business to varying degrees, including provisions that require Medicare Part D plans to cover with $0 in cost sharing the cost of adult vaccines recommended by the U.S. Advisory Committee on Immunization Practices, or ACIP. The IRA also includes provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it will not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general are not yet known.

In addition, there have been several judicial challenges to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. These include challenges to the government's reimbursement formula on specified covered outpatient drugs and disputes over potential product diversion through the use of "contract pharmacies," among other issues. It is unclear how these challenges could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal

and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. For example, FDA released regulations implementing the section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which went into effect on November 30, 2020 and which provide guidance for states to build and submit importation plans for drugs from Canada. In January 2024, FDA issued its first approval to Florida for a state plan on importation of certain drugs. CMS has stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates.

On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed, and the IRA extended the moratorium on implementation until January 1, 2032. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Although a number of these and other proposed measures may require additional authorization to become effective, Congress and President Biden have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Additional state and federal healthcare reform measures may be adopted in the future. Further, it is possible that additional governmental action is taken in response to COVID-19. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

Employees and Human Capital Resources

As of December 31, 2023, we had 130 full-time and part-time employees, of which 95 were located in the United Kingdom, 34 located in the United States and 1 located in Switzerland. As of December 31, 2023, 62% of our workforce and 54% of our leadership (at Director level and above) were female. In addition, 20% of our workforce were racially or ethnically diverse. Of our full and part-time employees, 31 have Ph.D. or M.D. degrees, and 88 are engaged in research and clinical development activities.

A breakdown of the employment statistics as of December 31, 2023 is as follows:

Position	Male	Female	Total
Executives	3	2	5
Director/Vice President	14	18	32
Managers	9	15	24
Scientists and Support Functions	24	45	69
Total	**50**	**80**	**130**

Demographic	Male	Female	Total
Asian	5	10	15
Black, Caribbean, or African	4	3	7
Mixed, other or multiple ethnic groups	1	3	4
White	40	64	104
Total	**50**	**80**	**130**

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. We engage with our employees in multiple ways

including through company-wide events, social events and team events. We also have a bonus scheme and equity incentive plan in which all employees are entitled to participate. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the grant of equity-based compensation awards. We believe that attracting and retaining talent increases shareholder value and furthers the success of our company by motivating our employees to perform to the best of their abilities and achieve our objectives.

We employ individuals based on their experience and ability, and we are committed to promoting diversity and inclusion in our work environment. We focus on hiring and retaining qualified candidates by promoting a supportive and inclusive working environment for all. We believe that fostering diversity, equity, and inclusion is a key element to discovering, developing, and bringing transformative therapies to patients.

The safety of our workforce, including consultants and visitors to our office/laboratory, has and remained of paramount importance to us. We have a Health and Safety Committee that focuses on implementing policies and training programs to enhance workplace safety.

As we continue to grow, we also intend to expand our overall environmental, social, and governance, or ESG, efforts. In 2022, we assigned oversight for ESG to the Nominating and Governance Committee who were tasked with performing an assessment of our ESG impacts and establishing initiatives. Following this assessment, we have created specific goals and objectives to monitor and improve specific metrics. These include:

1. Environmental – the impact we have on the environment, including its assessment of carbon footprint and the reporting thereof for new facilities.

2. Social – the impact we have on society, including the impact on external groups through the development of life-saving products, the impact in low- and middle-income countries and clinical trial diversity. For internal groups the focus is on employees and how Barinthus Bio monitors and maintains gender pay parity, expands employee diversity, enhances engagement and morale, and minimizes staff turnover.

3. Corporate Governance – how is the company run, to include diversity and inclusion within the company and the board of directors, board independence and the ratio of executive compensation to employee compensation.

Carbon emissions

The group has calculated the emissions for the year ended December 31, 2023 and 2022 in tons of carbon dioxide equivalent ("tCO2e"). The carbon footprint for the group for the years ended December 31, 2023 and 2022 are as follows:

	December 31, 2023		December 31, 2022	
Scope	**tCO2e**	**% Total emissions**	**tCO2e**	**% Total emissions**
Scope 1	6.54	2%	5.59	5%
Scope 2	360.00	98%	107.63	95%
Total	**366.54**	**100%**	**113.22**	**100%**

For clarity, scope 1 emissions are direct emissions produced from activities owned or controlled by us. Scope 2 emissions are indirect emissions related to the generation of the electricity consumed and purchased by us. We have used the most recent evidence or estimates provided by our energy supply partners to generate our disclosure of emissions for the period. Standard emissions factors from the "UK Government GHG Conversion Factors for Company Reporting (2023)" guidance were applied to estimate emissions. Electricity, heating and cooling usage at our leased facilities in the United States and the United Kingdom are responsible for a significant amount of our greenhouse gas emissions, with the remainder due to operations conducted within our laboratory. The increase in emissions is primarily attributable to the relocation of our U.S laboratory and office facilities which completed in June 2023. The relocation provides approximately 19,700 square foot of state-of-the-art wet laboratory and office facilities in Germantown, Maryland.

The group has elected not to include the voluntary disclosure for Scope 3 emissions.

For the year ended December 31, 2023, the split of emissions by geography is as follows:

Scope	Location	tCO2e	% Total emissions	
Scope 1	U.K.	1.56	0%	[1]
	U.S.	4.98	1%	
Scope 2	U.K.	94.21	26%	
	U.S.	265.79	73%	
Total		**366.54**	**100%**	

[1] Indicates amount less than one percent

The group considers that the intensity ratio of tons of carbon dioxide per full-time employee, as a suitable metric for its operations for the years ended December 31, 2023, and 2022 are as follows:

	December 31, 2023		December 31, 2022	
Ratio	**tCO2e /employee**	**Average employees**	**tCO2e /employee**	**Average employees**
Intensity ratio	2.98	123	1.26	90

The tons of carbon dioxide per employee has increased year on year, primarily as a result of an increase in the size of our leased facilities in the United States. Additionally, as we have expanded our facilities and increased headcount, more employees have been able to work from the office and therefore consumed more greenhouse gas emissions than in 2022, when many non-laboratory based employees were still working from home due to space limitations at the prior facilities.

The directors have established that the Nominations and Corporate Governance Committee are to have oversight of the assessment and strategy on how to reduce our energy consumption and thereby reducing our carbon footprint.

Available Information

We maintain an internet website at https://www.Barinthusbio.com/ and make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act of 1934, or the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors," as a source of information about us.

The information on our website is not incorporated by reference into this Annual Report and should not be considered to be a part of this Annual Report. Our website address is included in this Annual Report as an inactive technical reference only.

Item 1A. Risk Factors

Investing in our American Depositary Shares ("ADSs") involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this report, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as our other filings with the Securities and Exchange Commission. Our business, results of operations, financial condition, and prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe to be material. If any of the risks actually occur, our business, results of operations, financial condition, and prospects could be harmed. In that event, the market price of our ADSs could decline, and you could lose part or all of your investment.

Risks Related to Our Financial Position and Capital Needs

We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history, and we are in the early stages of our development efforts. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain marketing authorization and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. We have incurred net losses each year since inception through to December 31, 2021. For the year ended December 31, 2022, we generated net income of $5.3 million, primarily as a result of revenues arising from AstraZeneca sales of Vaxzevria and our agreement with OUI. For the year ended December 31, 2023, we incurred net losses of $73.4 million. As of December 31, 2023 and 2022, we had an accumulated deficit of $176.6 million and $103.2 million, respectively, and we do not currently expect profits or positive cash flows from operations in the foreseeable future. We anticipate that our expenses will increase substantially if, and as we:

- seek marketing authorizations for product candidates that successfully complete clinical trials, if any;
- conduct preclinical studies and clinical trials for our current and future product candidates based on our proprietary biologic and synthetic platforms, including the Chimpanzee Adenovirus Oxford ("ChAdOx") and Modified vaccinia Ankara ("MVA"), vectors, SNAP-TI, SNAP-CI and our other technologies;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- establish our manufacturing capabilities through third parties or by ourselves and scale-up manufacturing to provide adequate supply for clinical trials and commercialization;
- expand, maintain, protect and enforce our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- acquire or in-license other product candidates and technologies; and
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates and we may never generate revenue that is significant or large enough to achieve profitability. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

We have not yet generated any material revenue from our product candidates.

Our ability to become profitable depends upon our ability to generate revenue. We do not expect to generate significant revenue from our current or future product candidates unless or until we successfully complete clinical development and obtain marketing authorization for, and then successfully commercialize, at least one of our product candidates.

Certain of our product candidates are in the preclinical stages of development and will require additional preclinical studies, and all of our product candidates will require additional clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We have not yet administered certain of our product candidates to humans

and, as such, we face significant translational risk as our product candidates advance into and through the clinical stage, as promising results in preclinical studies may not be replicated in subsequent clinical trials, and testing on animals may not accurately predict human experience. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our manufacturing, preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- delays out of our control, such as participant willingness to enroll;
- our ability to complete IND, enabling trials and successfully submit INDs or comparable applications, for our product candidates;
- whether we are required by the FDA, the EMA, or the MHRA or similar foreign regulatory authorities, to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, potency, purity, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates and such regulatory authorities' acceptance of our development strategy;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional approaches, including antivirals, immune modulators, siRNA, CRISPR editing, capsid inhibitors, novel entry inhibitors, or other small molecules, RNA, DNA, nanoparticle, VLP, peptide, protein, whole-killed or other vaccine technologies;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative immunotherapies, therapeutic and prophylactic vaccines and competitive product candidates and technologies; our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if approved;
- our ability to establish, maintain, protect and enforce intellectual property rights in and to our product candidates or any future product candidates;
- the ability of our licensees and collaborators to develop and commercialize our products effectively;
- the risk that some or all of the patients that receive Vaxzevria develop neutralizing antibodies against ChAdOx, which could limit the immunological response from subsequent dosing with one of our product candidates;
- the possibility that immunogenicity may not translate into clinical benefit; and
- the increased costs and complexities associated with manufacturing and
- funding for the development of product candidates contributed by third parties, such as CRUK, CEPI and CanSino, whether spent directly by them or by grant or other funding into our company.

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

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

We may evaluate acquisitions and strategic partnerships in the future, including licensing or acquiring complementary product candidates, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our shareholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates to achieve marketing authorizations; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, we may assume or incur debt obligations, incur large one-time expenses and/or acquire intangible assets that could result in significant future amortization expense.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with no approved products and a limited operating history. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, filing patent applications, identifying potential product candidates, undertaking preclinical studies, in-licensing product candidates for development, and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials, as well as sponsoring and conducting clinical trials up to Phase 2b. We have not yet demonstrated our ability to successfully complete clinical trials beyond Phase 2b, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing current and future product candidates based on our proprietary biologic and synthetic platforms, including the ChAdOx and MVA vectors, SNAP-TI, SNAP-CI and our other technologies through clinical development. Developing and commercializing products for therapeutic indications is expensive, and we do not expect to generate meaningful product revenues in the foreseeable future.

As of December 31, 2023, our cash and cash equivalents were $142.1 million. Based on our current business plan, our management believes that we have sufficient cash to support our operations into the fourth quarter of 2025, without additional financing. Our fundraising efforts to raise additional capital may divert our management from their day-to-day activities, which may adversely affect our ability to develop our platforms. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other

operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to revise our business plan and strategy, which may result in us significantly curtailing, delaying or discontinuing one or more of our clinical trials, decreasing headcount or may result in our being unable to expand our operations or otherwise capitalize on our business opportunities. As a result, our business, financial condition and results of operations could be materially affected.

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

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

To the extent that we raise additional capital through the sale of ordinary shares, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common shareholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

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

We may require substantial additional funding in the future. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our platform and our product candidates developed using our platform. Preclinical studies, clinical trials and additional research and development activities will require substantial funds to complete. We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our preclinical and clinical development activities to identify new product candidates and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

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

We had cash and cash equivalents of $142.1 million as of December 31, 2023. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of preclinical development and clinical trials for our product candidates;
- the extent to which we enter into additional collaboration arrangements with regard to product candidate development or acquire or in-license products or technologies;
- the costs, timing and outcome of regulatory review of our product candidates;

- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, enforcing and protecting our intellectual property rights and defending intellectual property-related claims including litigation costs and any damages awarded in such litigation.

Identifying potential product candidates, manufacturing them and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our ordinary shares or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new product candidates, retain or expand our current levels of personnel, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance our technological infrastructure and our existing solutions;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our ordinary shares. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank was swept into receivership.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have financial arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could

involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delays, inability or reductions in our ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our third-party manufacturers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a third-party manufacturer or supplier may default under their agreements with us, become insolvent or declare bankruptcy, or determine that they will no longer deal with us as a customer. In addition, a third-party manufacturer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any third-party manufacturer or supplier bankruptcy or insolvency, or any breach or default by a third-party manufacturer or supplier, or the loss of any significant third-party manufacturer or supplier relationships, could result in material losses to us and may have a material adverse impact on our business.

Actual payments we may receive in connection with certain milestones or net sales under the AstraZeneca License Agreement may differ from those described in this Annual Report, and there can be no assurance that we will receive any such payments at all.

We received a share of certain milestones and royalties on net sales of certain vaccines under the research collaboration and exclusive worldwide license agreement (the "AstraZeneca License Agreement"), between Oxford University Innovation Limited ("OUI") and AstraZeneca UK Limited ("AstraZeneca"), through to the second quarter of 2023, however there can be no assurance as to the timing or amount of any such milestones or royalties on future net sales.

In particular, we are not party to the AstraZeneca License Agreement, and we do not have any direct claim against AstraZeneca to receive a share of any milestones or net sales, or any other payments under the AstraZeneca License Agreement. Instead, we are party to the amendment, assignment and revenue share agreement, or the OUI License Agreement Amendment, with OUI, to the license agreement we entered into with OUI in March 2016, pursuant to which OUI agreed to pay us approximately 24% of payments, including royalties and milestones, received by OUI in connection with the commercialization of any ChAdOx1 vector-based or ChAdOx2 vector-based vaccine in the field of SARS-CoV2 covered by or disclosed in the assigned patent application. As a result, we will only receive a share of any milestones or royalties paid on net sales of any such vaccine under the AstraZeneca License Agreement if, and to the extent that, OUI receives a share of any such milestones or royalties pursuant to that agreement.

Our understanding of the terms of the AstraZeneca License Agreement is based solely on an extract of the agreement provided by the parties to that agreement. We are not a party to the AstraZeneca License Agreement and do not have access to a copy of that agreement to verify such extract. In addition, no party to the AstraZeneca License Agreement has confirmed that there are no material terms in that agreement that could adversely impact the economic and other terms of the AstraZeneca License Agreement. Moreover, there can be no assurance that the AstraZeneca License Agreement is an enforceable agreement, that the parties thereto will comply with their obligations under the agreement (including any obligations of AstraZeneca to make milestone or royalty payments to OUI), that the agreement will not be terminated pursuant to its terms or otherwise, or that the terms of the agreement (including royalty rates and other economic terms) will not be modified by the parties in the future. Accordingly, these and other factors could cause amounts received by OUI pursuant to the AstraZeneca License Agreement, and accordingly any share of the revenue under that agreement that we may receive, to fluctuate. Any such fluctuations could be material. Additionally, our understanding of the terms of the AstraZeneca License Agreement is that AstraZeneca is required to notify OUI of OUI's shares of milestone and royalty payments within 30 days following the close of a fiscal quarter. OUI is then required to notify us of our share of the payments within 30 days after the end of a quarter when OUI received such milestone or royalty payments from AstraZeneca. If the required notifications are not made in accordance with the terms of the agreements, we may not be able to recognize revenue in the period in which it is earned.

In addition, the announcement of adverse events observed in individuals who receive Vaxzevria and any negative impact on the perceptions of Vaxzevria safety may reduce sales of the vaccine and AstraZeneca may decide not to market Vaxzevria, and therefore reduce the potential payments that we would receive from royalties paid on net sales of Vaxzevria. Any association of Vaxzevria with adverse events, or the perception of such association, may otherwise adversely impact the development of, and our ability to commercialize, any of our product candidates.

Risks Related to Our Business and Industry and Risks Related to Clinical Development

If we are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval or reimbursement and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

All of our product candidates are in early stages of development, including our lead product candidates VTP-300 and VTP-200, and as such will require extensive preclinical and clinical testing, as applicable. Product candidates may not meet targeted clinical or safety endpoints during clinical trials such as the MVA-based influenza vaccine candidate, VTP-100, which did not meet defined primary clinical endpoints in two concurrent Phase 2b trials and we subsequently discontinued further development of this program. Our product candidate VTP-1100 in HPV cancer was paused in January 2024 to prioritize the other pipeline candidates already in the clinic, and the advancement of VTP-1100 may depend on our ability to fund or how we prioritize our pipeline. Our ability to generate product revenues, which we do not expect to occur for several years, if ever, will depend heavily on the successful development and eventual commercialization or out-license of the product candidates we develop, which may never occur. Before we are able to generate any revenues from product sales, our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of preclinical, clinical, and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts. The success of our current and future product candidates will depend on several factors, including the following:

- successful completion, with sufficient safety and efficacy profiles, of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs or equivalent clinical trial authorizations in other regions for our planned clinical trials or future clinical trials;
- successful enrollment and completion of our ongoing and future clinical trials;
- sufficient data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of marketing authorizations from applicable regulatory authorities;
- scale-up of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization;
- establishing our own manufacturing capabilities or agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- ability to develop product candidate designs and formulations that provide sufficient genetic and thermal stability for long term storage and shipment to meet market requirements;

- entry into collaborations, where needed, to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of the product candidate's benefits and uses, if and when approved, by patients, the medical community and third- party payors;
- the prevalence and severity of adverse events experienced with our product candidates;
- maintaining a continued acceptable benefit/risk profile of the product candidates following authorization;
- effectively competing with other therapies, including new therapies that may be developed and approved;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- qualifying for, maintaining, enforcing, and defending intellectual property rights and claims; and
- the risk that foreign regulatory authorities may not authorize our clinical trial protocols and other clinical trial documentation, including manufacturing documentation, even when previously authorized by the FDA, EMA or MHRA, which could lead to a delay in starting such clinical trials. For example, our HBV002 clinical trial conducted in South Korea experienced delays due to additional regulatory review of our clinical protocol. We have limited experience obtaining such approvals in foreign jurisdictions and therefore may need more time to navigate the regulatory process as a result.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. We have no control over third-party use of ChAdOx and MVA technologies outside of our exclusively licensed field under license from OUI, and such third-party use could have a negative impact on our ability to develop current and future product candidates, which would materially harm our business.

Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support marketing authorization of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- new treatments may become standard of care during the process of completing a clinical trial, which may impact the initial clinical trial design or future patient care pathways;
- significant changes in relevant regulatory requirements may cause a delay in the start of a clinical trial, due to additional requirements needing to be met;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- clinical trials of our product candidates may not produce differentiated or clinically significant results across infectious diseases, cancers and autoimmune diseases;

- the number of participants required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient or timely product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;

- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experience delays or challenges in identifying participants with the eligibility criteria required for our clinical trials, we may have to reimburse sites for the cost of testing of additional participants in order to encourage enrollment of additional participants;

- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;

- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and

- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

In addition, the ChAdOx vectors are currently being evaluated in clinical trials outside of our licensed fields conducted by Oxford and other third parties to which OUI has granted licenses. We have no control over these other clinical trials and any adverse results in these clinical trials could impact public perception and regulatory approval of our product candidates. Even after any of our product candidates obtain regulatory marketing authorization, the announcement of adverse events observed in individuals who receive these products may impact public perception and may result in increased regulatory scrutiny across our platform. For example, in March 2021, several countries announced plans to either temporarily suspend the use of a particular batch of Vaxzevria or the use of Vaxzevria altogether following reports of very rare thromboembolic events in people following vaccination. While the EMA subsequently issued an update confirming the overall risk-benefit profile of Vaxzevria remains positive, and Vaxzevria later received full marketing authorization in the EU in November 2022, the applicable regulatory authorities continue to assess available safety data as Vaxzevria continues to be administered and have made recommendations regarding updates to the vaccine's labeling and use in certain populations. These recommendations may continue to evolve, and these types of announcements may affect public perception of the safety of Vaxzevria, which may extend to product candidates we are developing. Other very rare events have been reported in people who have received Vaxzevria, including thrombocytopenia (low platelet numbers in the blood), capillary leak syndrome, and neurological syndromes such as Guillain Barre Syndrome and transverse myelitis. Perception about the efficacy of Vaxzevria, such as its effectiveness against emerging COVID-19 variants, may also impact perception of our product candidates. Additionally, these announcements may lead to additional inquiries or scrutiny from regulators on whether similar safety or efficacy signals have been observed with our other candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs, or ethics committees of the institutions in which such clinical trials are being conducted, or by the FDA or other regulatory authorities, or suspended or terminated based on recommendations by the Data Safety Monitoring Board or equivalent for such clinical trial.

Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, any disclosure of negative data of clinical trials being conducted by our collaborators could have an adverse impact on our business.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the clinical trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of any preclinical study or clinical trial of our product candidates, or our preclinical studies or clinical trials are terminated, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and authorization procedure and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing authorization for our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline may have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the more complete data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies or clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our ADSs.

In addition, the ChAdOx vectors are currently being evaluated in clinical trials conducted by Oxford and other third parties to which Oxford has granted licenses. We have no control over these other clinical trials and any adverse results in these clinical trials could impact public perception and regulatory approval of our product candidates. The information these third parties choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and shareholders may not agree with what these third parties determine is material or otherwise appropriate information to include in their disclosure. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and shareholders may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from more complete results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our product candidates are based on a novel approach to the treatment of infectious disease, autoimmunity and cancer, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated our research and development efforts on components of our proprietary platforms to develop product candidates that stimulate powerful, targeted immune responses against pathogens and tumor cells, which is a novel approach. Our future success depends on the successful development of these platforms. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA or foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA,

there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing other testing and manufacturing methods, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of novel immunotherapies. Any novel immunotherapies that are approved may be subject to extensive post- approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

Difficulty in enrolling participants could delay or prevent clinical trials of our product candidates and prevent us from realizing the full commercial potential of any products we may develop.

Identifying and qualifying participants to participate in clinical trials of our product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit participants to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible participants to participate in these trials as required by the FDA, the EMA or other foreign regulatory authorities. For example, randomized clinical controlled trials for MERS are difficult due to the sporadic and low incidence of cases. Our ability to enroll participants may be significantly delayed when potential participants for our clinical trials have had previous exposure to the ChAdOx1 vector, as we may not be able to enroll these individuals in a clinical trial or their enrollment may be delayed due to the concern that neutralizing antibodies might be present for some time after ChAdOx exposure. For example, we may not be able to enroll or may need to delay the enrollment of potential subjects who received the Vaxzevria vaccine. Although we believe the presence and impact of such neutralizing antibodies is transient, we do not have full data on this yet and our assessment may change. The initiation of our Phase 1/2a clinical trial for VTP-200, our Phase 1b/2a clinical trial for VTP-300 and our Phase 1/2a clinical trial for VTP-600, were delayed due to COVID-19. We cannot anticipate the next pandemic or how that may or may not impact future clinical trial enrollment. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and participants who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

The enrollment of patients and participants further depends on many factors, including:

- the phase of clinical testing;
- the proximity of participants to clinical trial sites;
- the increased inconvenience to patients by participating in a clinical trial, such as increased doctor visits, missed work, travel costs and time;
- the design of the clinical trial, including the number of site visits, whether the clinical trial includes a placebo arm and invasive assessments required;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain participant consents;
- reporting of the preliminary results of any of our clinical trials;
- the risk that some or all of the patients that receive Vaxzevria develop neutralizing antibodies against ChAdOx, which could limit the immunogenicity from subsequent dosing with one of our product candidates;
- the risk that participants enrolled in clinical trials will drop out of the clinical trials before clinical trial completion; and
- factors we may not be able to control, such as potential pandemics that may limit participants, principal investigators or staff or clinical site availability (*e.g.*, the COVID-19 pandemic).

Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of participants who are available for our clinical trials at such clinical trial sites. Moreover, because certain of our product candidates represent a departure from more commonly used methods for treatment of disease, particularly in cancer, and because certain of our product candidates have not been tested in humans before, potential participants and their doctors may be inclined to use conventional therapies, rather than enroll participants in a future clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented.

Our product candidates may cause serious adverse events, serious side effects or have other properties that could halt their clinical development, prevent their marketing authorization, require expansion of the trial size, limit their commercial potential or result in significant negative consequences.

Serious side effects caused by our product candidates could cause us or regulatory authorities, including IRBs and ethics committees, to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing authorization by the FDA, the EMA or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. Because of our dose escalation design for our clinical trials, undesirable side effects in initial cohorts could also result in the need to expand the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, because certain of our product candidates, including Vaxzevria, have been administered to substantial numbers of participants on a more rapid basis than is standard in clinical trials, undesirable side effects could result in a negative impact across a larger participant population. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. If we do observe serious side effects in our clinical trials, our ongoing clinical trials may be halted or put on clinical hold prior to completion if there is an unacceptable safety risk for participants.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the EMA or other comparable foreign regulatory authorities, or local regulatory authorities such as IRBs or ethics committees, could order us to cease clinical trials. Competent national health authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Even if the side effects presented do not preclude the product from obtaining or maintaining marketing authorization, treatment-related side effects could also affect participant recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.

We intend to develop certain of our product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop certain of our product candidates in combination with one or more other approved therapies, such as anti-PD-1 antibodies and other checkpoint inhibitors to treat certain cancers and chronic infections. Even if any product candidate we develop were to receive marketing authorization or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, the EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current product candidates and any other future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, the EMA or comparable foreign regulatory authorities. We will not be able to market and sell our current product candidates or any product candidate we develop in combination with any unapproved therapies for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA, the EMA or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the products we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

Risks Related to Our Approach

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

Cancer therapies are sometimes characterized by line of therapy (first line, second line, third line, fourth line, etc.), and the regulatory authorities, including the FDA, often approve new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone

therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to seek approval of VTP-600 as a component of first line therapy but we expect to seek approval of our other oncology product candidates initially as second or third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial as third line or second line therapies, if any, we would expect to seek approval as earlier line therapies, but there is no guarantee that our product candidates, even if approved as a second or third line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the infectious diseases and cancers we are targeting, as well as the subset of people with these infectious diseases and cancers in a position to receive a particular line of 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, commissioned reports, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of these cancers and chronic infections. The number of patients may turn out to be lower 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 within our addressable patient population, because the potential target populations are small, we may never achieve profitability without obtaining marketing authorization for additional indications, including use as first or second line therapy.

Negative developments in the fields of infectious disease and immuno-oncology could damage public perception of any of our product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of immunotherapies and viral vector-based antigen-delivery platforms. Adverse events in clinical trials of VTP-300 and VTP-200, or in clinical trials of similar products developed by others and the resulting publicity, as well as any other negative developments in the field of infectious disease and immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for any product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial participants may be discouraged from enrolling in our clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain marketing authorization or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, prospects and results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Our present product candidates consist of modified viruses. Adverse developments in clinical trials of other immunotherapy products based on viruses, such as oncolytic viruses, may result in a disproportionately negative effect for our platform as compared to other products in the field of infectious disease and immuno-oncology that are not based on viruses. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates.

We may not be successful in our efforts to identify and successfully commercialize additional product candidates.

Part of our strategy involves researching and developing novel product candidates. We have developed a pipeline of product candidates and intend to pursue clinical development of additional product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;

- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

Developing, obtaining marketing authorization for and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

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

We may choose to focus our efforts on and allocate resources to a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we are unable to evaluate the commercial potential or target market for a particular product candidate, identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

Risks Related to Sales, Marketing and Competition

We face substantial competition in an environment of rapid technological change, which may result in others discovering, developing, obtaining marketing authorization approval or commercializing products before or more successfully than we do, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates.

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, platform technology and development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, as well as public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, marketing authorizations and product marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Specifically, we expect that our product candidates will compete against alternative or more conventional approaches, including antivirals, immune modulators, antisense oligonucleotides, siRNA, CRISPR editing, capsid inhibitors, novel entry inhibitors, or other small molecules, RNA, DNA, nanoparticle, VLP, peptide, protein, whole-killed vaccines or other technologies.

If our product candidates are approved for the indications for which we are currently conducting or planning clinical trials, they will likely compete with the competitor products mentioned above and with other products that are currently in development. Key product features that would affect our ability to effectively compete with other therapeutics include the safety, efficacy, formulation, stability, and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain marketing authorizations from the FDA or other regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Risks Related to the Development of Our Product Candidates

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency, purity, and efficacy of any of our product candidates, which would prevent or delay development, marketing authorization and commercialization. Furthermore, success in preclinical studies or clinical trials may not be indicative of results in future clinical trials for the same or other product candidates.

Before obtaining marketing authorization for the commercial sale of our product candidates, we must demonstrate the safety, purity and potency of our investigational biologics for use in each target indication through lengthy, complex and expensive preclinical studies and clinical trials. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired risk-benefit profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. VTP-100 demonstrated tolerability and immunogenicity during small Phase 1 clinical trials but did not demonstrate sufficient clinical activity during adequately powered Phase 2b clinical trials to warrant continued development of this product candidate. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later phase clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. The vast majority of product candidates that commence preclinical studies and early phase clinical trials are never approved as products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency, purity and efficacy necessary to obtain regulatory authorization to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, potency, purity, and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing authorization for certain of our product candidates. In some instances, there can be significant variability in safety, potency, purity, or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. While we have not yet initiated clinical trials for certain of our product candidates, such as VTP-1000, and are in early stages of clinical trials for certain of our product candidates, VTP-300, VTP-500, VTP-200, VTP-400, VTP-850 and VTP-600, as is the case with all novel immunotherapeutics and viral-vector based antigen-delivery platforms, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny authorization of certain of our product candidates for any or all targeted indications. Treatment-related side effects could also affect participant recruitment or the ability of enrolled participants to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Even if we obtain marketing authorization for our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of novel immunotherapeutics, nanoparticle and viral-vector based product candidates to target the treatment and prevention of infectious diseases, and cancer and autoimmune diseases is a recent development and may not become

broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments, including the adoption of our treatment as the standard of care;
- our ability to demonstrate the advantages of our product candidates over other vaccines and cancer, or chronic infectious disease or immune tolerance disease medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other immunotherapeutics and public perception of other immunotherapeutics;
- the prevalence and severity of any side effects for other viral-vector based antigen-delivery platforms and public perception of other viral-vector based antigen-delivery platforms;
- The prevalence and severity of any side effects for other nanoparticle-based therapeutics and public perception of other nanoparticle-based therapeutics
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the approved labeling;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other immunotherapeutic and viral-vector based approaches, serious adverse events or deaths in other clinical trials involving immunotherapeutic and viral-vector based product candidates, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

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

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

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

and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch.

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to conduct certain of our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain marketing authorizations for, or commercialize, our product candidates and our business could be substantially harmed.

We utilize and depend, and expect to continue to utilize and depend, upon independent investigators and collaborators, such as medical institutions, contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and strategic partners to conduct and support certain of our preclinical studies and clinical trials under agreements with us. For example, we are dependent on our regional partner, CanSino Biologics, to conduct a Phase 1 clinical trial of VTP-400 for herpes zoster prevention.

We expect to have to continue to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development.

Regulatory authorities enforce GCP 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 MMAs. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test participants. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of participants may require us to repeat clinical trials, which would delay the marketing authorization process.

Moreover, our business may be implicated if any of these third parties performing services or otherwise acting on our behalf violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

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

We may form or seek additional strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

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

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- despite agreements, collaborators may develop our product candidates to standards that only meet their local regulatory requirements and therefore clinical data cannot be applied in support regulatory submissions in other jurisdictions;
- collaborators in certain countries may require joint ventures to manufactures and commercialize products in their territory, which may increase costs, increase dilution to shareholders, and offer lack of clarity on revenue and intellectual property sharing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;

- collaboration and grant funding agreements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and

- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or third parties to manufacture our product candidates, if approved. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet manufactured our product candidates on a commercial scale and may not be able to do so for any of our product candidates.

Manufacturing of biologic and synthetic products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up, validating the production process and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including lot consistency, stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- the production process for our product candidates is complex and requires specific know-how that only a limited number of CMOs can provide, as a result, we compete with other companies in the field for the scarce capacities of these organizations and may not be able to secure sufficient manufacturing capacity when needed;

- we may be unable to identify manufacturers on acceptable terms, or at all because the number of potential manufacturers is limited and the FDA or other regulatory authorities may inspect any manufacturers for current cGMP compliance as part of our marketing application;

- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;

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

- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;

- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates 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, if any;

- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign

standards and we have no 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 product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- our third-party manufacturers may prioritize another customer's needs in front of ours, especially in the event of a global pandemic;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects, may be in short supply, and may significantly increase in price;
- our contract manufacturers and critical suppliers may be subject to inclement weather, pandemics, as well as natural or man- made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

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

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, EMA or other appropriate regulatory authorities and result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification 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 and the FDA, or other regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

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

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

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

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

Risks Related to Government Regulation

The marketing authorization processes of the FDA, the EMA, MHRA and other comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain marketing authorizations for our product candidates, or the marketing authorization is for a narrower indication than we seek, our business will be substantially harmed.

The time required to obtain marketing approval from the FDA, the EMA, MHRA and other comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not yet obtained a marketing authorization for any product candidate and it is possible that none of our current or future product candidates will ever obtain marketing authorizations.

Our current and future product candidates could fail to receive marketing authorizations for many reasons, including the following:

- the availability of financial resources to commence and complete planned clinical trials;
- the FDA, the EMA, MHRA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics Licensing Application ("BLA") to the FDA, or an MAA to the EMA or other comparable submission to regulatory authorities in other regions, to obtain authorization in the United States, the European Union, or elsewhere;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA, MHRA or regulatory authorities in other regions that a product candidate has an overall suitable benefit/risk profile for its proposed indication;
- the FDA, the EMA, MHRA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA, the EMA, MHRA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- the risk that foreign regulatory authorities may not authorize our clinical trial protocols and other clinical trial documentation, including manufacturing documentation, even when previously authorized by the FDA, EMA or MHRA, which could lead to a delay in starting such clinical trials. For example, the conduct of our HBV002 clinical trial in South Korea experienced delays due to additional regulatory review of our clinical protocol. We have limited experience obtaining such approvals in foreign jurisdictions and therefore may need more time to navigate the regulatory process as a result.

The unpredictability of clinical trial results may result in our failing to obtain marketing authorizations for any product candidate we develop, which would significantly harm our business, results of operations and prospects. The lengthy approval process in many regions may cause delays in market access, particularly if regulatory authorities have a large number of objections to the initial applications for marketing authorization which need to be addressed.

We have conducted, and intend to conduct, clinical trials of certain of our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data are

subject to certain conditions imposed by the FDA, including compliance with all applicable U.S. laws and regulations. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP, including review and approval by an independent ethics committee and informed consent from participants. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the participant population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. There can be no assurance the FDA will accept data from trials conducted outside of the United States.

The FDA, the EMA and other comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether marketing authorization will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA, MHRA or any other comparable foreign regulatory authorities.

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

We may seek Orphan Drug Designation for drug candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity. In addition, even if we obtain orphan drug exclusivity for any of our product candidates, such exclusivity may not protect us from competition.

As part of our business strategy, we may seek Orphan Drug Designation for any drug candidates we develop, and we may be unsuccessful in obtaining such designation. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the EU, the European Commission grants designation after receiving the opinion of the Committee for Orphan Medicinal Products on a designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating, or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

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

Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the drug candidate from competition because different therapies can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug candidate nor gives the drug candidate any advantage in the regulatory review or approval process. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. While we may seek Orphan Drug Designation for applicable indications for our current and any future drug candidates, we

may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

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

We may seek Breakthrough Therapy designation for certain of our current and future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, defined as those that measure an effect on irreversible morbidity or mortality or on symptoms that represent serious consequences of the disease. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

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

A Fast Track designation by the FDA, even if granted for certain of our current or future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for certain of our current or future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

Accelerated approval by the FDA, even if granted for certain of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of certain of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update FDA on the status of these studies, and under FDORA, the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. In addition, the FDA currently requires sponsors, unless otherwise informed by the agency, to request pre-approval of promotional materials for products receiving Accelerated Approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

If approved, our investigational products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

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

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

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Even if we obtain FDA, EMA or MHRA approval for our current or future product candidates that we may identify and pursue in the United States, Europe or the United Kingdom, we may never obtain approval to commercialize any such product candidates outside of those jurisdictions, including in Asian markets wherein we intend to commercialize VTP-300, which would limit our ability to realize their full market potential.

Obtaining and maintaining marketing authorization for our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing authorizations in any other jurisdiction, while a failure or delay in obtaining marketing authorization in one jurisdiction may have a negative effect on the approval process in others. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign marketing authorization could result in difficulties and costs and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our current or future product candidates in those countries. The foreign marketing authorization process may include all of the risks associated with obtaining FDA, EMA or MHRA approval, in addition to country-specific risks and challenges. For example, we are developing VTP-300 for chronic hepatitis B, which is most prevalent in China and other countries in Asia. We have limited development experience in this market and we may need to rely on a local, third-party partner to help us navigate the applicable regulatory requirements. Additionally, governments in this target market may deem the eradication of HBV infections to be a national priority which could impact the framework for available reimbursement or our ability to achieve a standard commercial return based on the value of our product, if approved. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining marketing authorizations in international markets for our current or future product candidates. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if marketing authorization in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our current or future product candidates will be harmed.

Future changes to tax laws could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders.

We conduct business globally and file tax returns in multiple jurisdictions. The tax treatment of the Company or any of the group companies could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration (such as those related to the Organization for Economic Co-Operation and Development's Base Erosion and Profit Shifting 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 (which may be retroactive) may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which we operate, could affect our financial position, future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders and increase the complexity, burden and cost of tax compliance.

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

We operate in a number of countries throughout the world. Consequently, we are subject to tax laws, treaties, and regulations in the countries in which we operate, and these laws and treaties are subject to interpretation. We have taken, and will continue to take, tax positions based on our interpretation of such tax laws. A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example HMRC, the IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. There can be no assurance that a taxing authority will not have a different interpretation of applicable law and assess us with additional taxes. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material tax liabilities, interest and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable, or result in other liabilities. If we are assessed with additional taxes, this may result in a material adverse effect on our results of operations and/or financial condition.

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

As a U.K. incorporated and tax resident entity, we are subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since inception and therefore have not paid any U.K. corporation tax. As of December 31, 2023, we had cumulative carryforward tax losses of approximately $92.7 million (December 31, 2022: $39.6 million). Subject to any relevant criteria and restrictions (including those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half of our ordinary shares and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits, if any. The use of loss carryforwards in relation to U.K. profits incurred on or after April 1, 2017 is generally limited each year to £5.0 million plus an incremental 50% of U.K. taxable profits.

As a company that carries out extensive research and development activities, we seek to benefit from the U.K. research and development tax relief programs, being the Small and Medium-sized Enterprises R&D tax relief program, or SME Program, and, to the extent that our projects are grant funded or relate to work subcontracted to us by third parties, the Research and Development Expenditure Credit program. Under the SME Program, where available, we may be able to surrender some of our trading losses that arise from our qualifying research and development activities for cash or carry forward such losses for potential offset against future profits (subject to relevant restrictions). The majority of our research, clinical trials management and manufacturing development activities are eligible for inclusion within these tax credit cash rebate claims. Our eligibility to claim payable research and development tax credits may be limited or eliminated because we may no longer qualify as a small or medium-sized company. In addition, the SME Program has been amended by the Finance Act 2021 which came into force in April 2021. This legislation introduced a cap on claims under the SME Program to a multiple of payroll taxes (broadly, to a maximum payable credit equal to £20,000 plus three times the total PAYE and NICs liability of the company) subject to an exception which prevents the cap from applying. That exception requires the company to be creating, taking steps to create or managing intellectual property, as well as having qualifying research and development expenditure in respect of connected parties which does not exceed 15% of the total claimed. If such exception does not apply, this could restrict the amount of payable credit that we claim.

Changes to the U.K. R&D tax relief legislation that have been recently enacted or proposed, and which took effect from April 2023, reduce the R&D cash rebate rate under the SME Program, and may introduce restrictions on relief that may be claimed for expenditure on sub-contracted R&D activity, broadly requiring either that workers carrying on such activity are subject to U.K. PAYE or, where work is undertaken outside the U.K., that this must be due to geographical, environmental, social or other conditions that: (i) are not present in the U.K.; and (ii) it would be wholly unreasonable to replicate in the U.K. This rate reduction and any proposed restrictions may impact the quantum of R&D relief that we are able to claim in the future. In addition, the U.K. government is currently consulting on the potential replacement of the SME Program and RDEC Program with a single program, operating similarly to the RDEC Program, which may, inter alia, change the present treatment of sub-contracted R&D work and introduce different thresholds and caps on expenditure and relief. If enacted, the new program would be expected to have effect for expenditure incurred from April 2024 onwards, and could have a material impact on the quantum of R&D relief that we are eligible to claim. This announcement also saw the introduction of a higher rate of relief for loss-making R&D-intensive small and medium enterprises, the SME Intensive Scheme.

Companies claiming under the existing SME Intensive Scheme tax relief will be eligible for a higher payable credit rate if they meet the definition for R&D intensity. We will assess if we can claim under the new loss-making R&D-intensive SME Intensive Scheme for the accounting period ending December 31, 2024 and future periods, which will provide benefits consistent with those claimed under the current SME Programs.

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

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

Risks Related to Ongoing Regulatory Obligations

Even if we receive marketing authorization for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

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

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

Additionally, under FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit

or delay marketing authorization of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

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

The insurance coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for any of our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our or their commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval. See section entitled "Business – Government Regulation – Coverage and Reimbursement."

Our ability to successfully commercialize our product candidates or any other products that we or they may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within the HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs and commercial payors are critical to new product acceptance. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;

- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and certain other major markets where we plan to commercialize may put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems, and pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, efforts by governmental and other third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. Many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. As a result, increasingly high barriers are being erected to the entry of new products.

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

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

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product candidate. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be modified or invalidated. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs, and could have a material adverse effect on our business, financial condition, and results of operations.

Our business activities will be subject to the Foreign Corrupt Practices Act ("FCPA"), and similar anti-bribery and anti- corruption laws in other jurisdictions.

As we engage in and expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or the SEC, and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

For example, over the last several years the U.S. government has shut down several times and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Healthcare providers, including physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various U.S. federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the AKS, the federal civil and criminal false claims laws, and the law commonly referred to as the Sunshine Act, along with regulations promulgated under such laws. These laws impact, among other things, our clinical research activities, proposed sales, marketing and educational programs, and other arrangements and relationships with third-party payors, healthcare professionals, and other parties through which we market, sell and distribute our product candidates for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). See section entitled "Business – Government Regulation – Other Healthcare Laws and Compliance Requirements."

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

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

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

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, CROs or CMOs, principal investigators, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the regulations of the FDA and other comparable foreign regulatory bodies, provide true, complete and accurate information to the FDA and other comparable foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Misconduct by persons acting on our behalf could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our collaborators and third-party providers are subject to national, supranational, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security. With respect to Europe, the collection and processing of personal data regarding (i) individuals in the EEA and UK, and/or (ii) carried out in the context of the activities of our establishments in the EEA or UK, is subject to the GDPR, as well as other national data protection legislation in force in relevant EEA member states and the UK, (including the UK Data Protection Act 2018).

The GDPR is wide-ranging in scope and impose numerous obligations 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, requiring data protection impact assessments for high risk processing and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR also provides individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection. The GDPR defines personal data to include pseudonymized or coded data and require different informed consent practices and more detailed notices for clinical trial participants and investigators than applies to clinical trials conducted in the United States. We are required to apply GDPR standards to any clinical trials that our EEA and UK established businesses carry out anywhere in the world.

The GDPR impose strict rules on the transfer of personal data to countries outside the EEA and UK, including the United States in certain circumstances, unless a derogation exists or we incorporate a GDPR transfer mechanism (such as the European Commission approved standard contractual clauses ("SCCs") or the UK International Data Transfer Addendum

("IDTA")) into our agreements with third parties to govern such transfers of personal data and carry out transfer impact assessments to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal information under the GDPR, including an analysis of the laws in the recipient's country. Carrying out such restricted transfers, therefore, comes with a significant compliance burden, requiring significant effort and expense to overcome. Failure to implement valid mechanisms for personal data transfers from Europe may result in increased exposure to regulatory actions, substantial fines, and injunctions against processing personal data from Europe. If we are unable to export personal data, this may also restrict our activities outside of Europe and require us to increase processing capabilities within Europe at significant expense or otherwise segregate our systems and operations. Switzerland has adopted similar transfer restrictions as under the GDPR. Although the UK is regarded as a third country under the EU GDPR, the European Commission issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. Personal data transfers from the UK to the EEA remain free flowing by virtue of a UK government adequacy decision.

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

The UK's data protection regime is independent from but aligned to the EU's data protection regime. However following the Brexit, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these territories. For example, the UK has recently introduced a new Data Protection & Digital Information (No. 2) Bill, or the Data Reform Bill into the UK legislative process with the intention for this bill to reform the UK's data protection regime following Brexit. if passed, the Data Reform Bill could reshape the UK's data protection regime, distancing it from the EU's data protection regime and threaten the UK's adequacy decision from the EC. This lack of clarity on future UK laws and regulations and their interaction with those of the EU could add legal risk, uncertainty, complexity, and cost to our handling of European personal data and our privacy and security compliance programs; and any resulting divergence in laws could increase our risk profile and may require us to implement different compliance measures for the UK and EEA.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (*e.g.*, Section 5 of the FTCA), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. For example, California recently enacted the CCPA which became effective on January 1, 2020. 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. US states are constantly amending existing laws, requiring attention to frequently changing regulatory requirements. At this time, we do not collect personal data on residents of California but should we begin to do so, and in the context of doing so, become subject to the CCPA, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

In addition to the CCPA, a California ballot initiative, the CPRA, was passed in November 2020. Effective as of January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

Some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. For example, on January 1, 2023, the CDPA became effective. Further, many additional United States state privacy laws will go into effect throughout 2023: the CPA (July 1, 2023); the CTDPA (July 1, 2023); and the UCPA (December 31, 2023). The CDPA, CPA, CTDPA, and UCPA are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and information governed by HIPAA. Any of these laws may broaden their scope in the future, and similar laws have been proposed on both a federal level and in more than half of the states in the United States. While the CDPA, CPA, CTDPA, and UCPA incorporate many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the laws that will change the operational practices of regulated businesses. The new laws will, among other things, impact how regulated

businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

A number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

In addition to general privacy and data protection requirements, many jurisdictions around the world have adopted legislation that regulates how businesses operate online and enforces information security, including measures relating to privacy, data security and data breaches. Many of these laws require businesses to notify data breaches to the regulators and/or data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome.

In many jurisdictions, enforcement actions and consequences for non-compliance with protection, privacy and information security laws and regulations are rising. In the EU and the UK, data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to €20 million (£17.5 million in the UK) or 4% of annual global revenue, whichever is greater. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non-compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws. In the United States, possible consequences for non-compliance include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies.

In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs.

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

Compliance with 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. It could also require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Failure by us or our collaborators and third-party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and orders preventing us from processing personal data), private litigation and result in significant fines and penalties against us. Moreover, clinical trial participants about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by in-licensing intellectual property relating to our platform technology and filing patent applications relating to our technologies that are important to our business. If we or our licensors are unable to obtain or maintain patent protection with respect to our product candidates, our competitive position, business, financial conditions, results of operations, and prospects could be materially harmed. We do not own any issued patents with respect to our product candidates and rely primarily on in-licensed patents and patent applications. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. Failure to obtain issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. In addition, it is uncertain whether the World Trade Organization ("WTO") will waive certain intellectual property protections now or in the future on certain technologies. It is unknown if such a waiver would be limited to patents, or would include other forms of intellectual property including trade secrets and confidential know-how. We cannot be certain that any of our current or future product candidates or technologies would not be subject to an intellectual property waiver by the WTO. We also cannot be certain that any of our current or future intellectual property rights, whether patents, trade secrets, or confidential know-how would be eliminated, narrowed, or weakened by such a waiver. Given the uncertain future actions by the WTO and other countries and jurisdictions around the world, including the United States, it is unpredictable how our current or future intellectual property rights or how our current or future business would be impacted. With respect to both our in-licensed and owned intellectual property, we cannot predict whether the patent applications that we and our licensors are currently pursuing or that we may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

The patent prosecution process is expensive, time-consuming, and complex, and we and our licensors may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may become subject to a third party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings and other similar proceedings 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 products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others and if we fail to comply with our current or future obligations in any agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates. These and other future agreements impose, and may continue to impose, numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution and enforcement obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our current and future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. For example, we do not control the preparation, filing, prosecution or maintenance of patents in-licensed from OUI. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

Any termination of these licenses, or any failure of the underlying patents to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our product candidates, and competitors or other third parties would have the freedom to seek marketing authorization for, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships and the amount of fees payable as a result of sublicensing arrangements;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and/or us and/or our partners.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

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

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors and other third parties may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be materially and adversely harmed. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties,

we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful and could have a material adverse effect on our business, financial conditions, results of operations and prospects.

The intellectual property landscape around immunotherapeutic, nanoparticle and viral vector-based products is crowded and dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights and such claims may be costly and time-consuming and may prevent or delay our product discovery and development efforts.

The intellectual property landscape around immunotherapeutic, nanoparticle and viral vector-based products is crowded and dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review, and post-grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our licensors or strategic partners may be party to, exposed to, or threatened with, adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of viral vectors and vaccines or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. For example, we are aware of third-party patents in the United States and Europe with claims which may be relevant to our VTP-300 and VTP-850 product candidates. In the event that these patents were asserted against us in an infringement action, we may have to argue that the manufacture, use, sale or importation of our VTP-300 or VTP-850 product candidates in the United States and Europe do not infringe any valid claim of the asserted patents. There is no assurance that a court would find in our favor on questions of infringement or validity.

If a third party (including any third party that controls the above referenced patents) claims that we infringe, misappropriate or otherwise violate its intellectual property rights (including the above referenced patents), we may face a number of risks, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do, on commercially reasonable terms, or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our product candidates or processes so they do not infringe, misappropriate or violate third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our share price.

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

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

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

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

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

We currently have rights to intellectual property, through licenses from third parties, to develop and commercialize our product candidates. Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the field of infectious disease, immune tolerance and oncology and filing patent applications potentially relevant

to our business. Because our current and future product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require particular vector components or gene sequences encoding antigenic peptides to work effectively and efficiently and these rights may be held by others. Similarly, efficient production, delivery or use of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others.

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

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

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

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

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may in-license or own in the future. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require

us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices, where our foreign patents are challenged. For example, one of our in-licensed European patents relating to our now discontinued MVA influenza product candidate has been revoked in a European opposition proceeding. This decision is currently on appeal, although there can be no assurance that any such appeal will be successful. The costs of opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

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

If we or our licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our in-licensed patent applications or patents or any patent applications or patents we may own in the future in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we in-license or may own in the future, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

We have received confidential and proprietary information from third parties. In addition, as is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information or trade secrets of these third parties. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation or arbitration may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims and possible aftermath could result in substantial cost and be a distraction to our management and employees. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our share price. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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 that provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property, we may be unsuccessful in executing such an agreement with each party who, in fact, develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

Recent or future patent reform legislation could also increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we in-license or may own in the future. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act ("America Invents Act"), was signed into law, which includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, establish a new post-grant review system and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our patent applications or any patents we may own or in-license. These changes also allow third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents we in-license or may own in the future, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our European patents and patent applications could be challenged in the recently created Unified Patent Court (UPC) for the European Union, that is expected to be fully ratified in 2023. We may decide to opt out our European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. A successful invalidity challenge to a European patent under the UPC would result in loss of patent protection in those European countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of

patent protection in numerous European countries, rather than in each validated European country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, our intellectual property license agreements may not always include worldwide rights. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. As a result, in response to the COVID-19 pandemic, it is possible that certain countries may take steps to facilitate compulsory licenses that permit the distribution of a COVID-19 vaccine in those countries. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the relevant patent rights. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

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

Our trademarks or trade names may be challenged, infringed or diluted, lapsed, abandoned, circumvented or declared generic or determined to be infringing on or become dilutive of other marks, or otherwise invalidated through administrative process or litigation. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. Third parties may use trademarks similar to our trademarks and any potential confusion as to the source of goods or services could have an adverse effect on our business. For example, in April 2022, we received a letter asserting that our use of our "Vaccitech" trademark infringes a United Kingdom trademark held by a third party. We timely responded rejecting the claims and we believe that such claims are without merit. However, if such third party continues to assert its claims, we cannot provide any assurance whether we could reach a settlement relating to such claims or whether we would prevail in any litigation or action related to such claims.

Moreover, during the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademarks. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, at the USPTO and at comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks through opposition or cancellation proceedings against our trademarks, and if such third parties are successful, our trademarks may not survive such proceedings. In some cases, there may be third-party trademark owners who have prior rights to our trademarks or third parties who have prior rights to similar trademarks, and we may not be able to prevent such third parties from using and marketing any such trademarks. Litigation brought to protect and enforce our intellectual property rights could be costly, unpredictable, time-consuming and distracting to management, regardless of whether we are successful in such litigation. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business, results of operations and financial condition may be adversely affected.

Numerous factors may limit any potential competitive advantage provided by the relevant patent rights.

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

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

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

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Employee Matters

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Bill Enright, our Chief Executive Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facilities in Harwell, United Kingdom and Germantown, Maryland. These regions are headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in these markets is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. Changes to U.K., U.S. or similar foreign immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by

political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to the U.K. (including, but not limited to, those that result as a direct or indirect consequence of Brexit), U.S. or similar foreign immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with all our employees, these employment agreements with U.S. employees provide for at-will employment, which means that any of our U.S. employees could leave our employment at any time, by providing the required contractual notification of their intent to leave. The standard notice period for U.K. employed personnel is three calendar months or six calendar months for the senior executive team. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Risks Related to Our Business Operations and Growth

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

As of December 31, 2023, we had 130 full-time and part-time employees. As our development and commercialization plans and strategies develop, and as we continue to transition into operating as a public company, we expect to need additional managerial, operational, technical, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

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

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

There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing authorization for our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in the disclosure of confidential or proprietary information, including personal data, damage to our reputation, and subject us to significant financial and legal exposure and cause a material disruption of the development programs of our product candidates.

We and our third-party CROs and other contractors and consultants rely extensively on information technology systems to conduct and manage our business. Despite the implementation of security measures, our internal computer systems and those of our current and future third-party providers are vulnerable to damage from computer viruses and unauthorized access. The risk of a security breach or disruption, particularly through cyberattacks 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. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security,

confidentiality, integrity and availability. If such an event were to occur, it could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and result in a material disruption of our development programs and our business operations, such as the loss of clinical trial data from completed or future clinical trials. Such loss could result in delays in our marketing authorization efforts and significantly increase our costs to recover or reproduce the data.

Although we devote resources to protect our information systems, including organization-wide prevention software, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our business, financial condition, results of operations and prospects.

Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches.

Any breach in our or our third-party providers' information technology systems could lead to the unauthorized access, disclosure and use of non-public information, including information from our participant registry or other participant information, which is protected by HIPAA, and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our product candidates could be delayed. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyberattacks and any such attacks could result in losses described above as well as disputes with physicians, participants and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

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

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, pandemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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

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

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or participants;

- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

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

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our third-party suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Risks Related to Our International Operations

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA Office of Foreign Assets Control Anti-Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws, including the UK Bribery Act 2010 ("Bribery Act");
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism.

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

Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including the following:

- economic weakness, including inflation, political instability in particular in foreign economies and markets;
- differing regulatory requirements for drug approvals;
- differing jurisdictions potentially presenting different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates of the euro, U.S. dollar, pound sterling and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws or practice;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States and EU;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, terrorism, pandemics, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

The United States and the UK do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the UK. In addition, uncertainty exists as to whether the courts of England and Wales would entertain original actions brought in the UK against us or our directors or senior management predicated upon securities laws of the U.S. or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of England and Wales as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is an issue for the court making such decision. If the courts of England and Wales give a judgment for the sum payable under a U.S. judgment, the English

judgment will be enforceable by methods generally available for this purpose. These methods generally permit the courts of England and Wales discretion to prescribe the manner of enforcement.

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

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

Our ADSs trade on Nasdaq in U.S. dollars. Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the U.S. dollar, the pound sterling and the euro. Our reporting currency is denominated in U.S. dollars and our functional currency is the pound sterling (except that the functional currency of our U.S. subsidiaries is the U.S. dollar) and the majority of our operating expenses are paid in pound sterling. We also regularly acquire services, consumables and materials in U.S. dollars, pound sterling, AUS dollars and the euro. Further potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates between the pound sterling and these other currencies, which may also have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place. See Note 3 in the notes to our annual financial statements appearing elsewhere in this Annual Report for a description of foreign exchange risks.

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

In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the pound sterling, the U.S. dollar equivalent of the proceeds that a holder of ADSs would receive upon the sale in the U.K. of any ordinary shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in euros on our ordinary shares represented by ADSs could also decline.

Risks Related to Ownership of Our ADSs

An active trading market for our ADSs may not be sustained.

Prior to our IPO in May 2021, there had been no public trading market for our ADSs. Although our ADSs are listed on The Nasdaq Global Market, an active trading market for our shares may not be sustained. If an active market for our ADSs is not sustained, it may be difficult for holders of our ADSs to sell ADSs without depressing the market price for the shares, or at all. Further, an inactive market may also impair our ability to raise capital by selling our ADSs and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ADSs as consideration.

Our principal shareholders and management own a significant percentage of our stock and exert significant influence over matters subject to shareholder approval.

As of March 14, 2024, our executive officers, directors, and 5% shareholders beneficially owned approximately 42% of our voting stock. Depending on the level of attendance at our meetings of shareholders, these shareholders either alone or voting together as a group may be in a position to determine or significantly influence the outcome of decisions taken at any such meeting. Any shareholder or group of shareholders controlling more than 50% of the share capital present and voting at our meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure and the approval of certain significant corporate transactions. This may prevent or discourage unsolicited acquisition proposals or offers for our ADSs that holders of our ADSs may feel are in their best interest as shareholders.

The price of our ADSs is volatile and holders of our ADSs could lose all or part of their investment.

The trading price of our ADSs is highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Annual Report, these factors include:

- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;

- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive marketing authorization for our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our ADSs by us or our shareholders in the future;
- trading volume of our ADSs;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or shareholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance.

Holders of our ADSs are not treated as holders of our ordinary shares.

Holders of ADSs are not treated as holders of our ordinary shares, unless they withdraw the ordinary shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the ordinary shares underlying our ADSs. Holders of ADSs therefore do not have any rights as holders of our ordinary shares, other than the rights that they have pursuant to the deposit agreement.

Holders of our 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 to English corporate law, including the Companies Act 2006, in time to be able to exercise their right to vote.

Except as described elsewhere in this Annual Report and the deposit agreement, holders of 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.

Otherwise, ADS holders will not be able to exercise their right to vote, unless they withdraw the ordinary shares underlying the ADSs they hold to vote them in person or by proxy in accordance with applicable laws and regulations and our articles of association. However, ADS holders may not know about the meeting far enough in advance to withdraw those ordinary shares. A shareholder is only entitled to participate in, and vote at, the meeting of shareholders, provided that it holds our ordinary shares as of the record date set for such meeting and otherwise complies with our Articles. In addition, the depositary's liability to ADS holders for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreement. As a result, ADS holders may not be able to exercise their right to vote, and there may be nothing they can do if the ordinary shares underlying their ADSs are not voted as they requested or if their shares cannot be voted.

Holders of ADSs may 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 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.

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

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

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

deposit agreement and our ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

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

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

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

The trading market for our ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. Although we have obtained research coverage from certain analysts, there can be no assurance that analysts will continue to cover us, or provide favorable coverage. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

We are an emerging growth company, as defined in the JOBS Act enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we became a public company, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date we became a public company, (b) in which we have total annual gross revenue of at least $1.24 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our ADSs that are held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same timing of adoption of new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which may allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements. We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our stock price may be more volatile.

We will incur increased costs as a result of operating as an English public company listed in the U.S., and our board of directors will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As an English public company listed in the U.S., and particularly after we no longer qualify as an emerging growth company, we will 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these

rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, 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.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Global Market. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting. See section entitled "Controls and Procedures – Management's Annual Report on Internal Controls Over Financial Reporting." However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We will incur substantial additional professional fees and internal costs to expand our accounting and finance functions and expend significant management efforts.

General Risk Factors

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

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

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

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

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

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

The depositary for the ADSs has agreed to pay to holders of our ADSs the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. Shareholders will receive these distributions in proportion to the number of our ordinary shares our ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit distribution on the ADSs, ordinary

shares, rights or anything else to holders of the ADSs. This means that holders of our ADSs may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to holders of our ADSs. These restrictions may have an adverse effect on the value of our ADSs.

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

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

We have not paid dividends in the past on our ordinary shares. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our ADSs. Any return to shareholders and holders of our ADSs will therefore be limited to the appreciation of their stock, which may never occur.

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

English law provides that a board of directors may only allot shares (or grant rights to subscribe for or to convert any security into shares) with the prior authorization of shareholders, 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 our Articles or relevant ordinary resolution passed by shareholders at a general meeting. Such authority from our shareholders to allot shares (or grant rights to subscribe for or to convert any security into shares) for a period of five years from April 21, 2021 was included in the ordinary resolution passed by our shareholders on April 21, 2021, which authorization will need to be renewed upon expiration (*i.e.*, at least every five years) but may be sought more frequently for additional five-year terms (or any shorter period).

English law also generally provides shareholders with preemptive rights when new shares are issued for cash. However, it is possible for the Articles, or for shareholders to pass a special resolution at a general meeting, being a resolution passed by at least 75% of the votes cast, to disapply preemptive rights. Such a disapplication of preemptive rights may be for a maximum period of up to five years from the date of adoption of the Articles, if the disapplication is contained in the Articles, but not longer than the duration of the authority to allot shares to which this disapplication relates or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (*i.e.*, at least every five years). Such authority from our shareholders to disapply preemptive rights for a period of five years was included in the special resolution passed by our shareholders on April 21, 2021, which disapplication will need to be renewed upon expiration (*i.e.*, at least every five years) to remain effective, but may be sought more frequently for additional five- year terms (or any shorter period).

English law also generally prohibits a public company from repurchasing its own shares without the prior approval of 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.

Shareholder protections found in provisions under the UK City Code on Takeovers and Mergers (the "Takeover Code"), will not apply if our place of central management and control is considered to be outside of the UK (or the Channel Islands or the Isle of Man).

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

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

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

- in connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is "the subject of rumor or speculation" or there is an "untoward movement" in the company's share price, there is a

requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about its review of a potential offer;

- when any person acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares already held by that person and an interest in shares held or acquired by persons acting in concert with him or her) carry 30% or more of the voting rights of a company that is subject to the Takeover Code, that person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights in that company to acquire the balance of their interests in the company;

- when any person who, together with persons acting in concert with him or her, is interested in shares representing not less than 30% but does not hold more than 50% of the voting rights of a company that is subject to the Takeover Code, and such person, or any person acting in concert with him or her, acquires an additional interest in shares which increases the percentage of shares carrying voting rights in which he or she is interested, then such person is generally required to make a mandatory offer to all the holders of any class of equity share capital or other class of transferable securities carrying voting rights of that company to acquire the balance of their interests in the company;

- a mandatory offer triggered in the circumstances described in the two paragraphs above must be in cash (or be accompanied by a cash alternative) and at not less than the highest price paid within the preceding 12 months to acquire any interest in shares in the company by the person required to make the offer or any person acting in concert with him or her;

- in relation to a voluntary offer (*i.e.*, any offer which is not a mandatory offer), when interests in shares representing 10% or more of the voting rights of a class have been acquired for cash by an offeror (*i.e.*, a bidder) and any person acting in concert with it in the offer period and the previous 12 months, the offer must be in cash or include a cash alternative for all shareholders of that class at not less than the highest price paid for any interest in shares of that class by the offeror and by any person acting in concert with it in that period. Further, if an offeror acquires for cash any interest in shares during the offer period, a cash alternative must be made available at not less than the highest price paid for any interest in the shares of that class;

- if, after making an offer for a company, the offeror or any person acting in concert with them acquires an interest in shares in an offeree company (*i.e.*, a target) at a price higher than the value of the offer, the offer must be increased to not less than the highest price paid for the interest in shares so acquired;

- an offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company;

- special or favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree;

- all shareholders must be given the same information;

- each document published in connection with an offer by or on behalf of the offeror or offeree must state that the directors of the offeror or the offeree, as the case may be, accept responsibility for the information contained therein;

- profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers;

- misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately;

- actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group;

- stringent and detailed requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities; and

- employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website.

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

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

The principal differences include the following:

- under English law and our Articles, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings;

- under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank;

- under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise;

- under English law and our Articles, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the Articles. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve certain significant transactions;

- in the UK, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a "squeeze out" to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares (including those represented by ADSs) will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75% of the ordinary shares (including those represented by ADSs) voting for approval;

- under English law and our Articles, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law; and

- the quorum requirement for a shareholders' meeting is one or more qualifying persons present at a meeting and between them holding (or being the proxy or corporate representative of the holders of) at least thirty-three and one-third percent (33 1/3%) in number of the issued shares (excluding any shares held as treasury shares) entitled to attend and vote on the business to be transacted. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

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

Our Articles provide that, unless we consent by ordinary resolution to the selection of an alternative forum, the courts of England and Wales shall, to the fullest extent permitted by law, be the exclusive forum for: (a) any derivative action or proceeding brought on our behalf; (b) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us; (c) any action or proceeding asserting a claim arising out of any provision of the Companies Act 2006 or our Articles (as may be amended from time to time); or (d) any action or proceeding asserting a claim or otherwise related to our affairs (the "England and Wales Forum Provision".) The England and Wales Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our Articles further provide that unless we consent by ordinary resolution to the selection of an alternative forum, the United States District Court for the Southern District of New York shall be the exclusive forum for resolving any complaint

asserting a cause of action arising under the Securities Act or the Exchange Act (the "U.S. Federal Forum Provision.") In addition, our Articles provide that any person or entity purchasing or otherwise acquiring any interest in our shares is deemed to have notice of and consented to the England and Wales Forum Provision and the U.S. Federal Forum Provision; provided, however, that our shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

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

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our ordinary shares or ADSs. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our ordinary shares or ADSs.

If we were classified as a passive foreign investment company, it would result in adverse U.S. federal income tax consequences to U.S. Holders.

Under the Internal Revenue Code (the "Code"), we will be a passive foreign investment company, or PFIC, for any taxable year in which (i) 75% or more of our gross income consists of passive income or (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. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as holding and receiving directly its proportionate share of assets and income of such corporation. If we are a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares or ADSs, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements. A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs and is: (i) an individual who is a citizen or individual resident of the United States; (ii) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia; (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or (iv) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

Based on the current and expected composition of our income and the value of our assets, we were a PFIC for the year ended December 31, 2023 and expect to remain a PFIC for our current taxable year. No assurances regarding our PFIC status can be provided for the current taxable year or any future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering.

Each U.S. Holder should consult its own tax advisors with respect to the potential adverse U.S. tax consequences to it if we are or were to become a PFIC. If we were a PFIC for any taxable year during which a U.S. investor owns ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. investor. We will provide the information necessary for a U.S. investor to make a qualified electing fund election with respect to us.

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

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "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," "global intangible low-taxed income" and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. In addition, if a non-U.S. corporation owns at least one U.S. subsidiary, under current law, any current non-U.S. subsidiaries and any future newly formed or acquired non-U.S. subsidiaries of the non-U.S. corporation will be treated as CFCs, regardless of whether the non-U.S. corporation is treated as a CFC. Subpart F income generally includes dividends, interest, rents, royalties, gains from the sale of securities and income from certain transactions with related parties. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a United States person (as defined by the Code) who owns or is considered to own 10% or more of the value or total combined voting power of all classes of stock entitled to vote of such corporation.

We do not believe that we were a CFC in 2023, and we do not expect to be a CFC in 2024. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. An individual that is a Ten Percent Shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a Ten Percent Shareholder that is a U.S. corporation. Failure to comply with CFC reporting obligations may subject a United States shareholder to significant monetary penalties. We cannot provide any assurances that we will furnish to any Ten Percent Shareholder information that may be necessary to comply with the reporting and tax paying obligations applicable under the CFC rules of the Code. U.S. Holders should consult their own tax advisors with respect to the potential adverse U.S. tax consequences of becoming a Ten Percent Shareholder in a CFC.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

In addition, testing required to be conducted by us in connection with Section 404 of the Sarbanes-Oxley Act, and any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Deficient internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs.

Implementing any appropriate changes to our internal controls, including changes relating to our application of the requirements of Section 404 of the Sarbanes-Oxley Act, may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to continue to discover and develop novel immunotherapeutics and vaccines for the treatment and prevention of infectious diseases, immunetolerance and cancer.

We previously identified material weaknesses in connection with our internal control over financial reporting. Although we have taken steps to remediate these material weaknesses, we may identify other material weaknesses in the future, which could have a significant adverse effect on our business and the trading price of our ADSs.

For the year ended December 31, 2023, pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our senior management on our internal control over financial reporting. This report is required to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, while we remain an non-accelerated filer, we will not be 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 of the Sarbanes-Oxley Act, we have been 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 continue to 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.

Management previously reported, in our Annual Report for the year ended December 31, 2022, material weaknesses in our internal control over financial reporting related to: (i) our IT general control environment has not been sufficiently designed to include appropriate controls over program development, program changes, computer operations and user access rights and (ii) policies and procedures with respect to the review, supervision and monitoring of our accounting and reporting functions were either not designed and in place or not operating effectively. During fiscal years 2022 and 2023, we undertook efforts to remediate previously disclosed material weaknesses, implement a company-wide formal control program, and strengthen our internal controls. Implementing Section 404 of the Sarbanes-Oxley Act within our environment has been a significant undertaking. Although management has concluded that the actions taken to strengthen our internal control over financial reporting, as well as the results of our testing over the design and operating effectiveness of these controls, remediated the previously identified material weaknesses as of December 31, 2023, there is no guarantee that our internal control over financial reporting will be effective in the future periods and the effectiveness of our internal controls are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with applicable policies, processes and documentation requirements may deteriorate. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our ADSs.

We could be subject to securities class action litigation.

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

The United Kingdom's withdrawal from the EU could increase the regulatory burden of product development and authorization in the United Kingdom and European Union.

On June 23, 2016, a majority of voters in the United Kingdom voted in favor of the United Kingdom withdrawing from the European Union in a national referendum, commonly referred to as Brexit, and the United Kingdom formally left the European Union on January 31, 2020. There was a transition period during which EU pharmaceutical laws continued to apply to the United Kingdom, which expired on December 31, 2020. However, the EU and the United Kingdom have concluded a TCA which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of the United Kingdom and European Union pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion, and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns in the most part with EU regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of United Kingdom and European Union pharmaceutical legislation. For example, the new Clinical Trials Regulation which became effective in the EU on January 31, 2022 and provides for a streamlined clinical trial application and assessment procedure covering multiple European Union Member States has not been implemented into the United Kingdom law, and a separate application will need to be submitted for clinical trial authorization in the United Kingdom.

The cumulative effects of the disruption to the regulatory framework may add to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom. It is possible that there will be increased regulatory complexities which can disrupt the timing of our clinical trials and regulatory approvals. In addition, changes in, and legal uncertainty with regard to, national and international laws and regulations may present difficulties for our clinical and regulatory strategy.

In addition, as a result of Brexit, other European Union Member States may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union will have in the long-term and the full extent to which our business could be adversely affected.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 1C. Cybersecurity

In the normal course of business, we may collect and store personal information and other sensitive information, including proprietary and confidential business information, financial information, trade secrets, intellectual property, information regarding trial participants in connection with clinical trials, sensitive third-party information and employee information. In an effort to protect this information from cybersecurity risks, we have developed a cybersecurity program which incorporates policies and practices designed to protect the confidentiality, integrity and security of our sensitive information.

As part of our cybersecurity risk management procedures, we perform system monitoring and scanning and utilize security tools supported by a third-party managed services provider. We also conduct penetration testing performed by a third-party provider. Employees are enrolled in cybersecurity awareness training courses designed to help them identify cybersecurity concerns and take appropriate actions, and we conduct periodic simulated phishing tests in an effort to further raise cybersecurity awareness and reduce the risk of a successful cyberattack. We have established an incident response plan to guide us in responding to cybersecurity incidents. We also take steps to protect against business interruption and conduct annual restoration testing for major systems. In addition, we are developing a cybersecurity risk management program for our third-party vendors. This program aims to assess the cybersecurity maturity of vendors who have access to our data or systems through an evaluation of the vendor's cybersecurity practices.

Our cybersecurity program is managed by our IT Director, who reports directly to senior management on matters regarding cybersecurity, as appropriate. Our IT Director has over twenty years of experience in IT, including cybersecurity, and previously served as the IT Director at another biopharmaceutical company. Together, our senior management and IT Director are responsible for leading company-wide cybersecurity strategy, policies, standards, and processes.

The Audit Committee, pursuant to its charter, has oversight over management of cybersecurity risks. Senior management and our IT Director provide the Audit Committee with periodic updates on data management and cybersecurity initiatives, as well as on significant existing and emerging cybersecurity risks, including cybersecurity incidents, as applicable.

We have a process to record identified risks from cybersecurity threats in our risk register, along with an assessment of the severity of the potential impact and the likelihood of occurrence. This process is designed to facilitate a unified and integrated assessment of corporate risk and governance. The risk register is reviewed periodically by senior management and at least annually by the Board of Directors. Our cybersecurity program is also periodically evaluated by external security consultants, with the results of those reviews reported to senior management and the Audit Committee, as appropriate.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition; however, like other companies in our industry, we and our third-party vendors may experience threats and security incidents that could affect our information or systems. For more information about the cybersecurity risks we face, please see Section 1A. Risk Factors.

Item 2. Properties

Our principal executive offices are located on the Harwell Science and Innovation Campus, Harwell, Oxfordshire, United Kingdom, where we lease and occupy approximately 31,000 square feet of office and laboratory space. We also have 19,700 square feet of state-of-the-art wet laboratory and office space in Germantown, Maryland, United States.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

We have no penalties to report in accordance with The Revenue Procedure 2005-51 and Section 6707A(e) of the Internal Revenue Code, which requires the Company to disclose any IRS demand for payment of certain penalties related to tax-avoidance transactions under I.R.C. Sections 6662(h), 6662A, or 6707A.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our ordinary shares, nominal value £0.000025 per share, in the form of ADSs trade under the symbol "BRNS" on the Nasdaq Global Market.

Holders of Our ADSs

Our ADSs each represent one ordinary share, nominal value £0.000025 per share, of Barinthus Biotherapeutics plc. An ADS may be evidenced by an American Depositary Receipt issued by the Bank of New York Mellon as depositary bank. As of March 14, 2024, there was one holder of record of our ordinary shares, nominal value £0.000025 per share, and 70 holders of record of our ADSs. The closing sale price per ADS on the Nasdaq Global Market on March 14, 2024 was $2.51.

Dividends

We have never paid or declared any cash dividends on shares of our ordinary shares, ADSs or other securities and do not anticipate paying or declaring any cash dividends in the foreseeable future. We currently intend to retain all future earnings, if any, for use in the operation of our business.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Equity Securities

None.

Certain Material UK Tax Considerations

The following discussion is limited to an overview of the tax consequences of ownership and disposition of ordinary shares, or such shares represented by ADSs (those ordinary shares or ADSs deriving over 75% of their value otherwise than from United Kingdom land). Each shareholder should however seek individual tax advice as specific rules may apply in certain circumstances. The United Kingdom tax consequences discussed below do not reflect a complete analysis or listing of all the possible United Kingdom tax consequences that may be relevant to holders of our ordinary shares or ADSs.

Chargeable Gains

A disposal or deemed disposal of ordinary shares or ADSs by a holder resident in the United Kingdom for tax purposes or subject to UK taxation (a "**UK Holder**") may, depending on such holder's circumstances and subject to any available exemptions or reliefs (such as the annual exemption), give rise to a chargeable gain or an allowable loss for the purposes of UK capital gains tax (for individuals) and corporation tax on chargeable gains (for corporation tax payers).

If an individual UK Holder who is subject to UK income tax at either the higher or the additional rate is liable to UK capital gains tax on the disposal of ordinary shares or ADSs, the current applicable rate will be 20% (for the tax years 2023/2024 and 2024/2025). For an individual UK Holder who is subject to UK income tax at the basic rate and liable to UK capital gains tax on such disposal, the current applicable rate would be 10% (for the tax years 2023/2024 and 2024/2025), save to the extent that any capital gains when aggregated with the UK Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the capital gains tax rate currently applicable to the excess would be 20% (for the tax years 2023/2024 and 2024/2025).

If a corporate UK Holder is or becomes liable to UK corporation tax on the disposal (or deemed disposal) of ordinary shares or ADSs, the main rate of UK corporation tax would apply (currently at 25% for companies with profits of more

than £250,000 or 19% for companies with profits not exceeding £50,000 with a marginal relief applying to profits between £50,000 and £250,000, in each case, for the 2023/2024 and 2024/2025 tax years).

Any chargeable gain (or allowable loss) will generally be calculated by reference to the consideration received for the disposal of the ADSs less the allowable cost to the UK Holder of acquiring such ADSs.

If you are not resident in the UK for UK tax purposes (or, in the case of an individual, not temporarily non-resident), you should not normally be liable for UK tax on capital gains realized or accrued on the sale or other disposition of ordinary shares or ADSs unless the ordinary shares or ADSs are held in connection with your trade carried on in the UK through a branch or agency (or, in the case of a corporate holder, a permanent establishment) and the ordinary shares or ADSs are or have been used, held or acquired for the purposes of such trade or such branch or agency.

An individual holder of ordinary shares or ADSs who ceases to be resident in the UK for UK tax purposes for a period of less than five years and who disposes of ordinary shares or ADSs during that period may also be liable on returning to the UK (or upon ceasing to be regarded as resident outside the UK for the purposes of any relevant double taxation treaty) for UK capital gains tax despite the fact that the individual may not be resident in the UK at the time of the disposal.

Stamp Duty and Stamp Duty Reserve Tax

Stamp duty and/or stamp duty reserve tax ("SDRT") are imposed in the United Kingdom on certain transfers of securities (including shares in companies which, like us, are incorporated in the United Kingdom) at a rate of 0.5% of the consideration paid for the transfer. Certain transfers of shares to depositaries or into clearance systems are charged a higher rate of 1.5%. Transfers of interests in shares within a depositary or clearance system, and from a depositary to a clearance system, are generally exempt from stamp duty and SDRT.

Under current UK tax law, no UK SDRT (or, where effected by a written instrument, UK stamp duty) should generally be payable in respect of an issue or transfer of ordinary shares, including an unconditional agreement to transfer ordinary shares to a clearance service or a depositary receipt system (including to a nominee or agent for a person whose business is or includes the issue of depositary receipts or the provision of clearance services) where the transfer is carried out for the purpose of raising new capital, unless the clearance service has made and maintained an election under section 97A of the UK Finance Act 1986, or a section 97A election. It is understood that HMRC regards the facilities of DTC as a clearance service for these purposes and we are not aware of any section 97A election having been made by DTC. Any stamp duty or SDRT payable on a transfer of ordinary shares to a depositary receipt system or clearance service or in respect of a transfer within a depositary receipt system or clearance service, will strictly be accountable by the clearance service or depositary receipt system operator or their nominee, as the case may be, but will in practice generally be paid by the transferors or participants in the clearance service or depositary receipt system. Specific professional advice should be sought before incurring or reimbursing the costs of a UK stamp duty or UK SDRT charge in any circumstances.

Any transfer of, or unconditional agreement to transfer, our ordinary shares that occurs outside the DTC system, including repurchases by us, will ordinarily attract stamp duty or SDRT at a rate of 0.5% of the amount or value of the consideration payable for the transfer (and in the case of stamp duty, rounded up to the next multiple of £5), unless the transfer is to a connected company and in which case a market value may apply. This duty must be paid (and where applicable the transfer document stamped by HMRC) before the transfer can be registered in our books. Typically stamp duty would be paid by the purchaser of the ordinary shares.

Any transfer of, or unconditional agreement to transfer, our ordinary shares that occurs outside the DTC system, including repurchases by us, will ordinarily attract stamp duty or SDRT at a rate of 0.5% of the amount or value of the consideration payable for the transfer (and in the case of stamp duty, rounded up to the next multiple of £5), unless the transfer is to a connected company and in which case a market value may apply. This duty must be paid (and where applicable the transfer document stamped by HMRC) before the transfer can be registered in our books. Typically stamp duty would be paid by the purchaser of the ordinary shares.

A transfer of title in our ordinary shares from within the DTC system out of the DTC system will not attract stamp duty or SDRT if undertaken for no consideration. If that ordinary shares is redeposited into DTC (which may only be done via a deposit of the ordinary shares first with an appropriate offshore depositary followed by a transfer of the ordinary shares from the offshore depositary into DTC), however, the redeposit will attract stamp duty or SDRT at a rate of 1.5%.

No UK stamp duty or SDRT should be payable on the issue of ADSs in the Company.

No UK stamp duty or SDRT should be required to be paid in respect of a paperless transfer of ADSs through the facilities of DTC, provided that no section 97A election has been made and maintained by DTC, and such ADSs are held through DTC at the time of any agreement for their transfer. We are not aware of any section 97A election having been made by the DTC.

On the basis of current published HMRC guidance, an ADR is not regarded as stock or a marketable security for the purposes of UK stamp duty or a chargeable security for the purposes of UK SDRT and, as such, no UK stamp duty or SDRT should be required to be paid on the issue or transfer of (including an agreement to transfer) ADSs in the Company.

Taxation of Dividends

Under UK law, there is no withholding tax on dividends paid on the ordinary shares or ADSs.

An individual UK Holder may, depending on his or her particular circumstances, be subject to UK tax on dividends received from us. An individual holder of ADSs who is not resident for tax purposes in the UK should not be chargeable to UK income tax on dividends received from us unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the UK through a branch or agency to which the ADSs are attributable. There are certain exceptions for trading in the UK through independent agents, such as some brokers and investment managers.

Dividend income is treated as the top slice of the total income chargeable to UK income tax for an individual UK Holder. An individual UK Holder who receives a dividend in the 2023/2024 tax year will be entitled to a dividend tax-free allowance of £1,000. However, the UK government has legislated to reduce the dividend tax-free allowance to £500 with effect from April 2024 (i.e. for the 2024/2025 tax year). Income within the dividend tax-free allowance counts towards an individual's basic, higher or additional rate limits and may, therefore, affect the level of income tax personal allowance to which they are entitled. Dividend income received in excess of the dividend tax-free allowance will (subject to the availability of any income tax personal allowance) be charged at 8.75% to the extent the excess amount falls within the basic rate band, 33.75% to the extent the excess amount falls within the higher rate band and 39.35% to the extent the excess amount falls within the additional rate band.

A corporate holder of ADSs who is not resident for tax purposes in the UK should not be chargeable to UK corporation tax on dividends received from us unless it carries on (whether solely or in partnership) a trade in the UK through a permanent establishment to which the ADSs are attributable.

Corporate UK Holders should not be subject to UK corporation tax on any dividend received from us so long as the dividends qualify for exemption, which should be the case, although certain conditions must be met. It should be noted that the exemptions, whilst of wide application, are not comprehensive and are subject to anti-avoidance rules. If the conditions for the exemption are not satisfied, such anti-avoidance provisions apply, or such UK Holder elects for an otherwise exempt dividend to be taxable, UK corporation tax will be chargeable on the amount of any dividends (at the current rate of 25% for companies with profits of more than £250,000 or 19% for companies with profits not exceeding £50,000, with a marginal relief applying to profits between £50,000 and £250,000, in each case for the 2023/2024 and 2024/2025 tax years).

Use of Proceeds from Initial Public Offering

On May 4, 2021, we completed our initial public offering ("IPO") of 6,500,000 ADSs at a price of $17.00 per ADS for an aggregate offering price of approximately $110.5 million. Morgan Stanley & Co., Jefferies LLC, Barclays Capital Inc., William Blair & Company, L.L.C. and H.C. Wainwright & Co., LLC served as the underwriters of the IPO. The offer and sale of all of the ADSs in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-255158), which became effective on April 29, 2021.

We received aggregate net proceeds from the offering of approximately $102.8 million, after deducting underwriting discounts and commissions, as well as other offering expenses. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

Purchase of Equity Securities by the Issuer and Affiliated Purchases

None.

Item 6. [Reserved]

Not applicable.

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 together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and assumptions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis. You should carefully read the "Cautionary Note Regarding Forward Looking Statements" and "Risk Factors" sections of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity and cancer. Helping patients and their families is the guiding principle at the heart of Barinthus Bio. The Company stands apart through its broad pipeline, built around four proprietary platform technologies; two viral vector platforms, ChAdOx and MVA; and two synthetic SNAP platforms, SNAP-Tolerance Immunotherapy ("SNAP-TI") and SNAP-Cancer Immunotherapy ("SNAP-CI").These platforms are enabling us to develop antigen-specific immunotherapeutic candidates designed to optimize the disease-fighting capabilities of T cells and guide them towards a healthy balance. Our immunotherapeutic candidates are designed to work by increasing disease-specific CD8+ T cell activity in the case of chronic infectious diseases and cancers, or by dampening CD4+ and CD8+ T cells, and increasing regulatory T cells in autoimmunity.

Harnessing our range of proprietary viral vector and synthetic platform technologies, we are advancing a pipeline of four product candidates across a diverse range of therapeutic areas, including: VTP-300, a Phase 2 immunotherapeutic candidate designed as a potential component of a functional cure for chronic HBV infection; VTP-200, a Phase 2 non-surgical product candidate for persistent high-risk HPV with near term clinical read-outs; VTP-1000, our first preclinical autoimmune candidate designed to utilize the SNAP-TI platform to treat patients with celiac disease; and VTP-850, a second-generation Phase 2 immunotherapeutic candidate designed to treat recurrent prostate cancer.

Alongside these proprietary programs, we have partnerships in place to advance three additional prophylactic and therapeutic product candidates in MERS, Zoster and Non-Small Cell Lung Cancer ("NSCLC"). The Company also co-invented a COVID-19 vaccine with the University of Oxford, which has been exclusively licensed worldwide to AstraZeneca. The co-invention of the COVID-19 vaccine demonstrated our ability to navigate a changing environment with speed and efficiency and lead the way in responding to urgent medical needs, as well as providing a strong proof-of-concept for the ChAdOx platform.

We believe our proven scientific expertise, diverse portfolio and focus on product candidate development uniquely positions us to navigate towards delivering treatments for patients with infectious diseases, autoimmune disorders and cancers that have a significant impact on their every day lives.

On May 4, 2021, we completed our IPO pursuant to which we issued and sold 6,500,000 American Depository Shares, or ADSs, at a public offering price of $17.00 per ADS, resulting in net proceeds of $102.8 million, after deducting underwriting discounts and commissions and offering expenses. Prior to our IPO, we funded our operations primarily from private placements of our ordinary and preferred shares, private placements of loan notes convertible into ordinary shares, as well as from grants and licensing agreements, research tax credit payments, investments from non-controlling interest, and a $2.4 million upfront payment from OUI in July 2020 in connection with the Amendment, Assignment and Revenue Share Agreement, or the OUI License Agreement Amendment, related to the licensing of the COVID-19 vaccine, Vaxzevria. We do not expect to generate revenue from any of our own product candidates, excluding Vaxzevria, until we

obtain regulatory authorization for one or more of such product candidates, if at all, and commercialize our products, or we enter into out-licensing agreements with third parties.

On August 9, 2022, we filed a Registration Statement on Form S-3, as amended (the "Shelf"), with the Securities and Exchange Commission in relation to the registration and potential future issuance of ordinary shares, including ordinary shares represented by ADSs, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $200.0 million. The Shelf was declared effective on August 17, 2022. We also simultaneously entered into a sales agreement with Jefferies LLC, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate of $75.0 million of our ordinary shares represented by ADSs from time to time in "at-the-market" offerings under the Shelf. As of December 31, 2023, we sold 1,139,444 ordinary shares represented by ADSs under the sales agreement, amounting to gross proceeds of $3.1 million.

We have incurred net losses each year since inception through to December 31, 2021. For the year ended December 31, 2022, we generated net income of $5.3 million, primarily as a result of revenues arising from AstraZeneca sales of Vaxzevria and our agreement with OUI. For the year ended December 31, 2023, we incurred net losses of $73.4 million. As of December 31, 2023 and 2022, we had an accumulated deficit of $176.6 million and $103.2 million, respectively, and we do not currently expect profits or positive cash flows from operations in the foreseeable future. We expect to incur net operating losses for at least the next several years as we advance our product candidates through clinical development, seek regulatory approval, prepare for approval, and in some cases proceed to commercialization of our product candidates, as well as continue our research and development efforts and invest to establish a commercial manufacturing facility, as and when appropriate.

At this time, we cannot reasonably estimate, or know the nature, timing and estimated costs of all of the efforts that will be necessary to complete the development of any of our product candidates that we develop through our programs. We are also unable to predict when, if ever, material net cash inflows will commence from sales of product candidates we develop, if at all. This is due to the numerous risks and uncertainties associated with developing product candidates to approval and commercialization, including the uncertainty of:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs for our planned clinical trials or future clinical trials;
- successful and timely enrollment and completion of clinical trials;
- data from our clinical program supporting approvable and commercially acceptable risk/benefit profiles for our product candidates in the intended populations;
- receipt and maintenance of necessary regulatory and marketing approvals from applicable regulatory authorities, in the light of the commercial environment then existent;
- availability and successful procurement of raw materials required to manufacture our products for clinical trials, scale-up of our manufacturing processes and formulation of our product candidates for later stages of development and commercial production;
- establishing either our own manufacturing capabilities or satisfactory agreements with third-party manufacturers for clinical supply for later stages of development and commercial manufacturing;
- entry into collaborations where appropriate to further the development of our product candidates;
- obtaining and maintaining intellectual property and trade secret protection or regulatory exclusivity for our product candidates as well as qualifying for, maintaining, enforcing and defending such intellectual property rights and claims;
- successfully launching or assisting with the launch of commercial sales of our product candidates following approval;
- acceptance of each product's benefits and uses by patients, the medical community and third-party payors following approval;

- the prevalence and severity of any adverse events experienced with our product candidates in development;
- establishing and maintaining a continued acceptable safety profile of the product candidates following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors if necessary or desirable; and
- effectively competing with other therapies.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate, in either direction. Furthermore, our operating plans may change in the future owing to research outcomes or other opportunities, and we may need additional funds to meet operational needs and capital requirements associated with such altered operating plans. Unless and until we can generate a substantial amount of revenue from our product candidates, if approved, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. Based on our research and development plans, we expect that our existing cash and cash equivalents and other financial resources, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025. These estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources more quickly than we expect.

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

Impact of Israel and Gaza Conflict

In respect of the international conflict in Israel and Gaza, we have no operations or suppliers based in Israel or Gaza, and as a result, as of the date of this Annual Report, we believe the impact on our business, operations and financial condition will be minimal.

Impact of the Ukraine Crisis

In respect of the international situation in Ukraine, we have assessed the impact on us as minimal. We have no operations or suppliers based in Ukraine, Belarus, or Russia, and there is consequently no additional risk or negative impact on the consolidated financial statements.

Impact of Global Economic Conditions and Inflationary Pressures

Instability in global economic conditions and geopolitical matters, as well as volatility in financial markets, could have a material adverse effect on our results of operations and financial condition. These inflationary pressures and rising interest rates in the United States, the United Kingdom and elsewhere have given rise to increasing concerns that the U.S., U.K. and other economies are now in, or may soon enter, economic recession. Sustained inflationary pressures, increased interest rates, an economic recession or continued or intensified disruptions in the global financial markets could adversely affect our future financing capability or ability to access the capital markets. Additionally, we may incur future increases in operating costs due to additional inflationary increases.

Components of Our Operating Results

Revenue

To date, we have not generated any revenue from direct product sales and do not expect to do so in the near future, if at all. Most of our revenue to date has been derived from the OUI License Agreement Amendment with OUI relating to Vaxzevria.

In April 2020, we entered into the OUI License Agreement Amendment with OUI in respect of our rights to use the ChAdOx1 technology in COVID-19 vaccines to facilitate the license of those rights by OUI to AstraZeneca. Under this agreement, we are entitled to receive from OUI a share of payments, including royalties and milestones, received by OUI from AstraZeneca in respect of this vaccine. On March 28, 2022, pursuant to the OUI License Agreement Amendment, we were notified of the commencement of payments, arising from AstraZeneca's commercial sales of Vaxzevria. Under the terms of an exclusive worldwide license agreement between OUI and AstraZeneca, OUI is entitled to milestone payments and royalties on commercial sales of Vaxzevria that began after the pandemic period. As part of the assignment from us to OUI, we are entitled to receive approximately 24% of payments received by OUI from AstraZeneca. Our revenue for the year ending December 31, 2023 was $0.8 million (year ended December 31, 2022 $43.7 million), representing the amounts we have been notified of as due by OUI to date and an estimate of future receipts, constrained to the extent that it is probable that a significant reversal of revenue would not occur.

We determined that we have no further performance obligations under the terms of the OUI License Agreement Amendment, which comprised the transfer of intellectual property rights only. Accordingly, we plan to recognize these and any future amounts as revenue when earned, and it is probable that a significant reversal of revenue will not occur. There is, however, no guarantee or expectation that such payments will continue in the future and, if they do, that we will be notified of such payments in a timely manner.

Operating Expenses

Our operating expenses since inception have consisted of research and development costs and general administrative costs.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including establishing and building on our adenovirus platform, further enhancing our in-licensed ChAdOx1, ChAdOx2 and MVA vectors, developing new next generation adenoviral vector, acquiring new technology platforms including SNAP (SNAP-TI and SNAP-CI), conducting preclinical studies, developing various manufacturing processes, and advancing clinical development of our programs including Phase 2 clinical trials for VTP-100, which we subsequently discontinued development of, as well as initiating the clinical trials for VTP-200, VTP-300, VTP-600 and VTP-850 and readying, VTP-500 and VTP-1000 for clinical trials. Research and development activities account for a large portion of our operating expenses, and we expect research and development expenses to increase in the future. Research and development costs are expensed as incurred. These costs include:

- salaries, benefits and other related costs, including share-based compensation, for personnel engaged in research and development functions;
- expenses incurred in connection with the development of our programs including preclinical studies and clinical trials of our product candidates, under agreements with third parties, such as consultants, contractors, academic institutions and ("CROs");
- the cost of manufacturing drug products for use in preclinical development and clinical trials, including under agreements with third parties, such as contract manufacturing organizations, consultants and contractors;
- laboratory costs; and
- leased facility costs, equipment depreciation and other expenses, which include direct and allocated expenses.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel-related expenses, including share-based compensation, in our executive, finance, business development and other administrative functions. Other general and administrative expenses include consulting fees and professional service fees for auditing, tax and legal services, rent expenses related to our offices, depreciation, foreign exchange gains and losses on our cash balances, other central non-research costs and changes in fair value of contingent consideration. Significant judgment is used to determine the probability of success of achievement of the technology and clinical milestones and the date of the expected milestone used in the valuation model of the contingent consideration. We expect our general and administrative expenses to continue to increase in the future as we expand our operating activities in both the United Kingdom and United States and potentially prepare for manufacturing and/or commercialization of our current and future product candidates. These costs will increase as our headcount rises to allow full support for our operations as a public company, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with requirements of the

Nasdaq Global Market and the Securities and Exchange Commission, directors' and officers' liability insurance premiums and investor relations activities.

Other Income/ (Expense)

Interest Income

Interest income results primarily from the interest earned on our short-term cash deposits and cash balances held by Barinthus Biotherapeutics (UK) Limited in United States dollars and pounds sterling.

Interest Expense

Interest expense results primarily from the asset retirement obligation provision discounted over the length of the lease in respect of our headquarters.

Research and Development Incentives

Research and development incentives contain payments receivable from the United Kingdom government related to corporation tax relief on research and development projects in the United Kingdom. We account for such relief received as other income.

The Company benefits from the United Kingdom research and development tax credit regime, being the Small and Medium-sized Enterprises R&D tax relief program ("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 ("RDEC Program").

Until March 2023, under the SME Program, we were able to surrender some of its trading losses that arise from qualifying research and development activities for a cash rebate of (after taking into account the enhanced rate of deduction) up to 33.35% of such qualifying research and development expenditure. Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects. Certain staff, consumables (including utilities), subcontractors and externally provided workers qualifying research and development expenditures are eligible for a cash rebate of up to 21.67%. A large portion of costs relating to research and development, clinical trials and manufacturing activities are eligible for inclusion within these tax credit cash rebate claims.

From April 2023, under the SME Program the enhanced rate of deduction has decreased from 230% to 186%, the SME credit rate has was or has been reduced from 14.5% to 10% (except for R&D intensive SMEs, which are expected to benefit form a credit rate of 14.5%), and the SME cash rebate for us was or has been reduced from an effective rate of 33.35% to 18.6% (or 26.97% for R&D intensive SMEs) and from 21.67% to 12.1% for subcontractors. Furthermore, the SME credit rate will decrease to 10% for expenditure incurred on or after April 1, 2023 unless the SME qualifies as an R&D intensive business, i.e., R&D expenditure constitutes at least 40% (from April 1, 2023) or 30% (from accounting periods starting on or after April 1, 2024) of total expenditure.

The Company may not be able to continue to claim research and development tax credits under the SME program in the future because it may no longer qualify as a small or medium-sized company. In addition, the EU State Aid cap limits the total aid claimable in respect of a given project to €7.5 million which may impact our ability to claim R&D tax credits in future. Further, the U.K. Finance Act of 2021 introduced a cap on payable credit claims under the SME Program in excess of £20,000 with effect from April 2021 by reference to, broadly, three times the total Pay As You Earn ("PAYE"), and National Insurance Contributions ("NICs"), liability of the company, subject to an exception which prevents the cap from applying. That exception requires the company to be creating, taking steps to create or managing intellectual property, as well as having qualifying research and development expenditure in respect of connected parties, which does not exceed 15% of the total claimed. If such an exception does not apply, this could restrict the amount of payable credit that we claim. For the year ended December 31, 2022, the R&D tax credits were further restricted by the available tax losses in the UK for the period. There was no tax loss restriction applied to the R&D tax credits in the UK for the year ended December 31, 2023.

Unsurrendered UK losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of UK taxable profits.

Critical Accounting Policies and Use of Estimates

This discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue, income and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to fair value of contingent consideration and impairment of goodwill and intangible assets. Management bases its estimates on historical experience and on various other market specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

We believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

Goodwill and Purchased Intangible Assets

We assess goodwill and intangible assets for impairment at least annually, or more frequently if events or changes in circumstances indicate that the carrying amounts may not be recoverable. We have elected to assess goodwill for impairment by first performing a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis of determining whether it is necessary to perform the quantitative goodwill impairment test. We have one reporting unit. Accordingly, our review of goodwill impairment indicators is performed at the entity-wide level. This requires us to assess and make judgments regarding a variety of factors, including clinical data results, business plans, anticipated future cash flows, economic projections and other market data. Because there are inherent uncertainties involved in these factors, significant differences between these estimates and actual results could result in future impairment charges and could materially impact our future financial results. The goodwill of $12.2 million and the intangible asset of $25.1 million recognized as at December 31, 2023 wholly relate to the acquisition of Avidea on December 10, 2021. The Company performed the annual impairment assessment as of December 31, 2023, to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. Based on this assessment, the Company has not recognized any impairment losses related to goodwill or intangible assets for the year ended December 31, 2023.

Contingent consideration

The Company recognizes a contingent consideration liability related to the acquisition of Avidea. The liability is remeasured to fair value at each reporting date until the contingency is resolved. The fair value of the contingent consideration is a Level 3 valuation determined using significant unobservable inputs being the probability of success of achievement of the milestones and the expected date of the milestone achievement. Changes in fair value are recognized in general and administrative expenses in the consolidated statement of operations and comprehensive loss. Avidea's stockholders may be entitled to receive an aggregate of up to $40.0 million in additional payments, payable in a combination of cash and ADSs, upon the achievement of certain milestones. This contingent consideration is included within the purchase price and is recognized at its fair value on the acquisition date, and subsequently remeasured to fair value at each reporting date until the contingency is resolved. Changes in fair value are recognized in general and administrative expenses in the consolidated statements of operations and comprehensive loss. The fair value of contingent consideration is based on the probability of pursuit of the activity associated with the milestone, the probability of success of the achievement of the milestone, the expected date of milestone achievement and applying the relevant discount rate.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table sets forth the significant components of our results of operations (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022	Change
Revenue from Licenses, Grants and Services	$ 802	$ 44,703	$ (43,901)
Operating expenses:			
Research and development	44,874	42,350	2,524
General and administrative	39,842	6,394	33,448
Total operating expenses	84,716	48,744	35,972
Loss from operations	(83,914)	(4,041)	(79,873)
Other income/(expense):			
Interest income	2,877	3,103	(226)
Interest expense	(28)	(19)	(9)
Research and development incentives	3,461	1,240	2,221
Other income, net	1,082	567	515
Total other income	7,392	4,891	2,501
(Loss)/profit before income tax	(76,522)	850	(77,372)
Tax benefit	3,075	4,471	(1,396)
Net (loss)/income	$ (73,447)	$ 5,321	$ (78,768)

Revenue

For the year ended December 31, 2023, our revenue consisted of $0.8 million from the OUI License Agreement Amendment with respect to amounts owed to us by OUI for the commercial sales of Vaxzevria. The decrease in revenue from the OUI License Agreement Amendment, compared to the prior period, resulted from substantially declined sales of Vaxzevria in 2023. There is no guarantee that further payments will be received pursuant to the agreement in the future and, if such payments are made, that we will be notified of such payments in a timely manner.

For the year ended December 31, 2022, our revenue primarily consisted of $43.7 million from the OUI License Agreement Amendment with respect to amounts owed to us by OUI for the commercial sales of Vaxzevria, and $0.8 million attributable to upfront fees associated with a research and license agreement with Scancell.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2023 and 2022:

	Year ended December 31, 2023	Year ended December 31, 2022	Change
Direct research and development expenses by program:			
VTP-200 HPV	$ 4,950	$ 4,050	$ 900
VTP-300 HBV	11,276	13,700	(2,424)
VTP-600 NSCLC	597	532	65
VTP-850 Prostate cancer	2,726	5,011	(2,285)
VTP-1000/VTP-1100 Celiac/HPV Cancer	8,420	5,118	3,302
Other and earlier stage programs	1,787	1,916	(129)
Total direct research and development expenses	$ 29,756	$ 30,327	$ (571)
Indirect research and development expenses:			
Personnel-related (including share-based compensation)	12,702	10,424	2,278
Facility related	1,339	1,308	31
Other indirect costs	1,077	291	786
Total indirect research and development expenses	15,118	12,023	3,095
Total research and development expenses	$ 44,874	$ 42,350	$ 2,524

Our research and development expenses for the years ended December 31, 2023 and 2022 were $44.9 million and $42.4 million, respectively, and consisted of direct and indirect research and development expenses.

Direct expenses for the years ended December 31, 2023 and 2022 were $29.8 million and $30.3 million, respectively, and consisted of outside services, consultants, laboratory materials, clinical trials, manufacturing of clinical trial materials, as well as costs for external preclinical services and sample testing. Of the $0.6 million decrease, a $2.4 million decrease pertains to VTP-300 as a result of completing the HBV002 Phase 2 clinical trial with final data that was presented at the EASL Congress in June 2023, and continuing enrollment in the HBV003 Phase 2b clinical trial and the AB-729-202 Phase 2a clinical collaboration with Arbutus. A $2.3 million decrease pertains to VTP-850 which is currently enrolling PCA001, a Phase 1/2 open-label clinical trial, compared to the prior year which was a result of manufacturing spend. These decreases were partially offset by a $3.3 million increase in SNAP candidates, namely in VTP-1000 Celiac disease program costs which increased as the program progresses to regulatory submissions and towards the clinic.

Indirect research and development expenses for the years ended December 31, 2023 and 2022 were $15.1 million and $12.0 million, respectively. Of the $3.1 million increase, $2.3 million pertains to personnel-related expenses as a result of an increase in headcount across locations in the United Kingdom and United States and $0.8 million increase relates to other indirect cost mainly due to overhead allocations from the new U.S. laboratory and office facility that we relocated to in June 2023.

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2023 and 2022 were $39.8 million and $6.4 million, respectively. The increase of $33.4 million relates primarily to a change in foreign exchange gains and losses of $33.8 million from a gain of $26.0 million for the year ended December 31, 2022 to a loss of $7.8 million for the year ended December 31, 2023.

Interest Income

For the years ended December 31, 2023 and 2022, interest income was $2.9 million and $3.1 million respectively, which primarily resulted from the interest earned on our short-term cash deposits and cash balances held by Barinthus Biotherapeutics (UK) Limited in United States dollars and pound sterling.

Interest Expense

For the year ended December 31, 2023, interest expense was $0.03 million which related to an asset retirement obligation provision discounted over the length of the lease term in respect of the laboratory and office facilities in the United Kingdom and the United States. For the year ended December 31, 2022 interest expense was $0.02 million which related to an asset retirement obligation provision discounted over the length of the lease in respect of our headquarters in the United Kingdom, and $0.003 million interest paid on the debt recognized on the acquisition of Avidea, which was repaid in full in the first quarter of 2022.

Research and Development Incentives

For the years ended December 31, 2023 and 2022, we accrued research and development incentives of $3.5 million and $1.2 million respectively, with the increase mainly attributable to an increase in losses available to surrender for the receipt of research and development incentives in Barinthus Biotherapeutics (UK) Limited due to a reduction in revenue received from commercial sales of Vaxzevria. Such research and development incentives relate to corporation tax relief on research and development project incentive programs in the United Kingdom. We account for such relief received as other income.

Tax benefit

For the years ended December 31, 2023 and 2022, the tax benefit was $3.1 million and $4.5 million respectively, which primarily relates to movements in deferred tax resulting from the deferred tax liability recognized in respect of the acquired intangible asset.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through private and public placements of our ordinary and preferred shares as well as from grants and research incentives, various agreements with public funding agencies, the issuance of convertible loan notes and most recently from royalty and milestone payments from OUI in connection with the OUI License Agreement Amendment. Through December 31, 2023, we had received gross proceeds of approximately $327.9 million from the issuance of our ordinary and preferred shares and convertible loan notes. As of December 31, 2023, we had cash and cash equivalents of $142.1 million. Key financing and corporate milestones include the following:

- Between July 2020 and November 2020, we raised gross proceeds of $41.2 million from the issuance of convertible loan notes.
- In March 2021, we raised gross proceeds of $125.2 million from the issuance of our Series B shares.
- In May 2021, we raised gross proceeds of $110.5 million from the IPO of our ordinary shares on NASDAQ.
- Between April 2022 and December 2023, we received $44.5 million of cash from OUI for the commercial sales of Vaxzevria.
- Between December 2022 and December 2023, we raised net proceeds of $3.0 million from the issuance of shares represented by ADSs through “at-the-market” offerings under the sales agreement with Jefferies LLC.

On August 9, 2022, we filed the Shelf with the Securities and Exchange Commission in relation to the registration and potential future issuance of ordinary shares, including ordinary shares represented by ADSs, debt securities, warrants and/or units of any combination thereof in the aggregate amount of up to $200.0 million. The Shelf was declared effective on August 17, 2022. We also simultaneously entered into a sales agreement with Jefferies LLC, as sales agent, providing for the offering, issuance and sale by us of up to an aggregate of $75.0 million of our ordinary shares represented by ADSs from time to time in “at-the-market” offerings under the Shelf. As of December 31, 2023, we have sold 1,139,444 ordinary shares represented by ADSs under the sales agreement, amounting to net proceeds of $3.0 million.

We do not currently expect positive cash flows from operations in the foreseeable future, if at all. In most periods, we have incurred operating losses as a result of ongoing efforts to develop our novel T cell immunotherapeutic candidates, including conducting ongoing research and development, preclinical studies, clinical trials, providing general and administrative support for these operations and developing our intellectual property portfolio. We expect to continue to

incur net negative cash flows from operations for at least the next few years as we progress clinical development, seek regulatory approval, prepare for and, if approved, proceed to manufacture and commercialization of our most advanced product candidates. Operating profits may arise earlier if programs are licensed or sold to third parties before final approval, but this cannot be guaranteed.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash (in thousands) for each period presented:

	Year ended December 31, 2023	Year ended December 31, 2022
Net cash used in operating activities	$ (50,925)	$ (14,431)
Net cash used in investing activities	(5,413)	(5,750)
Net cash provided by financing activities	1,872	325
Effect of exchange rates on cash and cash equivalents	2,171	187
Net decrease in cash and cash equivalents	$ (52,295)	$ (19,669)

Cash Used in Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was $50.9 million, primarily resulting from our net loss of $73.4 million, adjusted by foreign exchange loss on translation of $7.5 million, share based compensation of $5.1 million, depreciation and amortization of $5.4 million, deferred tax benefit of $3.1 million and changes in our operating assets and liabilities, net decrease of $6.2 million primarily related to a $5.8 million decrease in accounts receivable, a $2.2 million decrease in prepaid expenses and other current assets, a $3.4 million decrease in accounts payable and a $2.0 million increase in accrued expenses.

During the year ended December 31, 2022, net cash used in operating activities was $14.4 million, primarily resulting from our net income of $5.3 million, adjusted by foreign exchange gain on translation of $24.8 million, share-based compensation of $9.9 million, depreciation and amortization of $4.3 million, and changes in our operating assets and liabilities, net of $5.5 million primarily resulting from the OUI receivable, and an increase in prepaid expense due to the payment of annual insurance premiums that occurred in the second quarter of 2022.

Net Cash Used in Investing Activities

During the year ended December 31, 2023, cash used in investing activities was $5.4 million primarily resulted from capital expenditures related to leasehold improvements on our new office in Germantown, Maryland, United States.

During the year ended December 31, 2022, cash used in investing activities was $5.8 million, primarily resulted from capital expenditures related to our new headquarters in Harwell, United Kingdom.

Net Cash Provided by Financing Activities

During the year ended December 31, 2023, cash provided by financing activities was $1.9 million primarily resulting from the issuance of ordinary shares in the form of ADSs through the “at-the-market” sales agreement with Jefferies LLC.

During the year ended December 31, 2022, cash provided by financing activities was $0.3 million resulting from $0.5 million from the issuance ordinary shares through the “at-the-market” sales agreement with Jefferies LLC, offset by $0.2 million repayment of debt incurred previously by the acquired company Avidea (acquired on December 10, 2021, that subsequently became Barinthus North America, Inc.).

Effect of exchange rates on cash and cash equivalents

During the years ended December 31, 2023 and 2022, the effect of foreign exchange on cash and cash equivalents was a $2.2 million gain and $0.2 million gain respectively, primarily as a result of fluctuations between the United States dollar and pound sterling exchange rates.

Future Funding Requirements

To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and conducting clinical trials of our product candidates. As a result, we have incurred losses in each year since our inception in 2016, through to December 31, 2021. We were profitable in 2022, however we have negative operating cash flows for the period ending December 31, 2023. As of December 31, 2023, we had an accumulated deficit of $176.6 million. We expect to continue to incur significant losses and negative cash flows from operations for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- pursue the clinical and preclinical development of our current product candidates;
- use our technologies to advance additional product candidates into preclinical and clinical development;
- seek marketing authorizations for product candidates that successfully complete clinical trials, if any;
- attract, hire and retain additional clinical, regulatory, quality control and other scientific personnel;
- establish our manufacturing capabilities through third parties or by ourselves and scale-up manufacturing to provide adequate supply for clinical trials and commercialization, including any manufacturing finishing and logistics personnel;
- expand our operational, financial and management systems and increase personnel appropriately, including personnel to support our manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand, enforce, and protect our intellectual property portfolio as appropriate;
- establish sales, marketing, medical affairs and distribution teams and infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- acquire or in-license other companies, product candidates and technologies; and
- incur additional legal, accounting and other expenses in operating our business, including office expansion and the additional costs associated with operating as a public company.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditure to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other factors that may adversely affect our business. The size of our future net losses will depend on the rate of future growth of our expenses combined with our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital unless and until eliminated by revenue growth.

We may require substantial additional financing in the future to meet any such unanticipated factors and a failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Since our foundation, we have invested a significant portion of our efforts and financial resources in research and development activities for our ChAdOx1, ChAdOx2 and MVA technologies, acquisition of additional complementary platforms such as SNAP-TI and SNAP-CI, development of new technologies in house, and our product candidates derived from these technologies. Preclinical studies and especially clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates and programs as well as any future product candidates we may elect to pursue, as well as the gradual gaining of control over our required manufacturing capabilities and other corporate functions. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and potentially in-house manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise as outlined above. Because the outcome of any preclinical study or clinical trial is uncertain and the rate of change of third-party costs is also unpredictable, we cannot reasonably estimate now the actual amounts which will be necessary to complete the development and commercialization of our current or future product candidates successfully.

Our future capital requirements may depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidates and programs, and of conducting preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue, and of other indications for our current product candidates that we may pursue;
- the stability, scale and yield of future manufacturing processes as we scale-up production and formulation of our product candidates either internally or externally for later stages of development and commercialization;
- the timing of, success achieved and the costs involved in obtaining regulatory and marketing approvals and developing our ability to establish license or sale transactions and/or sales and marketing capabilities, if any, for our current and future product candidates if clinical trials and approval processes are successful;
- the success of our collaborations with CEPI, CanSino, CRUK and the Ludwig Institute and any future collaboration partners;
- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements;
- the cost to the company of commercialization activities for our current and future product candidates that we may take on, whether alone or with a collaborator;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent and other intellectual property claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties or other income from, our future products, if any; and
- the emergence and success or otherwise of competing oncology and infectious disease therapies and other market developments.

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate, in either direction. Furthermore, our operating plans may change in the future owing to research outcomes or other opportunities, and we may need additional funds to meet operational needs and capital requirements associated with such altered operating plans. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing.

Based on our research and development plans, we expect that our existing cash and cash equivalents and other financial resources, will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025. These estimates are based on assumptions that may prove to be wrong, and we could use our available capital resources more quickly than we expect.

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

Lease, Purchase, and Other Obligations

We have operating lease obligations related to our property and equipment. The details of these leases are disclosed in Item 2. “Properties.”. The obligations related to both short- and long-term lease arrangements are set forth in Note 16 “Commitment and Contingencies” to our consolidated financial statements.

We enter into contracts in the normal course of business with CROs and other third parties for 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 noncancellable obligations of our service providers, up to the date of cancellation.

We have 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 our licenses; however, the amount, timing and likelihood of such payments are not known as of December 31, 2023. See section entitled "Business - Our Collaboration and License Agreements.

Emerging Growth Company Status

We are an emerging growth company under the JOBS Act. As an emerging growth company, we may delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our ADSs held by non-affiliates exceeded $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncement that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency and Currency Translation

We are subject to the risk of fluctuations in foreign currency exchange rates, specifically with respect to the euro, pound sterling, Swiss franc and Australian dollar. Our reporting currency is the United States dollar, and the functional currency of Barinthus Biotherapeutics plc and its consolidated subsidiaries, Barinthus Biotherapeutics (UK) Limited and VOLT, is the pound sterling. The functional currency of our wholly owned foreign subsidiary, Barinthus Bio NA is the United States dollar. The functional currency of our wholly owned foreign subsidiary, Barinthus Biotherapeutics Australia Pty, is the Australian dollar. The functional currency of our wholly owned foreign subsidiary, Barinthus Biotherapeutics S.R.L, is the euro. The functional currency of our wholly owned foreign subsidiary, Barinthus Biotherapeutics Switzerland GmbH, is the Swiss franc. Our cash and cash equivalents as of December 31, 2023 consisted primarily of cash balances held by Barinthus Biotherapeutics (UK) Limited in United States dollars.

Assets and liabilities are translated into United States dollars at the exchange rate in effect on the balance sheet date. Revenue and expenses are translated at the average exchange rate in effect during the period. Translation adjustments are included in the consolidated Balance Sheets as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in operating expenses, net in the consolidated Statements of Operations and Comprehensive Loss as incurred.

We incur significant operating costs in the UK and face exposure to changes in the exchange ratio of the United States dollar and the pound sterling arising from expenses and payables at our UK operations that are settled in pound sterling. For the year ended December 31, 2023, an average 10% weakening in the United States dollar relative to the pound sterling would have resulted in an immaterial change to our expenses denominated in pound sterling for the year ended December 31, 2023.

Interest Rate Sensitivity

We are not currently exposed significantly to market risk related to changes in interest rates, as we have no significant interest-bearing liabilities. We had cash and cash equivalents of $142.1 million as of December 31, 2023, which were primarily held as account balances with banks in the United Kingdom, United States and Australia. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Financial Statements and Supplementary Data

Consolidated Financial Statements

Our audited consolidated financial statements are included at the end of this Annual Report, starting at page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023.

The term "disclosure controls and procedures", means controls and other procedures of a company that are designed to provide reasonable assurance that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on our evaluation, our management, with the participation of our principal executive officer and principal financial officer, has concluded that, as of such date, that the previously reported material weaknesses have been remediated and our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, and for the assessment of the effectiveness of internal control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness of our internal controls in future periods are subject to the risk that such controls may become inadequate because of changes in conditions, or that the degree of compliance with applicable policies, processes and documentation requirements may deteriorate.

In making its assessment of the Company's internal control over financial reporting as of December 31, 2023, management used the criteria set forth in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and evaluated the internal control over financial reporting. Based on our assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2023, based on criteria in Internal Control-Integrated Framework (2013) issued by the COSO.

Remediation of Previously Reported Material Weaknesses

As previously reported in our Form 10-K for the fiscal year ended December 31, 2022, and in our subsequent Form 10-Q reports for the periods ending March 31, June 30 and September 30, 2023, management identified material weaknesses in our internal control over financial reporting related to the following: (i) our IT general control environment had not been

sufficiently designed to include appropriate user access rights, nor were controls over program development, program changes and computer operations designed, implemented and operating effectively, and (ii) policies and procedures with respect to the review, supervision and monitoring of our accounting and reporting functions were either not designed and in place or not operating effectively.

During fiscal years 2022 and 2023, we undertook efforts to remediate the previously disclosed material weaknesses. Our internal control remediation efforts focused on the areas detailed below.

(i) IT general controls environment

We took measures to address the IT environment and have implemented a new enterprise resource planning ("ERP") system, and completed the controls design and operation over program development, program changes, computer operations and access rights.

For the new ERP system and all other IT systems where material risks to financial reporting were identified, we implemented and tested the operating effectiveness of: (i) program change management controls to ensure that IT program and data changes affecting financial applications and underlying accounting records are identified, tested, authorized, and implemented appropriately; (ii) user access controls to ensure appropriate segregation of duties exist, to adequately restrict user and privileged access to certain financial applications, programs and data to appropriate company personnel; (iii) computer operations controls to ensure that critical batch jobs are monitored and data backups are authorized and monitored; (iv) testing and approval controls for program development to ensure that changes are aligned with business and IT requirements; and (v) identification and testing of system-generated information and calculations used in the execution of manual controls. In addition, we further developed and executed a testing protocol that allows us to validate the operating effectiveness of certain IT general controls to gain assurance that such controls are operating as designed.

(ii) policies and procedures with respect to the review, supervision and monitoring of our accounting and reporting functions

We took measures to address this material weakness, which included hiring appropriate personnel whose roles are to enhance policies and procedures with respect to the review, supervision, formalization and monitoring of our accounting and reporting functions. Additionally, we enhanced our business process controls through the following activities:

- evaluated and refined the design, implementation, and documentation of the internal controls to ensure controls address the relevant risks, are properly designed, and provide appropriate evidence of performance;
- enhanced the design of controls that address the completeness and accuracy of reports being utilized in the execution of internal controls;
- evaluated the assignment of responsibilities associated with the performance of control activities and hired additional resources, obtained third party assistance, and provided additional training to existing resources; and
- further developed and executed a testing protocol that allows us to validate the operating effectiveness of certain key controls over financial reporting and gain assurance that such controls are operating as designed.

Management has concluded that the actions taken to strengthen our internal control over financial reporting, as well as the results of our testing over the design and operating effectiveness of these controls, remediated the previously identified material weaknesses as of December 31, 2023.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for “emerging growth companies.”

Changes in Internal Control over Financial Reporting

Other than the remediation activities related to the previously reported material weaknesses noted above, no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the year ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

(a)

None

(b)

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 under this item is incorporated herein by reference and will be included in our definitive proxy statement for our 2024 Annual General Meeting to be filed with the U.S. Securities and Exchange Commission within 120 days of the end of our fiscal year.

We have adopted a Code of Conduct that applies to all officers, directors and employees in connection with their work for us. The full text of our Code of Conduct is posted on the investor relations page of our website at investors.barinthusbio.com/corporate-governance.

We intend to satisfy any disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Conduct by posting such information on our website, at the Internet address and location specified above.

Item 11. Executive Compensation

The information required under this item is incorporated herein by reference and will be included in our definitive proxy statement for our 2024 Annual General Meeting to be filed with the United States Securities and Exchange Commission within 120 days of our fiscal year.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated herein by reference and will be included in our definitive proxy statement for our 2024 Annual General Meeting to be filed with the U.S. Securities and Exchange Commission within 120 days of the end of our fiscal year.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required under this item is incorporated herein by reference and will be included in our definitive proxy statement for our 2024 Annual General Meeting to be filed with the United States Securities and Exchange Commission within 120 days of the end of our fiscal year.

Item 14. Principal Accounting Fees and Services

The information required under this item is incorporated herein by reference and will be included in our definitive proxy statement for our 2024 Annual General Meeting to be filed with the United States. Securities and Exchange Commission within 120 days of the end of our fiscal year.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements.

The financial statements filed as part of this report are listed on the Index to Consolidated Financial Statements in Item 8.

(2) Financial Statement Schedules.

No schedules are submitted because they are not applicable, not required, or because the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits.

EXHIBIT INDEX

Exhibits number	Description of exhibit
2.1†	Agreement and Plan of Merger and Reorganization, dated December 9, 2021, by and among Barinthus Biotherapeutics plc, VA Merger Sub 1 Inc., VA Merger Sub 2 Inc., Avidea Technologies Inc., and Benjamin Eisler, as the Securityholder Agent (Incorporated by reference to Exhibit 2.1 to our Periodic Report on Form 8-K (File No. 001-40367) filed on December 14, 2021).
2.2*†	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated March 11, 2022, by and between Barinthus Biotherapeutics plc and Benjamin Eisler, as Securityholder Agent (Incorporated by reference to Exhibit 2.2 to our Annual Report on Form 10-K (File No. 001-40367) filed on March 25, 2022).
2.3	Amendment No. 2 to Agreement and Plan of Merger and Reorganization, dated May 9, 2022, by and between Barinthus Biotherapeutics plc and Benjamin Eisler, as the Securityholder Agent (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-40367), filed with the Securities and Exchange Commission on August 9, 2022).
3.2	Articles of Association of the Registrant (Incorporated by reference to Exhibit 3.1 to our Form 8-K (File No. 001-40367) filed on May 10, 2021)).
4.1	Form of Deposit Agreement (Incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
4.2	Form of American Depositary Receipt (included in Exhibit 4.1).
4.3	Description of Registrant's Securities (Incorporated by reference to Exhibit 4.3 to our Annual Report on Form 10-K (File No. 001-40367) filed on March 25, 2022).
10.1#	EMI Option Scheme and form of award agreement thereunder (Incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.2#	2021 Stock Option and Incentive Plan and forms of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).

10.3#	2021 Employee Share Purchase Plan (Incorporated by reference to Exhibit 10.17 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.4†	License of Technology by and between the Registrant and Oxford University Innovation Limited, dated as of March 4, 2016, as amended on January 14, 2019 and as further amended April 29, 2020 (Incorporated by reference to Exhibit 10.3 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.5†	License Agreement by and between the Registrant and Oxford University Innovation Limited, dated as of September 8, 2017 (Incorporated by reference to Exhibit 10.4 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.6†	Master Collaboration Agreement by and between the Registrant and CanSino Biologics, Inc., dated as of September 4, 2018 (Incorporated by reference to Exhibit 10.5 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.9†	Clinical Trial and Option Agreement by and among Vaccitech Oncology Limited, Cancer Research Technology Limited, and Cancer Research UK, dated as of December 16, 2019 (Incorporated by reference to Exhibit 10.8 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.10#	Form of Deed of Indemnity between the Registrant and each of its directors and officers (Incorporated by reference to Exhibit 10.9 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.11#**	Form of Employment Agreement between the Registrant and William Enright (Incorporated by reference to Exhibit 10.10 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.12#**	Form of Employment Agreement between the Registrant and Graham Griffiths (Incorporated by reference to Exhibit 10.11 to our Registration Statement on Form S-1/A (File No. 333-255158) filed on April 27, 2021).
10.13	Registration Rights Agreement, dated March 28, 2022, by and among the Registrant and Benjamin Eisler, as the Securityholder Agent (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-40367) filed on May 11, 2022).
10.14	Service Agreement with Gemma Brown, effective September 15, 2022 (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-40367) filed on November 10, 2022).
10.15	Employment Agreement by and between Vaccitech Switzerland GmbH and Nadège Pelletier, effective February 1, 2023 (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on From 10-Q (File No. 001-40367) filed on May 12, 2023).
10.16	Form of Indemnification Agreement between the Registrant and each of its directors and officers (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 001-40367) filed on November 10, 2022).

10.17	Lease Agreement dated September 3, 2021 by and among The Harwell Science and Innovation Campus General Partner Limited, The Harwell Science and Innovation Campus Nominee Limited, The Harwell Science and Innovation Campus Limited Partnership and Barinthus Biotherapeutics (UK) Limited (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-40367) filed on November 12, 2021).
10.18*†	Funding Agreement by and between the Registrant, Coalition for Epidemic Preparedness Innovations and the University of Oxford, dated as of December 20, 2023
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page to this Annual Report).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.0	Compensation Recovery Policy (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-40367) filed on November 9, 2023).
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the iXBRL document).

* Filed or furnished herewith.
† Certain portions of this exhibit have been omitted because they are not material and the Registrant customarily and actually treats that information as private or confidential.
# Indicates a management contract or any compensatory plan, contract or arrangement.

** Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

+ The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to be furnished with this Annual Report and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

Item 16. Form 10-K Summary

Not Applicable.

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.

March 20, 2024

Barinthus Biotherapeutics plc

By: /s/ William Enright

William Enright
Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints William Enright and Gemma Brown, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ William Enright William Enright	Chief Executive Officer and Director (Principal Executive Officer)	March 20, 2024
/s/ Gemma Brown Gemma Brown	Chief Financial Officer (Principal Financial and Accounting Officer)	March 20, 2024
/s/ Robin Wright Robin Wright	Chairman and Director	March 20, 2024
/s/ Alex Hammacher Alex Hammacher	Director	March 20, 2024
/s/ Pierre A. Morgon Pierre A. Morgon	Director	March 20, 2024
/s/ Anne M. Phillips Anne M. Phillips	Director	March 20, 2024
/s/ Karen T. Dawes Karen T. Dawes	Director	March 20, 2024
/s/ Joseph C. F. Scheeren Joseph C. F. Scheeren	Director	March 20, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Barinthus Biotherapeutics plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Barinthus Biotherapeutics plc and its subsidiaries (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, consolidated statements of stockholders' equity, and consolidated statements of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/PricewaterhouseCoopers LLP
Reading, United Kingdom
March 20, 2024

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

BARINTHUS BIOTHERAPEUTICS PLC
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)

	As of December 31, 2023	As of December 31, 2022
ASSETS		
Cash and cash equivalents	$ 142,090	$ 194,385
Accounts receivable	—	323
Accounts receivable – related parties	—	5,524
Research and development incentives receivable	4,908	4,541
Prepaid expenses and other current assets	9,907	8,268
Total current assets	156,905	213,041
Goodwill	12,209	12,209
Property and equipment, net	11,821	7,957
Intangible assets, net	25,108	28,269
Right of use assets, net	7,581	7,753
Other assets	882	976
Total assets	$ 214,506	$ 270,205
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,601	$ 3,748
Accrued expenses and other current liabilities	9,212	8,061
Operating lease liability - current	1,785	433
Total current liabilities	12,598	12,242
Non-Current liabilities:		
Operating lease liability - non-current	11,191	8,340
Contingent consideration	1,823	1,711
Other non-current liabilities	1,325	965
Deferred tax liability, net	574	3,746
Total liabilities	$ 27,511	$ 27,004
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Ordinary shares, £0.000025 nominal value; 38,643,540 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 37,683,531)	1	1
Deferred A shares, £1 nominal value; 63,443 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 63,443)	86	86
Deferred B shares, £0.01 nominal value; 0 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 570,987)	—	8
Deferred C shares, £0.000007 nominal value, 0 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 27,828,231)	—	0 [1]
Additional paid-in capital	386,602	379,504
Accumulated deficit	(176,590)	(103,243)
Accumulated other comprehensive loss – foreign currency translation adjustments	(23,315)	(33,460)
Total stockholders' equity attributable to Barinthus Biotherapeutics plc shareholders	186,784	242,896
Noncontrolling interest	211	305
Total stockholders' equity	$ 186,995	$ 243,201
Total liabilities and stockholders' equity	$ 214,506	$ 270,205

[1] Indicates amount less than one thousand

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

BARINTHUS BIOTHERAPEUTICS PLC
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)

	Year Ended	
	December 31, 2023	December 31, 2022
License revenue [1]	$ 802	$ 44,694
Research grants and contracts	—	9
Total revenue	802	44,703
Operating expenses		
Research and development	44,874	42,350
General and administrative	39,842	6,394
Total operating expenses	84,716	48,744
Loss from operations	(83,914)	(4,041)
Other income /(expense):		
Interest income	2,877	3,103
Interest expense	(28)	(19)
Research and development incentives	3,461	1,240
Other income, net	1,082	567
Total other income, net	7,392	4,891
(Loss)/profit before income tax	(76,522)	850
Tax benefit	3,075	4,471
Net (loss)/income	(73,447)	5,321
Net loss attributable to noncontrolling interest	100	21
Net (loss)/income attributable to Barinthus Biotherapeutics plc shareholders	(73,347)	5,342
Weighted-average ordinary shares outstanding, basic	38,386,491	37,248,126
Weighted-average ordinary shares outstanding, diluted	38,386,491	38,169,307
Net (loss)/income per share attributable to ordinary shareholders, basic	$ (1.91)	$ 0.14
Net (loss)/income per share attributable to ordinary shareholders, diluted	$ (1.91)	$ 0.14
Net (loss)/income	$ (73,447)	$ 5,321
Other comprehensive gain/(loss) – foreign currency translation adjustments	10,151	(25,083)
Comprehensive loss	(63,296)	(19,762)
Comprehensive loss attributable to noncontrolling interest	94	132
Comprehensive loss attributable to Barinthus Biotherapeutics plc shareholders	$ (63,202)	$ (19,630)

[1] Includes license revenue from related parties for the year ended December 31, 2023 totaling $0.8 million (December 31, 2022: $43.7 million). License revenue is generated in the United Kingdom.

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

BARINTHUS BIOTHERAPEUTICS PLC
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS, EXCEPT NUMBER OF SHARES)

	Year ended December 31, 2023													
	Ordinary Shares		Deferred A Shares		Deferred B Shares		Deferred C Shares							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total stockholders' equity attributable to Barinthus Biotherapeutics plc stockholders	Non-Controlling Interest	Total Stockholders' Equity
Balance, January 1,2023	**37,683,531**	**$ 1**	**63,443**	**$ 86**	**570,987**	**$ 8**	**27,828,231**	**$ 0**	[1] **$ 379,504**	**$ (103,243)**	**$ (33,460)**	**$ 242,896**	**$ 305**	**$ 243,201**
Share based compensation	—	—	—	—	—	—	—	—	5,055	—	—	5,055	—	5,055
Issue of ordinary shares, net of issuance costs	960,009	0 [1]	—	—	—	—	—	—	2,035	—	—	2,035	—	2,035
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	—	10,145	10,145	6	10,151
Cancellation of deferred shares	—	—	—	—	(570,987)	(8)	(27,828,231)	—	8	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(73,347)	—	(73,347)	(100)	(73,447)
Balance, December 31,2023	**38,643,540**	**$ 1**	**63,443**	**$ 86**	**—**	**$ —**	**—**	**$ 0**	[1] **$ 386,602**	**$ (176,590)**	**$ (23,315)**	**$ 186,784**	**$ 211**	**$ 186,995**

[1] Indicates amount less than one thousand

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

BARINTHUS BIOTHERAPEUTICS PLC
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS, EXCEPT NUMBER OF SHARES)

	Year ended December 31, 2022													
	Ordinary Shares		Deferred A Shares		Deferred B Shares		Deferred C Shares							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total stockholders' equity attributable to Barinthus Biotherapeutics plc stockholders	Non-Controlling Interest	Total Stockholders' Equity
Balance, January 1,2022	**37,188,730**	**$ 1**	**63,443**	**$ 86**	**570,987**	**$ 8**	**27,828,231**	**0** [1]	**$ 369,103**	**$ (108,585)**	**$ (8,488)**	**$ 252,125**	**$ 437**	**$ 252,562**
Share based compensation	—	—	—	—	—	—	—	—	9,877	—	—	9,877	—	9,877
Issue of ordinary shares, net of issuance costs	494,801	0 [1]	—	—	—	—	—	—	484	—	—	484	—	484
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	—	(24,972)	(24,972)	(111)	(25,083)
Measurement period and contingent consideration adjustments	—	—	—	—	—	—	—	—	40	—	—	40	—	40
Net loss	—	—	—	—	—	—	—	—	—	5,342	—	5,342	(21)	5,321
Balance, December 31,2022	**37,683,531**	**$ 1**	**63,443**	**$ 86**	**570,987**	**$ 8**	**27,828,231**	**$ 0** [1]	**$ 379,504**	**$ (103,243)**	**$ (33,460)**	**$ 242,896**	**$ 305**	**$ 243,201**

[1] Indicates amount less than one thousand

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

BARINTHUS BIOTHERAPEUTICS PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS (IN THOUSANDS)

	December 31, 2023	December 31, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)/income	$ (73,447)	$ 5,321
Adjustments to reconcile net (loss)/income to net cash used in operating activities:		
Share based compensation	5,055	9,877
Depreciation and amortization	5,429	4,323
Non-cash lease expenses	1,328	1,216
Unrealized foreign exchange loss/(gain)	7,531	(24,905)
Change in contingent consideration	55	(73)
Non cash interest expense	28	19
Deferred tax expense	(3,075)	(4,337)
Profit on sale of property and equipment	—	(348)
Changes in operating assets and liabilities:		
Accounts receivable (including related parties)	5,800	(5,833)
Prepaid expenses and other current assets	2,200	(2,170)
Research and development incentives receivable	(127)	1,158
Accounts payable	(3,378)	1,140
Accrued expenses and other current liabilities	1,993	751
Deferred revenue	—	(183)
Operating lease liabilities	(445)	—
Other assets	128	(387)
Net cash used in operating activities	$ (50,925)	$ (14,431)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of property and equipment	—	388
Purchases of property and equipment	(5,413)	(6,138)
Net cash used in investing activities	$ (5,413)	$ (5,750)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issue of shares from the exercise of stock options	0 [1]	0 [1]
Proceeds from issue of ordinary shares, net of issuance costs	2,035	484
Payment of contingent consideration	(163)	—
Repayment of debt	—	(159)
Net cash provided by financing activities	$ 1,872	$ 325
Effect of exchange rates on cash and cash equivalents	2,171	187
Net decrease in cash and cash equivalents	(52,295)	(19,669)
Cash and cash equivalents, beginning of the year	194,385	214,054
Cash and cash equivalents, end of the year	$ 142,090	$ 194,385
Supplemental cash flow disclosures:		
Cash paid for interest	$ —	$ 0 [1]
Cash paid for income taxes	$ —	$ 0 [1]
Non-Cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 87	$ 559
ROU assets obtained in exchange for operating lease liabilities	$ —	$ 2,400
Asset retirement obligation	$ 287	$ 999
Changes to right-of-use asset resulting from lease reassessment event	$ 88	$ (207)
Measurement period adjustments	$ —	$ (38)
Contingent Consideration settled in equity	$ —	$ 78

[1] Indicates amount less than one thousand

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

BARINTHUS BIOTHERAPEUTICS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Nature of business

Barinthus Biotherapeutics plc (formerly Vaccitech plc) is a public limited company incorporated pursuant to the laws of England and Wales in March 2021. Barinthus Biotherapeutics plc and its direct and indirect subsidiaries, Barinthus Biotherapeutics (UK) Limited (formerly Vaccitech (UK) Limited), Barinthus Biotherapeutics Australia Pty Limited (formerly Vaccitech Australia Pty Limited), Vaccitech Oncology Limited ("VOLT"), Barinthus Biotherapeutics North America, Inc. (formerly Vaccitech North America, Inc.), Barinthus Biotherapeutics Switzerland GmbH (formerly Vaccitech Switzerland GmbH) and Barinthus Biotherapeutics S.R.L. (formerly Vaccitech Italia S.R.L.), are collectively referred to as the "Company" or "Barinthus Bio". The Company is a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity and cancer. The Company is headquartered in Harwell, Oxfordshire, United Kingdom. On November 6, 2023, the Company announced its renaming as Barinthus Bio to represent the evolution and expansion of its focus beyond vaccines.

In connection with the initial public offering of American Depositary Shares ("ADSs"), in March 2021, the Company completed a corporate reorganization wherein the shareholders of Barinthus Biotherapeutics (UK) Limited exchanged each of their ordinary shares, series A shares and series B shares of Barinthus Biotherapeutics (UK) Limited for the same quantity of ordinary shares, series A shares and series B shares in Barinthus Biotherapeutics plc (resulting in the shareholders of the Company holding the same percentage and class of shares in Barinthus Biotherapeutics plc as they had in Barinthus Biotherapeutics (UK) Limited). The group reorganization under common control constituted a change in reporting entity and has been given retrospective effect reflecting the net assets of Barinthus Biotherapeutics (UK) Limited and its subsidiaries and Barinthus Biotherapeutics plc at their historical carrying amounts. On April 4, 2022, a merger was effected between subsidiaries Vaccitech USA, Inc. and Barinthus Biotherapeutics North America, Inc., with Barinthus Biotherapeutics North America, Inc. being the surviving entity.

The Company operates in an environment of rapid technological change and substantial competition from pharmaceutical and biotechnology companies. The Company is subject to risks common to companies in the biopharmaceutical industry in a similar stage of its life cycle including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its vaccine product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of any of its products that are approved, and protection of proprietary technology. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain required regulatory approval or that any approved products will be commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales. If the Company does not successfully commercialize any of its products or mitigate any of these other risks, it will be unable to generate revenue or achieve profitability.

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission for annual financial reporting. The Company's reporting currency is the U.S. dollar.

As of December 31, 2023, the Company had cash and cash equivalents of $142.1 million and an accumulated deficit of $176.6 million and the Company expects to incur losses for the foreseeable future. The Company expects that its cash and cash equivalents will be sufficient to fund current operations into the fourth quarter of 2025, without additional financing. The Company expects to seek additional funding through equity financing, government or private-party grants, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or rights of the Company's stockholders. If the Company is unable to obtain sufficient capital, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business.

Guarantees and indemnifications

As permitted under the laws of England and Wales, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through the years ended December 31, 2023 and 2022, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue, income and expenses during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis, including those related to fair value of contingent consideration and impairment of goodwill and intangible assets. The Company's actual results may differ from these estimates under different assumptions or conditions.

As of the date of issuance of these consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained and are recognized in the consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the Company's financial statements.

2. Summary of Significant Accounting Policies

Principles of consolidation

The accompanying consolidated financial statements include the accounts of Barinthus Biotherapeutics plc and those entities in which it has a controlling interest. Intercompany amounts are eliminated on consolidation. Amounts attributable to the noncontrolling interest are presented as a separate element of equity in the accompanying consolidated financial statements.

Comprehensive loss

Comprehensive loss for all periods presented is comprised primarily of net (loss)/income and other comprehensive loss, which solely relates to foreign currency translation adjustments.

Foreign currency translation

The Company's reporting currency is the United States dollar. The functional currency of the parent and each subsidiary is the currency of the country and economic environment in which it is located. Assets and liabilities of each legal entity denominated or measured in a currency other than British Pounds are first translated into British pounds and consolidated. The consolidated balances are then converted into United States dollars at period-end exchange rates. Revenues and expenses are translated into British pounds, then into U.S. dollars at average exchange rates for each reporting period. Translation adjustments are reflected as accumulated other comprehensive loss within stockholders' equity. Gains and losses on foreign currency transactions are included in the consolidated statements of operations and comprehensive loss in the general and administrative expenses. The aggregate net foreign exchange gain or loss included in determining net loss was a loss of $7.6 million and gain of $26.4 million for the years ended December 31, 2023 and 2022, respectively.

Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment, the research and development of immunotherapies and vaccines.

Noncontrolling interest

In 2018, Barinthus Biotherapeutics plc established VOLT with a related party. As of December 31, 2021, Barinthus Biotherapeutics plc had contributed cash and intellectual property with an aggregate value of $11.9 million for a 76% controlling interest. The related party had contributed cash and intellectual property with an aggregate value of $3.8 million for a 24% noncontrolling interest. There were no further contributions in the years ended December 31, 2023 and 2022. The contributed intellectual properties were initially recorded at investment date fair value by VOLT and immediately expensed as research and development costs. The Company accounts for the noncontrolling interest in the accompanying consolidated financial statements initially at fair value with the subsequent carrying value adjusted for the noncontrolling share of VOLT's comprehensive loss.

Business Combinations

The Company accounts for business combinations using the acquisition method of accounting, which requires the recognition of tangible and identifiable intangible assets acquired and liabilities assumed at their estimated fair values as of the business combination date. The Company allocates any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in general and administrative expenses in the consolidated statements of operations and comprehensive loss. Transaction costs are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in the Company's operating results from the date of acquisition.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with remaining maturities of three months or less on the purchase date to be cash and cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that are actively traded (a Level 1 input). As of December 31, 2023, and 2022 there were no cash equivalents.

Revenue

The Company recognizes revenue when its 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 has entered into collaboration and license agreements, which are within the scope of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, to discover, develop, manufacture and commercialize product candidates. The terms of these agreements typically contain multiple promises or obligations, which may include licenses, or options to obtain licenses, to product candidates or future product candidates. The Company also derives revenue from government grants.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts recognized as revenue, but not yet received or invoiced are generally recognized as accounts receivable.

License revenue

The Company's arrangements may provide the collaboration partner with the right to select a target for licensing either at the inception of the arrangement or in the future. Under these arrangements, fees may be due to the Company (i) at the inception of the arrangement as an upfront fee or payment, (ii) upon the exercise of an option to acquire a license or (iii)

upon extending the selection period as an extension fee or payment. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for fee or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the inception of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or expires.

For arrangements that include sales-based milestones and royalties, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). This could require management to estimate the amount of revenue to recognize in the period if the actual data for the period has not been provided.

Research and development services

The promises under the Company's collaboration and license agreements generally include research and development services to be performed by the Company on behalf of the collaboration partner. For performance obligations that include research and development services, the Company recognizes revenue allocated to such performance obligations based on an appropriate measure of progress. The Company utilizes judgment to determine the appropriate method of measuring progress for the purposes of recognizing revenue, which may include an input measure such as costs incurred during the reporting period or ratably over the service period. Reimbursements from the partner are evaluated as to whether the Company acts as a principal or an agent in such relationships. The Company evaluates whether control over the underlying goods or services were obtained prior to transferring these goods or services to the collaboration partner. Where the Company does not control the goods or services prior to transferring these goods or services to the collaboration partner, such reimbursements are presented net of costs. At the inception of each arrangement that includes development milestone payments in respect of development efforts, the Company evaluates whether the development milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated development milestone value is included in the transaction price. Development milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular development milestone in making this assessment. There is judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each reporting period, the Company reevaluates the probability of achievement of all development milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. If a milestone or other variable consideration relates specifically to the Company's efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Company generally allocates the milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur. To date, the Company has not recognized any development milestone revenue resulting from any of its arrangements.

Grant income

The Company receives certain grant income which support its research efforts in defined projects and include contributions towards the research and development costs. When there is reasonable assurance that the Company will comply with the conditions attached to a received grant, and when there is reasonable assurance that the grant will be received, grant income is recognized as other operating income on a gross basis in the consolidated statements of operations and comprehensive loss on a systematic basis over the periods in which the Company recognizes expenses for the related costs for which the grants are intended to compensate. Grant income may be subject to review by the grantor in periods subsequent to its recognition and may result in the reversal of grant income previously recognized. Payments received in advance of incurring reimbursable expenses are recorded as deferred income.

Concentrations of credit risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents and accounts receivable. Periodically, the Company maintains deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses in these deposits. The Company's standard payment terms are 30 days'.

The Company recognizes revenue earned in connection with the license and services provided to customers and grantors. The Company provides credit to the grantors in the normal course of providing such services based on evaluations of their financial condition and generally does not require collateral. To manage accounts receivable credit risk, the Company monitors the creditworthiness of its grantors. Historically, the Company has not experienced any credit losses related to accounts receivable and does not maintain allowances for uncollectible amounts.

Licensees and grantors that represented 10% of more of the Company's revenue and accounted for 10% or more of accounts receivable are presented below:

Revenue	Country	Year ended December 31, 2023	Year ended December 31, 2022
Oxford University Innovation	U.K.	100 %	98 %

Accounts Receivable	Country	As of December 31, 2023	As of December 31, 2022
Oxford University Innovation	U.K.	— %	94 %

Allowance for credit losses

The Company evaluates its cash equivalents and accounts receivable for expected credit losses. Expected credit losses represent the portion of the amortized cost basis of a financial asset that an entity does not expect to collect. An allowance for expected credit losses is meant to reflect a risk of loss even if remote, irrespective of the expectation of collection from a particular issuer or debt security. The Company has not historically experienced any credit losses on any of its financial assets. With respect to cash equivalents and accounts receivable, given consideration of their short maturity, historical losses and the current market environment, the Company concluded there are no expected credit losses for these financial assets.

Property and equipment

Property and equipment are stated at cost, net of accumulated depreciation. Expenditures for maintenance and repairs are charged to operating expenses as incurred, whereas major betterments are capitalized as additions to property and equipment. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets as follows:

Asset Category	Estimated Useful Life
Office furniture and equipment	3 years
Laboratory equipment	4 years
Leasehold improvements	Lesser of lease term or estimated useful lives

Intangible assets acquired through business combinations

Intangible assets consist of acquired developed technology. Intangible assets are stated at cost less accumulated amortization and impairment losses. Amortization is computed using the straight-line method over the estimated useful lives of the respective assets, which is 10 years.

Impairment of long-lived assets

The Company reviews long-lived assets to be held and used, including property and equipment, intangible assets and operating lease right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be recoverable. Evaluation of recoverability is first based on an estimate of undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. In the event such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the assets are written down to their estimated fair values. No such impairments were recorded during the years ended December 31, 2023 and 2022.

Goodwill

Goodwill represents the excess of cost over the fair value of the net tangible and intangible assets of businesses acquired in a business combination. Goodwill is not amortized but rather is tested for impairment at least annually, or more frequently if events or changes in circumstances indicate that the carrying amount of goodwill may not be recoverable. The Company has elected to first assess the qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis of determining whether it is necessary to perform the quantitative goodwill impairment test. If the Company determines that it is more likely than not that its fair value is less than its carrying amount, then the quantitative goodwill impairment test will be performed. The quantitative goodwill impairment test identifies goodwill impairment and measures the amount of goodwill impairment loss to be recognized by comparing the fair value of a reporting unit with its carrying amount. If the fair value exceeds the carrying amount, no further analysis is required; otherwise, any excess of the goodwill carrying amount over the implied fair value is recognized as an impairment loss, and the carrying value of goodwill is written down to fair value. For the years ended December 31, 2023 and 2022, goodwill has been tested, and no impairments have been recorded.

Financial instruments

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, certain accrued expenses, contingent consideration and short-term debt. The carrying amounts of cash, cash equivalents, accounts receivable, security deposits, accounts payable, accrued expenses and short-term debt approximate their fair value due to the short-term nature of those financial instruments.

Fair value measurements

The Company follows the guidance in ASC 820, *Fair Value Measurements and Disclosures*, which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

- Level 1 – Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 – Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, the Company's own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. The Company uses prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may change for many instruments. This condition could cause an

instrument to be reclassified within levels in the fair value hierarchy. There were no transfers within the fair value hierarchy during the years ended December 31, 2023 and 2022.

The Company recognizes a contingent consideration liability related to the acquisition of Avidea Technologies, Inc. The liability is remeasured to fair value at each reporting date until the contingency is resolved. The fair value of the contingent consideration is a Level 3 valuation determined using significant unobservable inputs being the probability of success of achievement of the milestones and the expected date of the milestone achievement. Changes in fair value are recognized in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Leases

Leases are accounted for under ASC 842, *Leases* ("ASC 842") resulting in the recognition of lease liabilities and right-of-use assets. The Company only has operating leases. The Company has elected the practical expedient allowed under ASC 842 to account for each lease component (e.g., the right to use office space) and the associated non-lease components (e.g., maintenance services) as a single lease component. The Company also elected the short-term lease accounting policy for all asset classes; therefore, the Company is not recognizing a lease liability or right-of-use asset for any lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the Company is reasonably certain to exercise.

Variable lease payments such as the Company's share of real estate taxes, utilities, and common area maintenance, are reported as non-lease operating expenses.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

Right-of-use assets also include the effect of any lease payments made and exclude lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized as part of total operating expenses on a straight-line basis over the lease term. The difference between the value of the right of use asset and lease liability is due to the reclassification of prepaid rent and unamortized lease incentives.

Research and development

Research and development costs are expensed as incurred on an accruals basis. Research and development costs include payroll and personnel expense (including share-based compensation), consulting costs, external contract research and development expenses, raw materials, drug product manufacturing costs, and allocated overheads including depreciation and amortization, facility costs, and utilities. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Clinical trial costs

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activation, and other information provided to the Company by its vendors.

Patent and licensing costs

Patent and licensing costs are expensed as incurred because their realization is uncertain.

Ordinary shares

Ordinary shares are classified in stockholders' equity and represent issued share capital.

Additional paid-in capital

Additional paid-in capital is classified in stockholders' equity and represents the share premium account, where the difference between the price paid per share and the nominal value is recognized. The equity element of share based compensation is also recognized in additional paid in capital.

Share based compensation

The Company grants options over ordinary shares and restricted shares units to employees or Non-Executive Directors and accounts for share based compensation using the grant date fair value. Share based compensation awards are classified in the accompanying statements of operations based on the function to which the related services are provided. For service-based awards, compensation expense is generally recognized over the requisite service period of the awards, usually the vesting period. The Company applies the "multiple option" method of allocating expense. In applying this method, each vesting tranche of an award is treated as a separate grant and recognized on a straight-line basis over that tranche's vesting period. For performance-based awards where the vesting of the awards may be accelerated upon the achievement of certain milestones, vesting and the related share-based compensation is recognized as an expense when it is probable the milestone will be met. Assumptions used in the option pricing model include the following:

Expected volatility. Previously there was insufficient trading history for the Company's ordinary shares, therefore the expected price volatility for our ordinary shares was estimated using the average historical volatility of industry peers' shares as of the grant date of our options over a period of history commensurate with the expected life of the options. When selecting industry peers used in measuring implied volatility, the Company considered the similarity of their products and business lines, as well as their stage of development, size and financial leverage. The Company applied this process consistently using the same or similar public companies until 2023. During 2023, the Company determined that there is sufficient historical information on volatility of its share price available and the expected volatility used in the fair value calculation of new option grants is calculated based on a blended volatility of both historical volatility of the Company's share price and the expected volatility of the average historical volatility of industry peers' shares.

Expected term. The expected term of the Company's share options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The "simplified" method was determined to be appropriate as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded.

Risk-free interest rate. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods that are approximately equal to the expected term of the award.

Expected dividend. Expected dividend yield of zero is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

The Company has elected to recognize the effect of forfeitures on share-based compensation when they occur. Any differences in compensation recognized at the time of forfeiture are recorded as a cumulative adjustment in the period where the forfeiture occurs.

When awards are modified, the Company compares the fair value of the affected award measured immediately prior to modification to its value after modification. To the extent that the fair value of the modified award exceeds the original award, the incremental fair value of the modified award is recognized as compensation on the date of modification for vested awards, and over the remaining vesting period for unvested awards.

Income taxes

The financial statements reflect provisions for income taxes in the United Kingdom and foreign jurisdictions. Deferred tax assets and liabilities represent future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities and for loss carryforwards using enacted tax rates expected to be in effect in the years in which the differences reverse. A valuation allowance is recorded when it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The

tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date, the Company has not incurred interest and penalties related to uncertain tax positions nor has it recorded any unrecognized tax benefits.

Research and development incentives

In the United Kingdom, the Company had previously been entitled to a research and development tax credit regime, 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. Until March 2023, under the SME program, the Company was able to surrender some of its trading losses that arise from qualifying research and development activities for a cash rebate of up to 33.35% of such qualifying research and development expenditure. Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs and utilities costs incurred as part of research projects. Certain staff, consumables (including utilities), subcontractors and externally provided workers qualifying research and development expenditures are eligible for a cash rebate of up to 21.67%. A large portion of costs relating to research and development, clinical trials and manufacturing activities are eligible for inclusion within these tax credit cash rebate claims. From April 2023, under the SME program the additional deduction has decreased from 130% to 86%, the SME credit rate has reduced from 14.5% to 10% and the SME cash rebate for the Company has reduced from 33.35% to 18.6% and from 21.67% to 12.1% for subcontractors. Furthermore, the SME credit rate will decrease to 10% for expenditure incurred on or after April 1, 2023 unless the SME qualifies as an R&D intensive business i.e., R&D expenditure constitutes at least 40% (from April 1, 2023) or 30% (from accounting periods starting on or after April 1, 2024) of total expenditure. If the Company incurs tax losses, the Company is entitled to surrender the lesser of unrelieved tax loss sustained and the tax relief. As the realization of the tax relief does not depend on our generation of future taxable income or the Company's ongoing tax status or tax position, the Company does not consider the tax relief as an element of income tax accounting under ASC 740, *Income taxes* and records the tax relief as a form of government grant or assistance. For the years ended December 31, 2023 and 2022, the Company recognized research and development incentives of $3.5 million and $1.2 million respectively.

Net (loss)/income per share

Basic net (loss)/income per share is computed by dividing the net (loss)/income attributable to ordinary shareholders by the weighted-average number of ordinary shares outstanding for the reporting period without consideration for potentially dilutive securities. Net (loss)/income attributable to ordinary shareholders is computed as if all net (loss)/income for the period had been distributed. During periods in which the Company incurred a net loss, the Company allocates no net loss to participating securities because they do not have a contractual obligation to share in the net loss of the Company.

The Company computes diluted net (loss)/income per ordinary share after giving consideration to all potentially dilutive ordinary equivalents, including stock options outstanding during the period, except where the effect of such non-participating securities would be antidilutive.

Diluted net (loss)/income per share is computed by dividing the net (loss)/income attributable to ordinary shareholders by the weighted-average number of ordinary shares and dilutive ordinary share equivalents outstanding for the period, determined using the treasury-stock and if-converted methods.

Contingent liabilities

A provision for contingent liabilities is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. The Company is a party to certain litigation and disputes arising in the normal course of business. As of December 31, 2023, the Company does not expect that such matters will have a material adverse effect on the Company's business, financial position, results of operations, or cash flows.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different applications dates for public and nonpublic companies, the Company can adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards and have determined that such standards will not have a material impact on our consolidated financial statements or do not otherwise apply to our current operations.

3. Foreign Currency Translation in General and Administrative Expenses

The aggregate, net foreign exchange gain or loss included in determining net (loss)/income recognized in general and administrative expenses for the year ended December 31, 2023, and 2022, was a loss of $7.6 million and a gain of $26.4 million, respectively.

4. Net (Loss)/Income Per Share

The following table sets forth the computation of basic and diluted net (loss)/income per share for the years ended December 31, 2023 and 2022 (in thousands, except number of shares and per share amounts):

	Year Ended December 31,	
Numerator:	**December 31, 2023**	**December 31, 2022**
Net (loss)/income	$ (73,447)	$ 5,321
Net loss attributable to noncontrolling interest	100	21
Net (loss)/income attributable to Barinthus Biotherapeutics plc shareholders	$ (73,347)	$ 5,342
Denominator:		
Weighted-average ordinary shares outstanding, basic	38,386,491	37,248,126
Effect of dilutive stock options	—	921,181
Weighted-average ordinary shares outstanding, diluted	38,386,491	38,169,307
Net (loss)/income per share attributable to ordinary shareholders, basic	$ (1.91)	$ 0.14
Net (loss)/income per share attributable to ordinary shareholders, diluted	$ (1.91)	$ 0.14

Since the Company was in a loss position for 2023, basic net loss per share is the same as diluted net loss per share, as the inclusion of all potential ordinary share equivalents outstanding would have been anti-dilutive. For the year ended December 31, 2023, 6,207,664 potential ordinary shares issuable for stock options were excluded from the computation of diluted weighted-average shares outstanding because including them would have had an anti-dilutive effect. For the year ended December 31, 2022, 2,912,756 potential ordinary shares issuable for stock options, respectively, were excluded from the computation of diluted weighted-average shares outstanding because including them would have had an anti-dilutive effect.

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5. Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	December 31, 2023	December 31, 2022
Office furniture and equipment	$ 1,108	$ 1,041
Laboratory equipment	5,728	4,312
Leasehold improvements	8,673	3,926
Property and equipment, at cost	15,509	9,279
Less: accumulated depreciation	(3,688)	(1,322)
Property and equipment, net	$ 11,821	$ 7,957

Depreciation expense for the year ended December 31, 2023 was $2.3 million (December 31, 2022: $1.1 million).

6. Intangible assets, net

The gross amount of amortizable intangible assets, consisting of acquired developed technology, was $31.6 million at both December 31, 2023 and 2022 and accumulated amortization was $6.5 million and $3.3 million as of December 31, 2023 and 2022, respectively. The amortization expense for the year ended December 31, 2023 was $3.2 million (December 31, 2022: $3.2 million). The estimated annual amortization expense is $3.2 million for the years 2024 through to 2031.

7. Prepaid and other current assets

Prepaid and other current assets consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Prepayments and accrued income	$ 5,402	$ 5,887
Value Added Tax receivable	3,031	—
Lease incentives receivable	—	1,770
Other	1,474	611
Total	$ 9,907	$ 8,268

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Accrued manufacturing and clinical expenses	$ 4,003	$ 2,997
Accrued bonus	2,412	1,925
Accrued payroll and employee benefits	789	928
Accrued professional fees	942	1,270
Accrued other	1,066	941
Total	$ 9,212	$ 8,061

9. Out-licenses and Grants

OUI license

In April 2020, the Company entered into an Amendment, Assignment and Revenue Sharing Agreement ("License Agreement Amendment") with Oxford University Innovation, or OUI, which vested and assigned all intellectual property rights in relation to any ChAdOx1 or ChAdOx2 vector-based vaccine jointly owned by the Company and OUI in order to facilitate the license of vaccines based on the ChAdOx1 by OUI to AstraZeneca plc ("AstraZeneca"). Under this agreement, the Company is entitled to receive from OUI a share of all payments received by OUI from AstraZeneca in respect of the vaccine based on the ChAdOx1. On December 30, 2020, AstraZeneca announced that vaccine based on the ChAdOx1 which we refer to as Vaxzevria had been approved for emergency supply in the United Kingdom by the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA).

The Company determined that the intellectual property vested and assigned under the License Agreement Amendment is a functional intellectual property (that is, it has significant standalone functionality in the form of its ability to treat a disease or condition) and there is no expectation under the License Agreement Amendment that the Company will undertake activities to change the functionality. Consequently, the Company concluded that the nature of the Company's promise in transferring the intellectual property is to provide a right to use the Company's functional intellectual property. Accordingly, the Company recognizes revenue in manner that depicts the Company's progress toward satisfying its performance obligation of providing access to its intellectual property throughout the license period based on the terms of OUI's agreement with AstraZeneca.

On March 28, 2022, pursuant to the OUI License Agreement Amendment, we were notified of the commencement of payments, arising from AstraZeneca's commercial sales of Vaxzevria. Under the terms of an exclusive worldwide license agreement between OUI and AstraZeneca, OUI is entitled to milestone payments and royalties on commercial sales of Vaxzevria that began after the pandemic period. As part of the assignment from us to OUI, we are entitled to receive approximately 24% of payments received by OUI from AstraZeneca. For the year ended December 31, 2023, the Company recognized approximately $0.8 million as revenue (year ended December 31, 2022: $43.7 million) and had an outstanding receivable of nil as of December 31, 2023 (2022: $5.5 million). There is no guarantee that further payments will be received pursuant to the agreement in the future and, if such payments are made, that we will be notified of such payments in a timely manner.

Scancell contract

On November 2, 2022, the Company entered into an agreement with Scancell to grant a research and development license, consisting of upfront and development milestone and royalty payments, for the development and commercialization of the SNAPvax functional intellectual property. The Company recognized non-refundable upfront revenue, amounting to nil for the year ended December 31, 2023 (December 31, 2022: $0.7 million). As of December 31, 2023, nil was recorded as a receivable (December 31, 2022: $0.3 million).

Coalition for Epidemic Preparedness Innovations ("CEPI") Funding Agreement

On December 20, 2023, Barinthus Biotherapeutics (UK) Limited (the "Company"), the Chancellors, Masters and Scholars of the University of Oxford ("Oxford," together with the Company, the "Partners") and the Coalition for Epidemic Preparedness Innovations ("CEPI") entered into a Funding Agreement (the "Funding Agreement") pursuant to which CEPI will provide funding of up to $34.8 million to the Company to advance the development of VTP-500, the Company's vaccine candidate against Middle East Respiratory Syndrome ("MERS," and such development activities, the "Project"). In December 2023, VTP-500 received PRIME (PRIority MEdicines) designation by the European Medicines Agency.
Pursuant to the Funding Agreement, the Company has agreed to pay CEPI on a country-by-country basis increasing mid-single digit percentage royalties of net sales and net income with respect to future cash sales of VTP-500, less certain deductions, for a period starting on December 20, 2023 ("Effective Date") and ending the later of: (i) the expiration of the last valid patent claim included in intellectual property developed under the Project covering VTP-500 in such country, (ii) the expiration of Regulatory Exclusivity (as defined in the Funding Agreement) for VTP-500 in such country, and (iii) the tenth (10th) anniversary of the first commercial sale of VTP-500 (the "Royalty Term"). The Company shall also pay CEPI a mid-double digit percentage of net revenue earned on VTP-500 until CEPI has received payments from the Company under the Funding Agreement equaling the total amount of funding paid by CEPI to the Company and a low double-digit percentage of such net revenue thereafter. Sales for the benefit of end users in specified low and middle income countries

("LMICs") and upper and middle income countries ("UMICs") are excluded from the calculations of net sales and net revenue. Sales of product for the benefit of end users in LMICs and UMICs are subject to tiered discounted pricing requirements under the Funding Agreement. The Company is further required to pay a mid-double digit percentage of any proceeds earned on any priority review voucher related to VTP-500 during the Royalty Period.

For the year ended December 31, 2023, no proceeds have been received and no income has been recognized in relation to this contract as no activities eligible for the funding were undertaken during the period.

Contract assets and liabilities

The Company discloses accounts receivable separately in the consolidated balance sheets at the net amount expected to be collected. Contract assets primarily relate to the Company's conditional right to consideration for work completed but not billed at the reporting date. As of December 31, 2023 and 2022 the Company did not have any contract assets.

Contract liabilities primarily relate to payments received from customers in advance of performance under the contract and are disclosed as deferred revenue separately in the consolidated balance sheets. The Company's contract liabilities arise when payment is received upfront for various multi-period extended license and service arrangements.

Changes in the contract liabilities during the years ended December 31, 2023 and 2022, are as follows (in thousands):

	December 31, 2023	December 31, 2022
Beginning balance	$ —	$ 182
Revenue recognized related to contract liability balance	—	(158)
Foreign exchange translation	—	(24)
Ending balance	$ —	$ —

10. Ordinary Shares

On May 4, 2021, the Company closed its initial public offering ("IPO") of 6,500,000 ADS representing 6,500,000 ordinary shares having a nominal value of £0.000025 per share, at a public offering price of $17.00 per share, for aggregate net proceeds of $102.8 million after deducting underwriting commissions of $7.7 million and incurred offering costs of $2.2 million.

All ordinary shares rank pari passu as a single class. The following is a summary of the rights and privileges of the holders of ordinary shares as of December 31, 2023:

Liquidation preference: In the event of the liquidation, dissolution or winding up of the Company, the assets of the Company available for distribution to holders of the ordinary shares shall be distributed amongst all holders of the ordinary shares in proportion to the number of shares held irrespective of the amount paid or credited as paid on any share.

Dividends: Holders of the ordinary shares are entitled to dividends, as may be recommended from time to time by the Board and declared by the ordinary shareholders out of legally available funds.

Voting Rights: Each holder of ordinary shares is entitled to one vote for each share on all matters to be voted on by ordinary shareholders.

Preemption rights: Pursuant to section 561 of the Companies Act 2006, shareholders are granted preemptive rights when new shares are issued for cash. However, it is possible for our Articles, or shareholders at a general meeting representing at least 75% of our ordinary shares present (in person or by proxy) and eligible to vote at that general meeting, to disapply these preemptive rights. Such a disapplication of preemption rights may be for a maximum period of up to five years from the date of the 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) to remain effective.

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On April 21, 2021, our shareholders approved the disapplication of preemptive rights for a period of five years from the date of approval by way of a special resolution of our shareholders. This included the disapplication of preemption rights in relation to the allotment of our ordinary shares in connection with the IPO. This 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).

On November 6, 2023, we held a general meeting where our shareholders approved resolutions granting our board of directors or any duly authorized committee of the board of directors the authority to allot shares in the Company or grant rights to subscribe for or to convert any security into shares in the Company free from preemption rights. Pursuant to such approval, our board of directors was authorized to allot shares up to an aggregate nominal amount of £1,928 free from statutory preemption rights.

As of December 31, 2023, the Company has reserved the following ordinary shares for future issuance:

Exercise of stock options	6,207,664
Shares available for future stock incentive plan awards	1,623,840
Total	7,831,504

11. Deferred shares

All deferred shares rank pari passu as a single class. The deferred shares do not have rights to dividends or to participate in profits on a return of assets on liquidation, the deferred shares confer on the holders thereof an entitlement to receive out of the assets of the Company available for distribution amongst the shareholders (subject to the rights of any new class of shares with preferred rights) the amount credited as paid up on the deferred shares held by them respectively after (but only after) payment shall have been made to the holders of the ordinary shares of the amounts paid up or credited as paid up on such shares and the sum of £1.0 million ($1.4 million) in respect of each ordinary share held by them respectively. The deferred shares shall confer on the holders thereof no further right to participate in the assets of the Company.

On March 29, 2023, all deferred B shares (nominal value of £0.01 each) and deferred C shares (nominal value of £0.00007362459546925556 each) previously in issue were transferred back to the Company and subsequently cancelled. These deferred shares had previously been issued to certain pre-IPO shareholders in connection with the implementation of certain stages of the Company's pre-IPO share capital reorganization. The Company received shareholder pre-approval on April 21, 2021 (pursuant to the shareholder resolutions passed on that date) in order to effect the transfer back and cancellation of the deferred shares for nil consideration in accordance with sections 659 and 662 of the Companies Act 2006.

The Company's deferred A shares with a nominal value of £1.00 each remain in issue for the purposes of satisfying the minimum share capital requirements for a public limited company as prescribed by the Companies Act 2006.

12. Fair Value

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, certain accrued expenses, contingent consideration and short-term debt. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, certain accrued expenses, contingent consideration and short-term debt approximated their respective fair value due to the short-term nature and maturity of these instruments.

As of December 31, 2023, the Company had a contingent consideration liability of $1.8 million related to the acquisition of Avidea Technologies, Inc. The fair value of the contingent consideration is a Level 3 valuation with the significant

unobservable inputs being the probability of success of achievement of the milestones and the expected date of the milestone achievement. Significant judgment is employed in determining the appropriateness of certain of these inputs.

The following table summarizes changes in the fair value of Contingent Consideration (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Beginning balance	$ 1,711	$ 2,371
Change in fair value recognized in net loss	55	(73)
Settlement of contingency	(163)	(325)
Foreign exchange translation recognized in other comprehensive loss	219	(262)
Ending balance	$ 1,823	$ 1,711

13. Goodwill

The following table summarizes changes in goodwill (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Beginning balance	$ 12,209	$ 12,630
Measurement period adjustments	—	(421)
Ending balance	$ 12,209	$ 12,209

14. Share-Based Compensation

On April 8, 2021, the Board of the Company adopted the Barinthus Biotherapeutics plc Share Award Plan 2021 ("the Plan") and the Barinthus Biotherapeutics plc Non-Employee Sub-Plan which is a sub-plan of the Plan. Under the terms of the Plan, the Board is permitted to grant awards to employees as restricted share units, options, share appreciation rights and restricted shares. The aggregate number of shares initially available for issuance under the Plan and the Barinthus Biotherapeutics plc Non-Employee Sub-Plan cannot exceed 3,675,680 ordinary shares (the "Initial Limit"). Beginning calendar year 2023, the total number of ordinary shares available for issuance under the Plan shall be increased on January 1 of each year in an amount equal to the lesser of (i) 4% of the Company's issued and outstanding ordinary shares (which 4% limit shall be measured as of January 1 of such year) and (ii) such number of ordinary shares as determined by the Compensation Committee of the Board in its discretion (the "Annual Increase"). In accordance with the terms of the Annual Increase, the total number of ordinary shares available for issuance under the Plan increased by 1,507,341 of January 1, 2023. The awards generally vest based on the grantee's continued service with the Company during a specified period following grant as determined by the Board and generally expire ten years from the grant date. Option awards generally vest over three years, but vesting conditions can vary at the discretion of the Company's Board. As of December 31, 2023 and 2022, 1,623,840 and 1,670,268 ordinary shares are available for future grants, respectively.

In 2018, the Company's board of directors adopted the Enterprise Management Incentive Share Option Scheme (the "EMI Plan") which provided for the grant of incentive stock options and nonqualified stock options to non-director employees of the Company. The Company also has a nonqualified stock option plan for officers and directors. The awards generally vest based on the grantee's continued service with the Company during a specified period following grant as determined by the board of directors and generally expire ten years from the grant date. Option awards generally vest over three years, but vesting conditions can vary at the discretion of the Company's board of directors. A total of 3,530,634 ordinary shares were reserved for issuance in accordance with the provisions of the EMI Plan and restricted stock unit ("RSUs") plan. Upon adoption of the Plan, no further awards are to be made under the EMI Plan.

BARINTHUS BIOTHERAPEUTICS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The fair value of each stock option issued to employees was estimated at the date of grant using Black-Scholes with the following weighted-average assumptions:

	Year Ended,	
	2023	2022
Expected volatility	97.1 %	94.7 %
Expected term (years)	6	6
Risk-free interest rate	3.7 %	2.4 %
Expected dividend yield	— %	— %

Prior to the IPO, the Company applied a discount for lack of marketability calculated using the Finnerty model

Expected volatility: Previously there was insufficient trading history for the Company's ordinary shares, therefore the expected price volatility for our ordinary shares was estimated using the average historical volatility of industry peers' shares as of the grant date of our options over a period of history commensurate with the expected life of the options. When selecting industry peers used in measuring implied volatility, the Company considered the similarity of their products and business lines, as well as their stage of development, size and financial leverage. The Company applied this process consistently using the same or similar public companies until 2023. During 2023, the Company determined that there is sufficient historical information on volatility of its share price available and the expected volatility used in the fair value calculation of new option grants is calculated based on a blended volatility of both historical volatility of the Company's share price and the expected volatility of the average historical volatility of industry peers' shares.

Expected term (years): Expected term represents the period that the Company's option grants are expected to be outstanding. There is not sufficient historical share exercise data to calculate the expected term of the stock options. Therefore, the Company elected to utilize the simplified method to value option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Risk-free interest rate: The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the daily U.S. Treasury yield curve rate in effect as of the date of grant.

Expected dividend yield: The Company does not anticipate paying any dividends in the foreseeable future.

A summary of stock option activity is presented below:

	Number of Stock Options	Weighted-average Exercise Price Per Option	Weighted-average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, January 1, 2023	4,884,720	$ 9.04	7.36	$ 2,619
Granted	2,288,236	2.51		
Exercised	(72,386)	0.00026		
Forfeited/expired	(892,906)	7.30		
Outstanding, December 31, 2023	6,207,664	$ 6.91	7.95	$ 6,044
Exercisable, December 31, 2023	2,839,791	$ 8.91	7.33	$ 2,883

The weighted-average grant date per-share fair value of stock options granted during the year ended December 31, 2023 was $1.99 per share (December 31, 2022: $3.51 per share). The aggregate intrinsic value of stock options exercised during the year ended December 31, 2023 was $0.2 million (December 31, 2022: $0.8 million). As of December 31, 2023, there was $3.0 million (2022: $7.1 million) of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 1.60 years.

Share based compensation expense is classified in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Research and development	$ 2,011	$ 2,668
General and administrative	3,044	7,209
Total	$ 5,055	$ 9,877

15. Income Taxes

(Loss) income before income taxes are as follows (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
United Kingdom	$ (50,534)	$ 15,511
United States	(24,507)	(14,648)
Other foreign	(1,481)	(13)
(Loss)/income before income taxes	$ (76,522)	$ 850

The components of income tax benefit are as follows (in thousands):

	Year ended December 31, 2023	Year ended December 31, 2022
Current income tax benefit/(expense):		
United States	$ (28)	$ 133
Other Foreign	(45)	—
Deferred income tax benefit:		
United States	3,148	4,338
Total income tax benefit	$ 3,075	$ 4,471

A reconciliation of the UK statutory income tax rate to the Company's effective tax rate as reflected in the consolidated financial statements is as follows:

	Year ended December 31, 2023	Year ended December 31, 2022
Statutory tax rate	23.52 %	19.00 %
Increase (decreases) resulting from:		
Permanent differences	1.03	(103.46)
Provision to return adjustments	(4.09)	(105.66)
Research and development credits	(4.94)	(307.09)
Foreign rate differential	1.23	(149.82)
Change in valuation allowance	(11.84)	146.55
Share based compensation	(0.84)	(10.21)
Effective tax rate	4.07 %	(510.69)%

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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income and for tax carryforwards. Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Net operating loss carryforwards	$ 23,589	$ 9,940
Research and development credit carryforwards	40	3,146
Deferred revenue	—	54
Share based compensation	4,226	3,956
Lease liability	3,404	2,257
Accruals and intangibles	745	765
Capitalized Research and Development expenditure	4,228	2,522
Other	1	1
Gross deferred tax asset	36,233	22,641
Valuation allowance	(25,057)	(13,707)
Net deferred tax assets	11,176	8,934
Deferred tax liabilities:		
Depreciation	(1,652)	(1,704)
Right-of-use lease asset	(1,922)	(1,993)
Unrealized gain on investment	(1,267)	(1,204)
Intangible assets	(6,909)	(7,779)
Net deferred tax liabilities	(11,750)	(12,680)
Total deferred tax, net	$ (574)	$ (3,746)

Specified research and experimentation costs under Section 174 of the Internal Revenue Code are required to be capitalized and amortized ratably over five years for domestic expenditures and over 15 years for foreign expenditures. This provision of Section 174 became effective for tax years beginning after December 31, 2021. As a result of the capitalization of these costs in the current year, the Company has recorded a $4.2 million deferred tax asset (2022: $2.5 million).

As of December 31, 2023, the Company had a valuation allowance of $25.1 million (2022: $13.7 million) against its deferred tax assets, which consisted principally of net operating loss and research and development credit carryforwards. The Company considered the positive and negative evidence bearing upon its ability to realize the deferred tax assets. In addition to the Company's history of cumulative losses, the Company cannot be certain that future taxable income will be sufficient to realize its deferred tax assets. Accordingly, a valuation allowance has been provided against its deferred tax assets. When the Company changes its determination as to the amount of its deferred tax assets that can be realized, the valuation allowance is adjusted with a corresponding impact to the provision for income taxes in the period in which such determination is made.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2023 and 2022 related primarily to the increase in net operating loss and credit carryforwards, and were as follows:

	Year ended December 31, 2023	Year ended December 31, 2022
Valuations allowance at beginning of year	$ 13,707	$ 13,500
Changes in valuation allowance arising from in-year additions	1,052	—
Increases recorded to income tax provision	9,605	1,500
Foreign exchange translation	693	(1,293)
Valuation allowance at end of year	$ 25,057	$ 13,707

As of December 31, 2023, the Company had net operating loss ("NOL") carryforwards totaling approximately $92.7 million which have an unlimited carryforward period, of which $74.2 million originate in the United Kingdom. As of December 31, 2023, the Company had $0.04 million of research and development tax credit carryforwards which also have an unlimited carryforward period.

As of December 31, 2022, the Company had NOL carryforwards totaling approximately $39.6 million which have an unlimited carryforward period, of which $35.1 million originate in the United Kingdom. As of December 31, 2022, the Company had $3.1 million of research and development tax credit carryforwards which also have an unlimited carryforward period.

As of December 31, 2023 and 2022, the Company does not have any material unrecognized tax benefit liabilities. The Company files corporation/income tax returns in the United Kingdom, Australia, and the United States. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. In the United Kingdom, tax years from 2020 remain subject to examination by HMRC. In all other jurisdictions, the tax years since inception remain subject to examination by the applicable taxing authorities as of December 31, 2023 and 2022.

16. Commitments and Contingencies

In-License Agreements

The Company is party to a number of licensing agreements, these agreements serve to provide the Company with the right to develop and exploit the counterparties' intellectual property for certain medical indications. As part of execution of these arrangements, the Company paid certain upfront fees, which have been expensed as incurred because the developing technology has not yet reached technical feasibility, the lack of alternative use, and the lack of proof of potential value. The agreements cover a variety of fields, including influenza, cancer, HPV, HBV and MERS. The Company's obligations for future payments under these arrangements are dependent on its ability to develop promising drug candidates, the potential market for these candidates and potential competing products, and the payment mechanisms in place in countries where the Company retains the right to sell. Each agreement provides for specific milestone payments, typically triggered by achievement of certain testing phases in human candidates, and future royalties ranging from 1 to 5% for direct sales of a covered product to 3 to 7% of net payments received for allowable sublicenses of technology developed by the Company. The obligation to make these payments is contingent upon the Company's ability to develop candidates for submission for phased testing and approvals, and for the development of markets for the products developed by the Company. The Company has not made any material payments under these license agreements during the years ended December 31, 2023, and 2022.

Leases

The Company leases certain laboratory and office space under operating leases, which are described below.

The Oxford Science Park, Oxford

The Company leased an office and laboratory space from a related party in Oxford, England under an operating lease with a contractual term expiring in 2028. The lease was terminated on July 31, 2022, and the Company relocated its corporate headquarters to The Harwell Science and Innovation Campus, Oxfordshire, in the third quarter of 2022.

The Harwell Science and Innovation Campus, Oxfordshire

On September 3, 2021, the Company entered into a lease agreement for the lease of approximately 31,000 square feet in Harwell, Oxfordshire which expires in September 2031. The property is the Company's corporate headquarters. As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date, being the rate incurred to borrow on a collateralized basis over a similar term at an amount equal to the lease payments in a similar economic environment. The Company has provided the lessor with a refundable security deposit of $0.7 million which is included in Other assets.

Germantown, Maryland

On June 14, 2022, the Company entered into a lease agreement for the lease of approximately 19,700 square feet in Germantown, Maryland. The site will house the Company's state-of-the-art wet laboratory in the United States of America. The lease expires on February 28, 2034, with the Company having a single right to extend for an additional five years on the same terms and conditions other than for the base rent. The Company has a rent-free period up to February 29, 2024 and is entitled to up to $3.5 million for leasehold improvements to the premises desired by the Company. The Company has provided the lessor with a refundable security deposit of $0.2 million which is included in Other assets.

The Company recorded a right-of-use asset and a lease liability on the effective date of the lease term. The Company's right-of-use assets and lease liabilities are as follows (in thousands):

	December 31, 2023	December 31, 2022
Right-of-use asset	$ 7,581	$ 7,753
Lease liability, current	$ 1,785	$ 433
Lease liability, noncurrent	$ 11,191	$ 8,340
Other information		
Operating cash flows from operating leases	$ 639	$ 1,081
Weighted average remaining lease term (years)	8.93	9.44
Weighted average discount rate	7.5 %	7.6 %
Lease Costs		
Short-term lease costs	$ 189	$ 529
Fixed Lease Costs	$ 883	$ 1,216
Total lease cost	$ 1,072	$ 1,745

Maturities of the Company's minimum lease liabilities as of December 31, 2023 were as follows (in thousands):

Maturity of lease liabilities:	
2024	$ 1,785
2025	1,936
2026	1,960
2027	1,985
2028	2,010
Thereafter	7,999
Total minimum lease payments	17,675
Less: imputed interest	(4,699)
Total lease liability	$ 12,976

Non-lease and other costs paid to the lessors are primarily related to services provided by the lessors in operating the premises that includes fees, operating costs, taxes, and insurance related to the leased premises.

Other contingencies

The Company is a party in various contractual disputes, litigation, and potential claims arising in the ordinary course of business. The Company does not believe that the resolution of these matters will have a material adverse effect on its financial position or results of operations.

17. Employee Benefit Plans

In the United Kingdom, the Company has adopted a defined contribution plan (the U.K. Plan) which qualifies under the rules established by HM Revenue & Customs. Contributions to the U.K. Plan are charged to the consolidated statements of operations and comprehensive loss in the year to which they relate.

The Company has 401(k) defined contribution retirement plans in which all its employees located in the United States are eligible to participate. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. Contributions to the plans are charged to the consolidated statements of operations and comprehensive loss in the year to which they relate.

During the year ended December 31, 2023, the Company provided a total of $0.7 million (December 31, 2022: $0.5 million) in contributions under both the U.K. Plan and the 401(k) plans.

18. Related Party Transactions

During the year ended December 31, 2023, the Company incurred expenses of $0.4 million (December 31, 2022: $0.4 million) from its shareholder, the University of Oxford, related to clinical study costs. As of December 31, 2023, the Company owed nil (2022: $nil).

During the year ended December 31, 2023, the Company incurred expenses of $0.6 million (December 31, 2022: $0.4 million) from Oxford University Innovation Limited which is a wholly owned subsidiary of the Company's shareholder, the University of Oxford. As of December 31, 2023, the Company owed $2 thousand (December 31, 2022: nil) to Oxford University Innovation Limited.

During the year ended December 31, 2023, the Company recognized license revenue of $0.8 million (December 31, 2022: $43.7 million) from Oxford University Innovation Limited which is a wholly owned subsidiary of the Company's shareholder, the University of Oxford. As of December 31, 2023, the Company was owed nil (2022: $5.5 million) from Oxford University Innovation Limited.

19. Subsequent Events

In accordance with the terms of the Annual Increase of the Barinthus Biotherapeutics plc Share Award Plan 2021, the total number of ordinary shares available for issuance under the Plan increased by 4% of the Company's issued and outstanding ordinary shares as of January 1, 2024.

In January 2024, the Company granted a total of 1,592,423 share options to employees and directors with a weighted average exercise price of $3.70.

CERTAIN INFORMATION IDENTIFIED WITH [***] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

19 December 2023

Funding Agreement Agreement Summary

PARTNER INFORMATION	
Names:	**The Chancellors, Masters and Scholars of the University of Oxford** ("**Oxford**"); and **Barinthus Biotherapeutics (UK) Limited**, a private limited company incorporated in England and Wales with company number 09973585 ("**Barinthus Bio**"), (each of Oxford and Barinthus Bio a "**Partner**" and together the "**Partners**")
Mailing Address:	For Oxford: University Offices, Wellington Square, Oxford, OX1 2JD For Barinthus Bio: Barinthus Biotherapeutics (UK) Limited, Units 6 to 10 Zeus Building, Rutherford Avenue, Harwell, Oxfordshire, Didcot OX11 0DF
Project Lead:	For Oxford: [***] For Barinthus Bio: [***]
Management Contact:	For Oxford: [***] For Barinthus Bio: [***]
Bank Account Details:	For Oxford Account Name: University of Oxford Account Number: [***] IBAN Number: [***] Bank Sort Code Number: [***] Swift Code: [***] Bank: [***] Bank Address: [***] For Barinthus Bio Account Name: Barinthus Biotherapeutics (UK) Limited Account Number: [***]

	IBAN Number: [***] Bank Sort Code Number: [***] Swift Code: [***] Bank: [***] Bank Address: [***].

CEPI INFORMATION	
Mailing Address:	**Coalition for Epidemic Preparedness Innovations** ("**CEPI**") Postbox 1030 Hoff, 0218 Oslo, Norway
Project Lead:	[***]
Management Contact:	[***]

AGREEMENT INFORMATION	
Project Name	CEPI – Oxford – Barinthus Bio ChAdOx1 MERS vaccine development
Effective Date	Date of last signature below
Expiry Date	As described in Clause 19.1 of the Terms and Conditions in Annex A.
This Agreement includes and incorporates by reference:	The agreement (the "**Agreement**") means this Agreement Summary together with the following: - Terms and Conditions (Annex A) - Team Charter (Annex B) - Integrated Product Development Plan and Work Package(s) (Annex C) - Budget for Work Packages (Annex D) - Equitable Access Plan (Annex E) - List of UMICs, HICs and LMICs as at the Effective Date (Annex F) - List of Sub-Contractors (Annex G) - COGs (Annex H) - CEPI's Policies: Third Party Code, Cost Guidance and Transparency and Confidentiality Policy (Annex I) - Stage Gate(s) (Annex J) - Template Technical Report (Annex K) - List of CEPI Affiliates as at the Effective Date (Annex L) - Clinical Trial Policy (Annex M)

THIS AGREEMENT is between The Chancellor, Masters and Scholars of the University of Oxford, Barinthus Biotherapeutics (UK) Limited and the Coalition for Epidemic Preparedness Innovations and is effective as of the date of the last signature, below (the "**Effective Date**"). Each party to this Agreement may be referred to individually as a "**Party**" and together as the "**Parties**."

Signed for and on behalf of:

COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS

Signature: /s/ In-Kyu Yoon…… Name: In-Kyu Yoon

Title: Acting Executive Director, R&D …….. Date: December 19, 2023

THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD

Signature: …/s/ Carly Banner…… Name: Carly Banner ……..

Title: Assistant Director (Research Contracts) …….. Date: December 20, 2023

BARINTHUS BIOTHERAPEUTICS (UK) LIMITED

Signature:/s/ William Enright Name: William Enright

Title: CEO Date: December 20, 2023

Annex A: Terms and Conditions

1. DEFINITIONS:

1.1 "**Affiliate**" means any business entity controlled by, controlling or under common control with, a Party. For clarity, for the purpose of this Clause 1.1 only, "control", "controlling" or "controlled" shall mean the ability to directly or indirectly control the management and/or business of the other entity, whether through ownership of voting stock or the power to appoint a majority of the Party's governing board, including, (a) direct or indirect, ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors in the case of a corporation or more than fifty percent (50%) of the equity interest in the case of any other type of legal entity; or (b) any other arrangement whereby the entity or person appoints or has the right to appoint (other than through the ownership of voting securities) a majority of the members of the board of directors or equivalent governing body of a corporation or other entity or has the ability to cause the direction of the management or policies of a corporation or other entity; provided, however, in the case of this clause (b), no person or entity will be deemed to be an Affiliate of such business entity solely by virtue of such person's or entity's direct or indirect ownership of any securities of such business entity. CEPI's "Affiliates" as of the Effective Date are listed in Annex L.

1.2 "**Agreement Summary**" means the signature page that identifies the Parties and to which this Annex A and other annexes are attached.

1.3 "**Annual Net Income**" means the total Net Income received by the Partners in a particular Calendar Year.

1.4 "**Annual Net Sales**" means the total Net Sales received by the Partners in a particular Calendar Year.

1.5 "**Assessors**" has the meaning described in Clause 11.1.

1.6 "**Background Intellectual Property**" (or "**Background IP**") means any and all Intellectual Property: (a) necessary for completion of the Project, or (b) for the purposes of the Public Health Licence only, that has been used or incorporated, or is used or incorporated by Barinthus Bio or its Affiliates at the time that the Public Health Licence is triggered pursuant to Clause 14.6, in the development or commercialisation of the Project Vaccine, in each case ((a) and (b)) that is owned or controlled by either Partner during the Term of this Agreement that is: (i) in existence as of the Effective Date, or (ii) later developed, acquired or in-licensed independently of the Project. For clarity, Background IP includes commercial freedom-to-operate licenses obtained by either Partner.

1.7 "**Barinthus Bio Licence Agreement**" has the meaning set out in Clause 14.9.

1.8 "**Budget**" means the schedule of funds identified in Annex D to be paid by CEPI to each of the Partners for the Project activities in the Work Package(s), as may be amended from time to time by the written agreement of the Parties.

1.9 "**Business Days**" means any day, other than (a) a Saturday or Sunday; and (b) any public holiday in London, England, Washington DC in the United States of America, or Oslo, Norway.

1.10 "**Calendar Year**" means each respective period of twelve (12) consecutive months

ending on December 31. For the avoidance of doubt, the first Calendar Year shall commence on the Effective Date, and the final Calendar Year shall end on the effective date of the expiration or termination of this Agreement.

1.11 "**CEPI Indemnitees**" has the meaning described in Clause 17.2.1.

1.12 "**CEPI Service Provider**" means a third party contracted and funded directly by CEPI, which CEPI, at its discretion, may make available to one or more of the Partners to support its activities under the Project.

1.13 "**Commercial Benefits**" means any economically quantifiable benefits that arise from: (i) the exploitation of the Project Vaccine, or (ii) the exploitation of the Project Intellectual Property or Project Results.

1.14 "**Confidential Information**" has the meaning described in Clause 18.1.

1.15 "**Cost Guidance**" means CEPI's explanatory document regarding eligible direct and indirect costs, non-eligible costs, and valuation of in-kind contributions, as further described in Clause 12.2 and attached hereto as Annex I.

1.16 "**Cost of Goods**" (or "**COGs**") has the meaning set forth on Annex H.

1.17 "**Cover**" means, with respect to a product, process, method, or service, that a Valid Claim would, absent a license thereunder, be infringed by the research, development, making, using, sale, offering for sale, importation, or other exploitation of such product, process, method, or service.

1.18 "**DSMB**" has the meaning described in Clause 7.5.2.

1.19 "**Enabling Rights**" means, with respect to a Partner, such Partner's Background IP and improvements thereto, Project IP and Project Results that could be asserted by the applicable Partner to block CEPI from exercising its rights under Clause 14.6 of this Agreement. For the purposes of this Agreement, 'Enabling Rights' also includes the contractual rights under contracts executed for the Project that control the use of such items, for example, in material transfer agreements.

1.20 "**Equitable Access**" means the principle that appropriate vaccines are first available to populations when and where they are needed to end an Outbreak or curtail an epidemic or pandemic, regardless of ability to pay, in accordance with CEPI's Equitable Access Policy, the terms of Clause 14 and the Equitable Access Plan.

1.21 "**Equitable Access Group**" means the group established in accordance with Clause 14.3.

1.22 "**Equitable Access Plan**" has the meaning described in Clause 14.2.

1.23 "**Financial Irregularity**" has the meaning described in Clause 19.4.6.

1.24 "**Financial Report**" has the meaning described in Clause 3.11.

1.25 "**First Commercial Sale**" means the first sale or supply of a Project Vaccine by either Partner or any of its Affiliates or its or their licensees or sublicensees for monetary value.

1.26 "**Force Majeure Event**" has the meaning described in Clause 21.8.

1.27 "**GMP**" means Good Manufacturing Practice as set forth in the ICH Good Manufacturing Guide for Active Pharmaceutical Ingredients Guideline Q7, as adopted by CPMP November 2000 as CPMP/ICH/4106/00, as amended, or analogous standards utilised by

the relevant Regulatory Authority, or the equivalent applicable laws and regulations as required for the manufacturing of the Project Vaccine in the country of manufacture.

1.28 "**HICs**" or "**Higher Income Countries**" means the countries identified as such in Part 2 of Annex F.

1.29 "**Increased Outbreak Preparation Need**" means when, having considered the reasonably accessible and relevant information including epidemiological data, travel and migration patterns and the likely availability of other products or product candidates, CEPI determines, acting reasonably following consultation with experts (for example a sub-group or subcommittee of CEPI's Scientific Advisory Committee that CEPI determines has appropriate expertise), that, as evidenced by an increase in the number of actual cases of MERS being reported, there is a heightened need for the Project Vaccine to address potential Outbreaks.

1.30 "**Initial Term**" has the meaning described in Clause 19.1.

1.31 "**Integrated Product Development Plan**" (or "**iPDP**") means the planning document setting out details of the various activities associated with the Project Vaccine described in the Work Package(s). The initial iPDP and Work Packages in support of such iPDP to which the Parties have mutually agreed are set forth in Annex C.

1.32 "**Intellectual Property**" or "**IP**" means: (a) inventions, patents, utility models, and rights in the foregoing; (b) trade marks, trade names, geographical indications and appellations of origin, rights under the law of passing off, unfair competition and equivalents; (c) copyright, rights in software, rights in performances and in recordings, moral rights, and database rights; (d) designs, design patents, registered and unregistered designs and design rights; (e) confidential information, trade secrets and rights under the law of breach of confidence and equivalents; and all other intellectual property rights of any kind however designated that may subsist anywhere in the world whether arising by operation of law, treaty, contract, conduct or otherwise, together with all registrations, applications, rights to priority, renewals, extensions, continuations, divisions or reissues thereof and all rights to bring action for infringement past, present and future.

1.33 "**Joint Monitoring and Advisory Group**" or "**JMAG**" has the meaning described in Clause 2.4.

1.34 "**LMIC or UMIC Recipients**" means any purchasers procuring in, or on behalf of, LMICs and/or UMICs (whether Gavi, UNICEF, CEPI, the World Health Organisation, their respective designees, funding or procurement mechanisms, governments, non-public purchasers, non-governmental organisations or any other third party for the purpose of supply only within LMICs and UMICs).

1.35 "**LMICs**" or "**Low and Middle Income Countries**" means the countries identified as such in Part 3 of Annex F.

1.36 "**Net Income**" means [***].

1.37 "**Net Revenue**" means [***]

1.38 "**Net Sales**" means [***].

1.39 "**Outbreak**" means a Public Health Emergency of International Concern declared by WHO, or a public health emergency on a national or regional scale declared by one or more public health agencies, with respect to Middle East respiratory syndrome (MERS) including any regional outbreak, an epidemic or a pandemic.

1.40 [***]

1.41 "**Project**" means the activities under the Work Package(s), as described therein and in the Budget, to be performed under this Agreement by or on behalf of the Partners and/or any Subawardee.

1.42 "**Project Clinical Trial**" has the meaning described in Clause 7.1

1.43 "**Project Clinical Trial Material**" means the clinical trial material consisting of quantities of Project Vaccine described in a Work Package(s) and manufactured by or on behalf a Partner using the funding to be provided by CEPI under any Work Package.

1.44 "**Project Continuity Plan**" has the meaning described in Clause 2.3.1.

1.45 "**Project Data**" means pre-clinical or clinical trial data generated by or on behalf of a Partner under any Work Package, including any such data with respect to negative results, model animal deaths and any toxicology study results. For clarity, Project Data shall not include any Chemistry, Manufacturing and Controls ("**CMC**") or other manufacturing- related information or data.

1.46 "**Project Intellectual Property**" (or "**Project IP**") means the Intellectual Property conceived, invented or made by or on behalf of any Partner (whether solely or jointly) and/or any Subawardee in the performance of the Project.

1.47 "**Project Materials**" means biological samples or, if applicable, animal models that are controlled by a Partner and are generated by or on behalf of Partner under any Work Package.

1.48 "**Project Results**" means the Project Materials, Project Data and Technical Reports that are generated by or on behalf of a Partner and/or any Subawardee under the Project, including with respect to results of assays necessary for Project Clinical Trial Material manufacturing in support of such manufacturing by or on behalf of a Partner and/or any Subawardee under the Project, whether in whole or in components or serum samples collected. For clarity, Project Results does not include Project Clinical Trial Materials.

1.49 "**Project Vaccine**" means the ChAdOx1 MERS (Middle Eastern Respiratory Syndrome) vaccine candidate, which induces a specific immune response against at least one MERS- CoV antigen for prophylactic use against MERS.

1.50 "**PRV Proceeds**" means amounts received by Barinthus Bio or any of its Affiliates from the sale of any priority review voucher relating to the Project Vaccine.

1.51 "**Public Health License**" has the meaning described in Clause 14.6.

1.52 "**Ready Reserve of Project Clinical Trial Material**" has the meaning described in Clause 13.1.2.

1.53 "**Regulatory Approval**" means, on an indication-by-indication and country-by-country basis, all approvals, licenses and authorizations of the applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical or biological product for a particular indication and a particular country, and, as applicable, including the approvals by the applicable Regulatory Authority of any expansion or modification of the label for such indication. For clarity: (a) Regulatory Approval shall not be deemed to occur with respect to an indication and a country until all approvals, licenses and authorizations of the applicable Regulatory Authority necessary to lawfully market and sell a pharmaceutical or biological product for such indication in such country have been obtained, and (b) any emergency use authorization issued by a Regulatory Authority shall be deemed a Regulatory Approval if sufficient to lawfully market and sell a pharmaceutical or biological product for the applicable country and indication. WHO Emergency Use Listing or Prequalification is considered a Regulatory Approval, if it is required to allow product distribution in the country(ies) of interest.

1.54 "**Regulatory Authority**" means any national or supranational governmental authority, including, as applicable, the FDA, the EMA, the MHRA or any health regulatory authority in any country or region that is a counterpart to the foregoing agencies, in each case, that holds the right to grant Regulatory Approval for a pharmaceutical or biological product in such country or region.

1.55 "**Regulatory Exclusivity**" means, with respect to any country or multi-country jurisdiction, an additional market protection, other than patent protection, granted by a Regulatory Authority in such country which confers on Barinthus Bio, its Affiliates or sublicensees the exclusive right, either through data exclusivity or market exclusivity, to market and sell a Project Vaccine in such country or multi-country jurisdiction and which prevents the Regulatory Approval of any Third Party pharmaceutical or biologic product containing the same or similar active pharmaceutical ingredient as contained in such Project Vaccine (e.g., new biologic entity exclusivity, new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, new patient population exclusivity, pediatric exclusivity, or any applicable data or marketing exclusivity).

1.56 "**Restricted Party**" means a person that is:

1.56.1 listed on any Sanctions List or targeted by Sanctions (whether designated by name or by reason of being included in a class of persons);

1.56.2 located in or incorporated under the laws of any country or territory that is the target of country- or territory-wide Sanctions; or

1.56.3 directly or indirectly owned or controlled by, or acting on behalf, at the direction, or for the benefit of, a person referred to in (a) and/or (to the extent relevant under Sanctions) (b) above.

1.57 "**Royalty Term**" means, on a Project Vaccine-by-Project Vaccine and country-by- country basis, the period starting on the Effective Date and ending on the later of:

1.57.1 the expiration of the last Valid Claim of a patent included in the Project Intellectual Property which Covers such Project Vaccine in such country of sale;

1.57.2 expiry of Regulatory Exclusivity for such Project Vaccine in such country of sale; and

1.57.3 the tenth (10th) anniversary of the First Commercial Sale.

1.58 "**Sanctions**" means any applicable (to any Party) laws, regulations or orders concerning any trade, economic or financial sanctions or embargoes.

1.59 "**Sanctions Authority**" means the Norwegian State, the United Nations, the European Union, the Member States of the European Union, the United Kingdom, the United States of America, Canada, Australia, and any authority acting on behalf of any of them or their respective legislative, executive, enforcement and/or regulatory authorities or bodies acting in connection with Sanctions.

1.60 "**Sanctions List**" means:

1.60.1 the lists of Sanctions designations and/or targets maintained by any Sanctions Authority; and/or

1.60.2 any other Sanctions designation or target listed and/or adopted by a Sanctions Authority,

in all cases, as amended, supplemented or replaced from time to time.

1.61 "**Selected Manufacturer**" means an LMIC-based manufacturer within CEPI's list of preferred manufacturers and which is either (i) agreed with the Partners under the iPDP

or (ii) otherwise agreed between CEPI and the relevant Partner(s).

1.62 "**Selling Price**" has the meaning set out in Clause 15.1.4.

1.63 "**Stage Gate**" means a mutually agreed "go/no go" decision point to continue a given Work Package or to commence activities in another Work Package.

1.64 "**Stage Gate Deadline**" has the meaning set out in Clause 2.2.

1.65 "**Stage Gate Review Committee**" has the meaning described in Clause 2.6.

1.66 "**Subawardee**" means a third party that is contracted by a Partner and receives CEPI funds from such Partner to perform activities or provide support under the Project. For clarity, Subawardees includes "Sub-Contractors".

1.67 "**Sub-Contractors**" has the meaning set out in Clause 3.2.

1.68 "**Team Charter**" means the team charter set out in Annex B.

1.69 "**Technical Report(s)**" has the meaning described in Clause 2.5.

1.70 "**Term**" has the meaning described in Clause 19.1.

1.71 "**Third Party Code**" (or "**Code**") means the consolidated statement of CEPI's values and of the policies, practices and principles described in Clause 12.2 and attached hereto in Annex I.

1.72 "**Third Party Code Declaration Letter**" means the declaration letter dated 19th February 2021 and attached hereto in Annex I.

1.73 "**Transparency and Confidentiality Policy**" means the statement of CEPI's standards regarding transparency with the public, Regulatory Authorities, CEPI's funders and others as attached hereto as Annex I, part 4.

1.74 "**Trial Steering Committee**" or "**TSC**" has the meaning described in Clause 7.5.2.

1.75 "**Trusted Collaborator**" has the meaning defined in Clause 4.3.1.

1.76 "**UMICs**" or "**Upper- and Middle-Income Countries**" means the countries identified in Part 1 of Annex F.

1.77 "**Valid Claim**" means a claim of an issued and unexpired patent which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.

1.78 "**Work Package(s)**" means a discrete set of Project activities agreed by the Parties from time to time.

2. PROJECT ORGANISATION AND MANAGEMENT

2.1 **Team Charter**. The Project shall be managed by the Parties under the oversight of the Parties' designated representatives as described in the Team Charter in Annex B.

2.2 **Work Packages**. Each Partner shall undertake its obligations under the Project, including using reasonable endeavours to achieve the deliverables, milestones and timelines of each Work Package and to achieve each Stage Gate by the agreed deadline (each a "**Stage Gate Deadline**"), it being understood that a Party cannot assure a positive technical outcome or timeline for any Work Package. The Project is organised into one or more Work Packages and each Work Package has an associated budget as set out in the Budget. Each Partner shall use all reasonable endeavours to pursue and perform its obligations under each Work Package in accordance with the Budget. CEPI will pay each Partner in accordance with the Budget and, where applicable, upon completion of a Stage Gate (as determined pursuant to Clause 2.6). Additional Work Package(s) may be agreed in writing by the Parties after the Effective Date, which, upon execution by all Parties, shall be annexed to and become a part of this Agreement. Work Packages may be modified or extended with the mutual written consent of all Parties in accordance with Clause 21.6.

2.3 **Project Continuity Plan**.

2.3.1 The iPDP shall include the following in order to address continuity of the Project in the event either or both Partners becomes unable to continue its activities under this Agreement and must delegate certain activities to another Party or third party (the "**Project Continuity Plan**"):

(i) responsibilities and level of access on the part of other collaborators, Sub- Contractors and consortium members, if any, to Project Results;

(ii) management of key Project Materials through participants in the Project and other entities;

(iii) the identification of a proposed third party for each Partner, for example, a Sub-Contractor, that will, with the prior written approval of CEPI, be contracted by such Partner and will be capable of performing such Partner's material or critical activities in the agreed Work Packages in geographically diverse locations, in the event that such Partner is unable to continue its activities under this Agreement or declines CEPI's request to undertake additional Work Packages; and

(iv) a preliminary identification of one or more Selected Manufacturers for technology transfer in the event of an Outbreak or Increased Outbreak Preparation Need in accordance with Clause 4.2.

2.3.2 Such Project Continuity Plan shall be agreed between the Parties within [***] of the Effective Date and, once agreed, shall be incorporated into the iPDP by reference.

2.4 **Joint Monitoring and Advisory Group**. Promptly following the Effective Date, the Parties will establish a joint monitoring and advisory group ("**JMAG**") that shall meet regularly as specified in the applicable Team Charter to monitor progress of and advance the Project. The JMAG shall coordinate the efforts of CEPI and the Partners, with respect to the following activities for each Work Package (in addition to the responsibilities set out in the applicable Team Charter):

2.4.1 facilitate communications between the Parties;

2.4.2 monitor the performance and technical content of each Work Package against the

milestones and their dates, and critically assess the results on an on-going basis to identify and address any weaknesses or delays in any Work Package;

2.4.3 approve the achievement of milestones (but the JMAG shall not have the right to approve final Project completion or confirm completion of Stage Gates, which shall be subject to the provisions of Clause 2.6);

2.4.4 provide a forum for discussion as to whether the activities currently agreed to are sufficient to satisfy CEPI's mission;

2.4.5 have the authority to approve extensions to Work Package timelines up to ten (10) percent of the originally planned timeframe as set out in the relevant Work Package, provided that each such extension is at no cost to CEPI and does not impact the overall completion date of the Project;

2.4.6 have the authority to approve transfer of funds between cost categories within a Budget, to the extent that any such changes are cost neutral;

2.4.7 review and approve proposed changes and updates to the iPDP including, but not limited to, the Project Continuity Plan;

2.4.8 review and discuss pre-clinical and clinical trial protocols, including CMC development study protocols, and any substantial changes;

2.4.9 review and approve the regulatory strategy for the use of the Project Vaccine and receive regular updates on regulatory filings and submissions;

2.4.10 review the contractual and operational status and capabilities of Trusted Collaborator(s);

2.4.11 review and discuss publications;

2.4.12 discuss each Partner's willingness to share any Project Results with any other CEPI awardees, such sharing of Project Results not to occur without the agreement of the Parties, unless otherwise agreed in a Work Package;

2.4.13 review and update the Equitable Access Plan (until the Equitable Access Group is established in accordance with Clause 14.3 in which case this will become a function of the Equitable Access Group);

2.4.14 discuss plans, as appropriate, for the development and manufacturing of the Project Vaccine and their scale-up and scale-out;

2.4.15 approve the Technical Reports and Project Results made available by a Partner pursuant to Clause 2.5;

2.4.16 review any reports and updates provided by any site visit groups;

2.4.17 keep CEPI updated on any progress with regard to the SPV, including plans for it to be established, funded, its proposed remit, any funding sources it may benefit from, the associated business case and any other relevant details;

2.4.18 provide a forum for coordinating the Parties' responses to issues with respect to the Project Vaccine, to the extent relating to CEPI's use, including unexpected disruptions to the supply of the Project Vaccine, recalls, safety issues or withdrawals of the Project Vaccine;

2.4.19 receive written notification of all Project Results;

2.4.20 discuss (i) any further cooperation of the Parties as further set forth in Clause 4.1 and Clause 4.3, and (ii) any collaboration in the event of an Outbreak as further set forth in Clause 4.2; and

2.4.21 discuss plans, as appropriate, for the development of manufacturing for the Project Vaccine, and its scale-up and scale-out.

The JMAG shall disband on completion of the Project.

2.5 **Technical Reports and Access to Project Results**. Each Partner shall disclose to CEPI's Project Lead at JMAG meetings the Project Data that such Partner has been responsible for generating under the Project, and details of progress made under the Work Package(s) for such Project, in a form (including level of abstraction) reasonably acceptable to CEPI and the applicable Partner and consistent with applicable laws and regulations. Each Partner shall provide written reports of progress made under the Work Package(s) for such Project using the template provided by CEPI and attached hereto as Annex K ("**Technical Reports**") every [***] during the Term in which activities under such Project are occurring. In addition, each Partner shall make Project Data available to CEPI as designated in and required by the applicable Work Package or otherwise as may reasonably be requested by CEPI from time to time, in a form (including level of abstraction) reasonably acceptable to CEPI and the applicable Partner, and consistent with applicable laws and regulations. Technical Reports and such Project Data and Project Results disclosed or provided by a Partner under this Clause 2.5 shall be such Partner's Confidential Information.

2.6 **Stage Gate Review**. Unless otherwise addressed in a Work Package for a given Stage Gate, when a Partner believes that a Stage Gate in a Work Package will be achieved in the near term, such Partner shall notify the JMAG promptly and provide relevant information (including the completion of a form provided by CEPI) and request a meeting of CEPI's committee authorised to assess whether Stage Gates have been completed (the "**Stage Gate Review Committee**"). Each Partner's Project Lead shall coordinate with CEPI's Project Lead to schedule a Stage Gate Review Committee meeting as early as possible, but generally no later than [***] before the planned meeting date. CEPI shall notify each Partner of the Stage Gate Review Committee's decision as to whether such Stage Gate was completed as soon as possible, but generally no later than [***] after the meeting date. If the Stage Gate Review Committee, acting reasonably, determines that the Stage Gate was not completed by the Stage Gate Deadline, the relevant Partner shall have the right either to (i) [***] or (ii) [***]. If following [***], CEPI reasonably determines that the Stage Gate has not been completed, then, without prejudice to the relevant Partner's rights and remedies under this Agreement, including Clause 20, CEPI shall have the right to terminate this Agreement pursuant to Clause 19.4.2.

3. USE OF FUNDS; PROCUREMENT; PROJECT RECORDS

3.1 **Use and Management of Funds**. The Budget sets out the total funding to be provided by CEPI to each Partner for each Work Package. Each Partner shall use this funding only in accordance with the applicable Work Package and this Agreement unless otherwise agreed in writing by CEPI in advance, subject to any transfer of funds between cost categories as approved by the JMAG under Clause 2.4.6. Each Partner shall manage all funds provided to it hereunder for the Project (whether CEPI funds or funds provided by a third party) with financial controls and practices consistent with U.S. GAAP, IFRS or local GAAP, as applicable, and further in compliance with applicable laws and CEPI policies and procedures as described in Clause 12 of this Agreement.

3.2 **Use of Sub-Contractors**. Each Partner may use third party service providers and/or Subawardees ("**Sub-Contractors**") to undertake work pursuant to the Work Packages on its behalf, provided that any such Sub-Contractors are listed in Annex G or the applicable Work Package, and are listed in the iPDP and Budget. The use of any Sub-Contractors that are not included in Annex G or the applicable Work Package and the iPDP and Budget are subject to the applicable Partner providing notice in advance in writing to CEPI and CEPI's prior written approval (such approval not to be unreasonably withheld, conditioned or delayed). The following terms shall apply to the engagement of any Sub-Contractors:

3.2.1 The applicable Partner shall select and oversee each Sub-Contractor in accordance with the terms of this Agreement.

3.2.2 Each Partner shall notify CEPI promptly in writing if, to its knowledge, any Sub- Contractor is not in compliance with the warranties related to Sanctions as shall be included in the sub-contract or sub-grant pursuant to Clause 3.2.3(vi).

3.2.3 A Sub-Contractor must agree to comply with all of the relevant obligations applicable to the relevant Partner, whether explicitly defined as such or as is reasonable from the nature of the obligation. Each sub-agreement with a Sub- Contractor must:

(i) be consistent with the Work Package structure as well as the associated milestones and budgets;

(ii) require the same record keeping obligations and provide CEPI the same access (either directly or indirectly through the relevant Partner) to iPDP and Financial Reports (as are applicable to such Partner);

(iii) require compliance with Clause 12.3 as if such Sub-Contractor were the applicable Partner for such purposes;

(iv) be consistent with the applicable Partner's obligations under this Agreement including in relation to Clause 4.2.2 (Technology Transfer in Event of Outbreak), Clause 5 (Ownership of Project Results; Intellectual Property), Clause 10 (Dissemination of Project Results; Publication) Clause 14 (Equitable Access), Clause 15 (Commercial Benefits), and Clause 19 (Term and Termination);

(v) prohibit the Sub-Contractor from subcontracting its obligations, except to the extent that such subcontracted obligations have a corresponding cost

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of [***] in any [***] period, when such subcontracting may be permitted provided that the applicable Partner notifies CEPI in writing in advance of such Sub- Contractor subcontracting its obligations and the contact details of the entity performing such obligations. In each case that the Sub-Contractor subcontracts any obligations under this Agreement it will use all reasonable endeavours to ensure that such subcontracted work is performed subject to the same obligations as those imposed on the Sub-
Contractor pursuant to this Agreement; and

(vi) ensure that equivalent warranties related to Sanctions as contained in Clause 16.1.9 and 16.1.10 of this Agreement, and the corresponding definitions, are incorporated into all sub-contracts and sub-grants entered into in connection with the performance of this Agreement.

3.2.4 On request from CEPI, each Partner shall disclose to CEPI a copy of any applicable agreement executed with any Sub-Contractor, which agreement shall be Confidential Information of the disclosing Partner and shall not be disclosed to any person other than a CEPI employee, contractor, consultant or outside professional advisor, including legal counsel, with a need to know the contents of such disclosed agreement for the purposes of confirming compliance with this Agreement. The Partners shall have the right to reasonably redact any such agreements provided to CEPI, and may redact any terms or content that relates to any product or activities that are not the subject of the Project, it being understood that the Partners will not redact terms or content that CEPI reasonably requires to assess activities being performed under the subcontract with respect to the Project.

3.2.5 If a Partner is using a Sub-Contractor to undertake work pursuant to a Work Package, the funding allocated for the Sub-Contractor will be consistent with the Budget, except to the extent such Partner elects to fund work by a Sub-Contractor other than through the use of funding under this Agreement. Each Partner shall be responsible for the acts and omissions of its Sub-Contractors that participate in the Project, as if such acts or omissions were the acts or omissions of such Partner under this Agreement.

3.2.6 Each Partner shall notify CEPI promptly in writing if it determines that any Sub- Contractor is not in material compliance with such Sub-Contractor's obligations under the applicable Sub-Contractor agreement in relation to work delegated to such Sub-Contractor under any Work Packages.

3.3 **CEPI Service Providers**. CEPI has entered into certain service agreements with CEPI Service Providers that have agreed to provide preferential charging to CEPI awardees. CEPI may make available various laboratory services or other support to one or more of the Partners provided by a CEPI Service Provider, for example, [***]. Each Partner agrees to utilise any CEPI Service Provider for the provision of services as may be, and solely if and to the extent, specified in a Work Package and agreed in writing between the Parties. Each Partner and the CEPI Service Provider may, at their own discretion, enter directly into an appropriate agreement between themselves setting out the terms on which the services will be provided. CEPI

shall, through the JMAG or otherwise, discuss with the applicable Partner protocols and data management related to any services provided by any CEPI Service Provider.

3.4 **Third Party Licences**. It will be each Partner's responsibility to ensure that it has obtained all necessary licences and consents to perform the Project. CEPI shall be entitled to retain funding or to condition any funding unless and until each Partner has reasonably satisfied CEPI that it has obtained all of the third party licences reasonably required to perform the Project and to supply the Project Vaccine. In the event that a Partner is bound by, or is to be bound by, certain obligations to any third party that holds IP rights necessary to develop and commercialize the Project Vaccine ("**Third Party Collaborators**"), such Partner shall (i) notify CEPI in writing of the identity of such Third Party Collaborators as well as such Partner's obligations in relation to them, (ii) use reasonable endeavours to facilitate the necessary arrangements between CEPI and Third Party Collaborators in the event the Public Health License is triggered under Clause 14.7, and (iii) use reasonable endeavours to secure all IP rights from Third Party Collaborators as required for a technology transfer under Clause 4.2.

3.5 **Payments**. Payment to each Partner under this Agreement shall be made in U.S. dollars (US$) to each Partner's bank account identified on the Agreement Summary or such other bank account as may otherwise be designated by such Partner in writing and agreed with CEPI, from time to time. CEPI shall make payments in tranches covering [***] periods as set out in the Budget, with each such payment intended to be made in advance of such [***] period. Each Partner shall be entitled to submit a payment request form to CEPI upon execution of this Agreement and thereafter at the same time as any relevant financial reporting. Tranches of funding for each payment request submitted under this Agreement in accordance with the Budget shall be paid by CEPI within [***] after receipt and approval by CEPI of all of the following: (i) the payment request from the applicable Partner, (ii) any Technical Report due from such Partner at the time of the payment request; and (iii) any Financial Report due from such Partner at the time of the payment request; each to be submitted and duly completed using templates provided by CEPI. Payments may be adjusted by CEPI to reflect any underspend as well as any interest earned on unutilized funds as noted in the Financial Report. In the event that money is not required by a Partner for the next [***] period, such Partner shall provide the reconciliation showing that [***].

3.6 **Delayed Payments**. CEPI may delay or condition a payment to a Partner if such Partner:

3.6.1 has not achieved a material milestone that it is required to achieve in accordance with the Work Package by the agreed time, unless such delay has been approved in writing by the JMAG in accordance with the Team Charter or otherwise by CEPI;

3.6.2 or any Sub-Contractors of such Partner are no longer in compliance with the representations and warranties in Clause 16 at the time the payment tranche is requested;

3.6.3 has not reasonably completed the payment request form or submitted reasonably satisfactory Technical Reports and Financial Reports;

3.6.4 in CEPI's reasonable belief, is unable to meet its financial commitments when due or is otherwise not in reasonable financial standing; or

3.6.5 is subject to any Sanctions, or any payment under this Agreement would be in breach of any Sanctions.

3.7 Subject to Clause 19.4.5, in the event that CEPI delays or conditions a payment in accordance with Clause 3.6, CEPI and the affected Partner shall work together in good faith to resolve any such impediments to payment and discuss any concerns raised by CEPI.

3.8 **Hold on Payment During a Material Breach**. CEPI is not obliged to pay any tranches of funding to a Partner for any Work Package for so long as that Partner is in material breach of this Agreement, unless such breach is cured within the cure period set forth in Clause 19.3.

3.9 **Retained Final Payment**. CEPI shall retain [***] of the payment tranche due to a Partner in respect of the final [***] of each Work Package and release it [***] after approving such Partner's final Technical Report and Financial Report for the final Work Package in a particular Project. CEPI shall act reasonably and in good faith in approving each such final Technical Report and Financial Report and shall provide its approval, or raise any queries regarding, such reports within [***] after receiving them.

3.10 **Foreign Exchange**. Each Partner shall abide by the CEPI Foreign Exchange Policy, or a substantially similar policy with CEPI's prior approval, for financial reporting and for budgeting purposes, including in relation to any Net Income, Net Sales or Net Revenue. Implementation of this policy shall remain consistent throughout the Project's life cycle and shall not be changed to ensure consistency.

3.11 **Financial Reports**. Each Partner shall provide reports of its expenditure under the Budget for the Project with supporting documentation and using a template provided by CEPI ("**Financial Reports**"). In addition to the completed Financial Report template (the financial summary, a narrative explanation of the expenses/variances, assets register, and payment request), each Partner will provide the following additional supporting documentation: (i) general ledger report of all direct cost transactions during the reporting period; (ii) labour report that lists time charged by individual staff for the reporting period;
(iii) sub-award invoices paid during the reporting period; and (iv) invoices/receipts/timesheets as requested by CEPI following receipt of general ledger report and based on a random sampling methodology. In addition, Barinthus Bio shall provide a copy of the published quarterly financial statements of Barinthus Biotherapeutics plc and the published annual statutory financial statements of Barinthus Bio.

3.12 **Frequency of Financial Reporting**. Each Partner shall submit financial reports within [***] of the end of its quarterly reporting period.

3.13 **Project Records**. Each Partner shall keep accurate records of its Project activities and expenditure under each Work Package and retain them for a period of [***] from the date of expiry or termination of this Agreement.

3.14 **Access to Financial Records**. During the Term and for a period of [***] after expiration or termination of this Agreement, CEPI's designee (which shall be an internationally recognised certified public accounting firm, not engaged on a contingent basis), and at CEPI's reasonable cost, shall have on-site access to inspect each Partner's

financial records with respect to the funding provided by CEPI pursuant to this Agreement once annually upon at least [***] advance written notice. Such inspections shall be conducted during normal operating hours in a manner to minimise disruption to such Partner's business. For clarity, access to such records also shall be provided to records related to Cost of Goods for the Project Vaccine, as described in Clause 14.4. CEPI's designee carrying out such inspection shall treat all financial records and other information subject to review under this Clause 3.14 in accordance with the confidentiality provisions of Clause 18. CEPI shall cause such designee to enter into a reasonably acceptable confidentiality agreement with the relevant Partner obligating such firm to retain all such financial records and other information in confidence pursuant to such confidentiality agreement.

3.15 **Project Financial Audits**. During the Term and for a period of [***] after expiration or termination of this Agreement, if requested by CEPI, and at CEPI's reasonable cost, once annually upon reasonable prior notice, each Partner agrees to an external audit firm appointed by CEPI, reasonably acceptable to such Partner, conducting an audit or agreed-upon procedures with respect to the funding provided by CEPI pursuant to this Agreement in accordance with ISA800 and/or ISA805 and like standards and provide CEPI with an audit report. Such inspections shall be conducted during normal operating hours, on advance notice of at least [***] on dates and at such times as reasonably agreed by CEPI and the applicable Partner, in a reasonable manner and in a manner to minimise disruption to such Partner's activities. The receiving Party shall treat all information subject to review under this Clause 3.15 in accordance with the confidentiality provisions of Clause 18. CEPI shall cause any auditor pursuant to this Clause 3.15 to enter into a reasonably acceptable confidentiality agreement with the relevant Partner obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

3.16 **Funding provided to Oxford in relation to MERS vaccine development prior to signature of this Agreement.** The Parties acknowledge that CEPI continues to provide funding to Oxford for the development of the ChAdOx1 MERS vaccine candidate separately, under the PADOVAX project, now governed by the terms of the [***]. For the avoidance of doubt, Oxford led Work Packages listed within Annex C that were initiated prior to the signature of this Agreement, specifically WP MERS 2.1.2 (MERS003), MERS 2.1.3 (Subcontracting of OXB for manufacture of GMP doses for Phase 2 Clinical Trial) are governed by the PADOVAX project under the [***] and do not fall under the terms of this Agreement. For the avoidance of doubt, where Oxford undertakes new Project activity, not previously initiated at the point of signature of this Agreement, the funding provided by CEPI for such activity will be reflected in Annex D to this Agreement.

4. FUNDING FOR FUTURE PROJECTS; TECHNOLOGY TRANSFER TO A SELECTED MANUFACTURER

4.1 **[***]**

4.1.1 [***]
4.1.2 [***]
4.1.3 In the case of Oxford only, the provisions of Clauses 4.1.1 and 4.1.2 shall not apply where Oxford [***].

4.2 **Collaboration in Event of Outbreak.**

Should there be an Outbreak or Increased Outbreak Preparation Need at any time during the Term:

4.2.1 if CEPI believes, in its reasonable discretion, that the Project Vaccine can be used to help address the relevant Outbreak or Increased Outbreak Preparation Need, each Partner shall, subject to receipt of sufficient funding, continue to develop, and, if relevant, manufacture or have manufactured (to GMP, or another clinical standard if agreed between the Parties), and distribute such Project Vaccine, as agreed with CEPI;

4.2.2 to the extent such technology transfer has not already occurred, at such time as is mutually agreed between the Parties, and on such terms as agreed between the Partner and the relevant third party, acting in good faith, each Partner shall use all reasonable endeavours to transfer or grant licenses or sublicenses to its Background IP, Project Data and Project IP (including, for the avoidance of doubt, all product data, product dossiers, and regulatory submissions submitted to a Regulatory Authority in relation to the Project Vaccine) necessary for the manufacture of the Project Vaccine to a Selected Manufacturer to manufacture such vaccines to address an Outbreak or Increased Outbreak Preparation Need, provided that the foregoing obligations shall apply only if:

(i) CEPI reasonably anticipates that the Partners cannot meet CEPI's good faith and reasonable estimate of the anticipated demand of public-sector customers in, or purchasing on behalf of, LMICs, in the timeframe required to address an Outbreak or Increased Outbreak Preparation Need and at a price consistent with the pricing provisions contained in Clause 14.5; and

(ii) the Partners have the right to grant necessary licenses or sublicenses to a third party under agreements with Third Party Collaborators, after using reasonable endeavours to secure such rights.

4.2.3 CEPI shall be responsible for the reasonable evidenced cost related to the technology transfer (including, without limitation, capacity reservation fees and process validation engineering runs), *provided that*, prior to commencing the technology transfer, each Partner has provided a good faith estimate of the costs that it will incur in carrying out such technology transfer and CEPI has provided written confirmation of its acceptance of such estimate. Should CEPI not provide such written confirmation then the relevant Partner shall have no obligation under Clause 4.2.2 to undertake such technology transfer. If CEPI accepts a Partner's costs estimate, the Parties shall negotiate and enter into a Work Package setting out which activities will be performed by such Partner and the associated Budget.

4.3 **Further Co-Operation**.

4.3.1 Each Partner shall, if notified by CEPI, promptly discuss in good faith a potential collaboration with a third party collaborator approved by such Partner and CEPI (a "**Trusted Collaborator**"). Any such collaboration agreement that a Partner may enter into with a Trusted Collaborator will be consistent with the terms of this Agreement and shall permit CEPI, the other Partner and specified third parties of the Trusted Collaborators, to access any vaccine materials and candidates that may be developed on terms substantially similar to the Project Results under this Agreement. For the avoidance of doubt, nothing in this Agreement shall impose an obligation on a Partner to enter into any collaboration agreement with a Trusted Collaborator in relation to the Project or otherwise.

4.3.2 The Partners acknowledge that CEPI is seeking third party collaborators developing innovative technologies, including but not limited to partners improving vaccine thermostability (each an "**Innovation Partner**"). If CEPI deems that the Project Vaccine may be suitable for collaboration with an Innovation Partner, CEPI shall notify the Partners, and the Partners shall promptly discuss in good faith a potential collaboration with the relevant Innovation Partner. For the avoidance of doubt, nothing in this Agreement shall impose an obligation on the Partners to enter into any collaboration agreement with the Innovation Partner in relation to the Project Vaccine or otherwise.

4.4 **Technology Transfer**

4.4.1 If agreed in any Work Package, or otherwise agreed between CEPI and the relevant Partner(s), each such Partner shall use all reasonable endeavours to transfer or grant licenses or sublicenses to its Background IP, Project Results and Project IP (including, for the avoidance of doubt, all product data, product dossiers, and regulatory submissions submitted to a Regulatory Authority in relation to the Project Vaccine) which are necessary for the manufacture and release of the Project Vaccine to a Selected Manufacturer to manufacture and

release such vaccines, subject to the relevant Partner having the right to grant necessary licenses or sublicenses to a third party under agreements with Third Party Collaborators, after using reasonable endeavours to secure such rights.

4.4.2 CEPI shall be responsible for the reasonable evidenced cost related to the technology transfer referenced in Clause 4.4.1 (including, without limitation, capacity reservation fees and process validation engineering runs), *provided that*, such cost has been agreed in a Work Package Budget or otherwise agreed between CEPI and the relevant Partner(s) and in no circumstance shall CEPI, the relevant Selected Manufacturer, or any third party, be required to pay any consideration for the transfer, or grant or exercise of the licences or sublicences referred to in Clause 4.4.1.

4.4.3 If any Selected Manufacturer ceases to meet the necessary requirements, to manufacture the Project Vaccine to GMP at a reasonable cost and within a reasonable timeframe, at any time, then CEPI and the Partners shall negotiate in good faith and agree on a replacement, either from other Selected Manufacturers or such other manufacturer as the Partners and CEPI may identify. The Partners may not unreasonably withhold agreement to a replacement manufacturer, and CEPI and the Partners shall use all reasonable endeavours to ensure that any replacement Selected Manufacturer shall have comparable rights to the original Selected Manufacturer considering all relevant circumstances including then- current demands for the Project Vaccine, manufacturing capacity or level of experience.

4.4.4 If a Partner wishes to manufacture or have manufactured Project Vaccine for sale or supply to one or more LMICs or UMICs, then prior to any manufacturer being granted the relevant rights or any orders for any such Project Vaccine doses being placed, the relevant Partner shall first notify CEPI of such intent and the identity of the Partner's proposed manufacturer, in writing, promptly after first forming such intent, and identifying such proposed manufacturer. The Parties shall discuss such proposal in good faith.

5. OWNERSHIP OF PROJECT RESULTS; INTELLECTUAL PROPERTY

5.1 **Partners' Background IP**. Each Partner shall retain ownership of its Background IP. Other than pursuant to Clause 14.6, nothing in this Agreement shall be deemed to assign any ownership interest in or grant any license or other right to or under such Background IP to CEPI or any other person.

5.2 **Partners' IP Responsibilities**. As between CEPI and the Partners, the Partners are solely responsible for having access to the Intellectual Property (via ownership or license) necessary to develop and commercialise the Project Vaccine and to comply with the Partners' obligations and CEPI's rights pursuant to this Agreement.

5.3 **Ownership of Project Intellectual Property**. Each Partner shall own all right, title and interest in and to the Project Intellectual Property created by or on behalf of such Partner. Each Partner shall have the right, but not the obligation, to seek patent or other intellectual property protection in respect of any Project Intellectual Property at its own cost. Upon reasonable written request, each Partner shall provide a written update to CEPI regarding

the status of any patent within the Project Intellectual Property that is filed by or on behalf of a Partner.

5.4 **Ownership of Project Results**. Each Partner shall own all right, title and interest in and to the Project Results created by or on behalf of such Partner. For clarity CEPI shall have the right to use Project Results solely as expressly set out in this Agreement.

5.5 **Third Party IP**. Each Party shall notify the other promptly regarding any published third party patent application it becomes aware of (whether or not yet granted) that such Party believes in good faith is likely to have a material adverse impact on any Partner's ability to perform its obligations under this Agreement. The Parties shall discuss in good faith the implications for the Project.

6. MANUFACTURE

6.1 **Manufacturing Standards**. Unless otherwise agreed by the Parties in writing, each Partner shall ensure that all components of the Project Vaccine are manufactured to GMP and any other applicable standards (including ISO9001).

6.2 **Raw Materials**. The Partners shall use reasonable endeavours to ensure that all manufacturing, whether performed by a Partner or by any third party acting on a Partner's behalf, and any raw materials, components and intermediates used in the production of the Project Vaccine, are available, in stock or for purchase, initially in sufficient quantities for research and development purposes, and subsequently in quantities sufficient to meet supply needs under the Equitable Access Plan and in the event of an Outbreak or Increased Outbreak Preparation Need.

6.3 **Excipients**. Each Partner shall ensure that the vaccine formulation excipients that it uses or procures are on the FDA's Generally Recognised as Safe ("**GRAS**") excipient list. Each Partner shall promptly inform CEPI if a novel excipient, which is not on the FDA's GRAS excipient list, is being considered by such Partner (or a third party acting on such Partner's behalf) for use in connection with a Project Vaccine and if so, such Partner shall (or shall cause such third party to), undertake a detailed risk assessment and seek advice from the relevant Regulatory Authorities regarding such novel excipient including the extent of data required to demonstrate the safety of such novel excipient, which may include preclinical toxicology study design and data generation during clinical development. Before use of such novel excipient in connection with a Project Vaccine, the relevant Partner shall notify CEPI and provide such information regarding such excipient to CEPI as CEPI may reasonably request.

6.4 **Manufacturing Process**. When developing the process for manufacturing the Project Vaccine, the Partners shall endeavour to make such process as suitable as possible for technology transfer to geographically diverse locations (including LMICs) at an affordable price, consistent with Equitable Access and the Partners' obligations under Clause 14.

6.5 **Records and Reporting**. Each Partner shall use all reasonable endeavours to ensure that all data in relation to the manufacture of the Project Vaccine is appropriately recorded and that all such records are kept up to date and maintained in accordance with applicable laws and regulations. Upon CEPI's reasonable request, each Partner will allow CEPI or its representative to review the data such Partner holds or controls from time to time in

respect of the progress of the development of the manufacturing process.

7. CLINICAL TRIALS

7.1 **Clinical Trials**. Each Partner shall undertake the clinical trial(s) listed as its responsibility in any Work Package (the "**Project Clinical Trials**") in compliance with all applicable laws and regulations, including applicable requirements related to the Partners' use of clinical data outside of the country in which a given Project Clinical Trial is conducted. Each Partner shall ensure that all Project Clinical Trials undertaken by it comply with CEPI's Clinical Trial Policy attached hereto as Annex M.

7.2 **Clinical Trial Protocols**: **Preparation**. Each Partner undertaking a Project Clinical Trial shall be responsible for the preparation of any clinical trial protocol(s) for such Project Clinical Trial. Each Partner shall provide CEPI and/or CEPI's designee with a draft of each clinical trial protocol for each Project Clinical Trial to be undertaken by such Partner, and shall consider any reasonable suggestions made by CEPI and/or its designee regarding the clinical trial protocols reasonably in advance of finalizing the relevant clinical trial protocol and submitting it to the institutional review boards, ethics committees, and/or Regulatory Authorities. Notification of any reasonable suggestions from CEPI and/or its designee must be received by the relevant Partner within [***] after the receipt of the draft by CEPI, failing which such Partner shall be free to assume that CEPI and/or its designee has no objection to the proposed protocol.

7.3 **Clinical Trial Protocols**: **Reporting of Submitted Versions**. Each Partner shall provide to CEPI a copy of all clinical trial protocols as approved by institutional review boards, ethics committees and Regulatory Authorities in respect of each Project Clinical Trial to be undertaken by such Partner. For clarity, all such information is the Confidential Information of the Partner who has submitted such information to CEPI hereunder.

7.4 **Clinical Data**. Each Partner shall include in the informed consent obtained from each clinical trial subject in any Project Clinical Trial to be undertaken by such Partner, terms to allow, to the extent permitted by and consistent with applicable laws and regulations:

7.4.1 the transfer of anonymised data to CEPI and/or CEPI's designee. CEPI shall treat such data confidentially and not disclose to third parties in accordance with all applicable data protection legislation. For the avoidance of doubt, where any personal data is to be transferred to CEPI, the Parties will enter into appropriate data protection agreements to enable compliance with applicable data protection legislation; and

7.4.2 the collection and use of Project Materials and the use of data (duly anonymised and, as the Parties may agree, blinded) derived from such Project Materials by CEPI or its designated Assessors, solely for the purpose of research under a study protocol which has received the appropriate ethical approval.

7.5 **Sponsorship and Management of Project Clinical Trials**.

7.5.1 As between the Parties, Barinthus Bio shall be the sponsor of any Project Clinical Trial (unless the Parties otherwise agree in writing), subject to all necessary approvals being obtained (including relevant internal approvals). Where a Partner is the sponsor of a Project Clinical Trial, such Partner shall be responsible for

obtaining and maintaining all regulatory and ethical committee approvals necessary for the conduct of such Project Clinical Trial.

7.5.2 In respect of each Project Clinical Trial, upon discussion with CEPI, the sponsoring Partner shall establish either an internal Trial Steering Committee ("**TSC**") or a Safety Monitoring Committee or Data Safety Monitoring Board (each, a "**DSMB**"), as applicable. CEPI shall be entitled to appoint, and the sponsoring Partner shall permit, a CEPI representative or designee to attend all meetings of each Project Clinical Trial's TSC and/or DSMB as an observer (either in person or by telephone, video or other electronic means), to the extent permitted by applicable laws and regulations and agreed by the TSC or DSMB, as applicable. Subject to Clause 7.5.3 below, the sponsoring Partner shall provide a copy to CEPI of all documents, correspondence and records that a member of the TSC and/or DSMB would be entitled to receive at the same time as any such documents, correspondence and records are provided to the members of the TSC and/or DSMB (as applicable), subject to compliance with applicable laws and regulations.

7.5.3 In the event that CEPI's attendance at a meeting of the TSC and/or DSMB or receipt of documents, correspondence and records would, in the sponsoring Partner's reasonable discretion acting in good faith, jeopardise the integrity/blinded nature of an ongoing Project Clinical Trial, the sponsoring Partner shall promptly notify CEPI of such fact and CEPI shall not be entitled to, and the sponsoring Partner shall not be required to permit CEPI to, attend such meeting or receive such documents, correspondence and records at that time. During an ongoing Project Clinical Trial, the sponsoring Partner will continue to provide CEPI with all open session DSMB documents, DSMB recommendation forms and other "open" documents identified by the Parties in the Work Package and/or protocol for such Project Clinical Trial. After the Project Clinical Trial is unblinded, and upon reasonable written request from CEPI, the Partners shall provide a copy of all documents, correspondence and records that were provided to the members of the TSC and/or DSMB and/or that a member of the TSC and/or DSMB would be entitled to receive.

7.6 **Safety Notifications**. Each Partner shall notify the JMAG in writing promptly following any single safety event of concern or a series of safety events which in each case is or are considered by the DSMB as relevant enough to recommend modification of study design, dosing regimen, or discontinuation of vaccination, in relation to any Project Vaccine or any Project Clinical Trial and within five (5) days from the time when the DSMB's recommendation in relation to such event or series of events becomes known to such Partner.

7.7 **Records and Reporting**. Each Partner shall use all reasonable endeavours to ensure that all clinical data in relation to any Project Clinical Trials and any other clinical trials that utilise Project Clinical Trial Materials are appropriately recorded and that all such records are kept up to date and maintained in accordance with applicable laws, regulations, and study site policies. The Partners will use all reasonable endeavours to ensure that CEPI is able to review and verify all anonymised data at the end of the relevant Project Clinical Trial or other clinical trial that utilises any Project Clinical Trial Materials and will promptly following the end of such Project Clinical Trial or other clinical trial that utilises

any Project Clinical Trial Materials provide a copy of such anonymised data to CEPI in such form as CEPI may reasonably require, in each case to the extent required by and consistent with applicable laws and regulations.

7.8 **Priority for Clinical Trials**. The Partners acknowledge that the pool of subjects available in areas of Outbreak to participate in a clinical trial to test the Project Vaccine may be limited. Accordingly, if WHO, CEPI or a Regulatory Authority in the area where the Project Clinical Trial is to be conducted determines that a product other than the Project Vaccine has substantially greater potential and should be prioritised instead for a particular clinical trial, the Partners shall consider in good faith any written request of CEPI not to proceed with the Project Clinical Trial of such Project Vaccine, it being understood and agreed that the determination of whether to proceed or not proceed with any such Project Clinical Trial shall be made by the Partner who was to act as the sponsor of such Project Clinical Trial, in its sole discretion. Each Partner shall be reimbursed for its reasonable, non-cancellable costs incurred (whether before or after the determination) resulting from any determination to not proceed as a result of CEPI's request.

7.9 **Potential WHO Clinical Trials**. In the event a Partner, pursuant to a subsequent written agreement with CEPI, participates in a Phase IIb or III clinical trial as requested by WHO to compare the Project Vaccine with any other vaccine candidates indicated for use against the same pathogen, each Partner will, promptly following the end of such clinical trial, meet and confer with CEPI regarding the results of such clinical trial and shall provide access to any data and final study reports relating to such clinical trial as may be set out in such subsequent written agreement, to the extent that WHO has given their prior written consent to such access.

8. REGULATORY ACTIVITIES

8.1 **Regulatory Strategy**. Upon completion of the development of the Project Vaccine, Barinthus Bio shall use [***] to obtain Regulatory Approval for such product in jurisdictions that would enable Equitable Access to such Project Vaccine. Barinthus Bio shall be responsible for developing the regulatory strategy for the Project Vaccine. Barinthus Bio shall use [***] to file for, obtain and maintain the appropriate licenses for the Project Vaccine with the relevant Regulatory Authorities.

8.2 **Meetings with Regulatory Authorities**. Each Partner shall notify CEPI in writing of any material meetings with Regulatory Authorities with respect to the Project Vaccine, or any Project Clinical Trial or other clinical trial that utilises any Project Clinical Trial Materials at least [***] in advance of such meetings, or if a Partner itself receives less than [***] notice of such a meeting, as soon as practicable. At CEPI's option, the Partners shall consult with CEPI or its designee regarding any material interactions between a Partner and Regulatory Authorities relating to the Project Vaccine, or any Project Clinical Trial or other clinical trial that utilises any Project Clinical Trial Materials. At CEPI's reasonable request, a Partner shall request a meeting with Regulatory Authorities to address any significant unresolved issues with respect to any Project Clinical Trial or other clinical trial that utilises any Project Clinical Trial Materials.

8.3 **Regulatory Strategy**. The Partners shall consult regularly with CEPI regarding the regulatory strategy for the Project Vaccine and each Project Clinical Trial or other clinical

trial that utilises any Project Clinical Trial Materials and shall provide copies of the clinical trial authorisation and all material regulatory submissions with respect to such trial(s) to CEPI no later than [***] prior to their contemplated submission to a Regulatory Authority. For the avoidance of doubt the Partners shall have final editorial control of such submissions. If a final version is not available by [***] prior to submission, then a mature draft version may be electronically delivered to CEPI for review at that time. Additionally, the Partners shall promptly make available for review by CEPI or its designated Assessors at one of the Partner's premises copies of the following to the extent reasonably required for CEPI to evaluate the progress of the conduct and completion of each Project Clinical Trial or other clinical trial that utilises any Project Clinical Trial Materials:

8.3.1 all submissions to Regulatory Authorities and regulatory filings for the Project Clinical Trial or other clinical trial that utilises any Project Clinical Trial Materials together with all data included or referenced therein (other than ministerial submissions that do not involve safety or efficacy issues); and

8.3.2 material documents and information exchanged between any Regulatory Authority and a Partner, including relating to the Project Clinical Trial or other clinical trial that utilises any Project Clinical Trial Materials including official meeting minutes.

8.4 **Referencing Market Authorisation package**. At the reasonable request of CEPI, each Partner agrees to co-operate with CEPI to allow CEPI or its nominee to cross-reference the market authorization package, the drug master file and all existing data of the Project Vaccine only for the purpose of supporting regulatory filings and submissions for any vaccines that may be used in the event of a potential public health emergency utilizing the same, or a similar, platform technology, if applicable. For clarity, (i) no Partner shall be required to disclose any non-public information that is proprietary to a third party other than to the Regulatory Agency with which the applicable market authorization package is filed, and (ii) a Partner's market authorization package or data may not be disclosed to or cross-referenced by a third party without prior approval of the applicable Partner, which shall not be unreasonably withheld or delayed.

8.5 **Redactions**. Notwithstanding any other provision of this Clause 8 or other terms or conditions of this Agreement, a Partner shall have the right to redact any documentation made available pursuant to this Agreement to the extent reasonably necessary to protect its trade secrets or other non-public sensitive information or financially sensitive information or data that is proprietary to a third party that Partner is prohibited from disclosing.

9. ANIMAL STUDIES

9.1 **Animal Studies**. Each Partner shall pursue any studies involving animals as described in any Work Package, in compliance with all applicable laws and regulations and further in compliance with Clause 12.

9.2 **Animal Study Protocols**. Each Partner shall be responsible for the preparation of any animal study protocol(s) for any studies involving animals. Each Partner shall, through the regular JMAG meetings, share the details of its protocols with CEPI and, upon CEPI's

reasonable request, provide CEPI and/or CEPI's designee with a draft of each animal trial protocol for any animal studies it has conducted or intends to conduct and shall consult with and consider any reasonable suggestions made by CEPI and/or its designee regarding the animal trial protocols. Each Partner represents and warrants that it will comply with principles of NC3Rs (Replacement, Refinement, and Reduction) in conducting animal studies hereunder.

10. DISSEMINATION OF PROJECT RESULTS; PUBLICATION

10.1 **Dissemination of Project Data**. CEPI encourages the timely publication and other dissemination of Project Results. The Partners shall make the Project Data available to specified third parties if and to the extent described in a Work Package, as agreed by the JMAG, or as otherwise may be agreed between the Parties, always in compliance with applicable data protection legislation.

10.2 **Dissemination of Project Materials**. The Partners shall make the Project Materials available to specified third parties if and to the extent described in a Work Package, as agreed by the Parties at the JMAG, or as otherwise may be agreed between the Parties, and in each case subject to each Partner's biobank standard operating procedures and policies and where there is appropriate ethical approval and informed consent. Such Project Materials shall be made available solely to the extent the applicable laws permit, as reasonably required by CEPI to inform the public health response and help save lives, and to the extent reasonably available after the Partners, their Affiliates and their (sub)licensees with respect to such materials have completed all research or development activities involving the use of such materials and applied for any desired patent protection, provided that, the dissemination of the Project Materials shall be delayed by no more than [***] to secure any such patent protection. Notwithstanding the foregoing, (i) the Partners shall be notified in advance of the purpose of use of Project Materials and the identity of recipient third parties, and (ii) any results of such use shall be promptly disclosed to the Partners. Any publication of the Project Material shall be subject to Clauses 10.3 and 10.5.

10.3 **Publication of Project Data for the Outbreak Research Community**. Each Partner shall promptly publish or cause to be published Project Data consisting of reasonably relevant and appropriate pre-clinical and clinical trial data (for clarity, excluding raw data) in a peer-reviewed scientific journal to inform the public health response and help save lives. Key principles of this sharing of data have been agreed to by funders, research organisations, government agencies, civil society organisations and for-profit life science enterprises, as described and provided in (i) WHO's 2016 Guidance for Managing Ethical Issues in Infectious Disease Outbreaks; and (ii) WHO's 2016 Guidance on Good Participatory Practices in Trials of Interventions Against Emerging Pathogens.

10.4 **Clinical Trial Registration and Results**.

10.4.1 Project Clinical Trials and any other clinical trials that utilise any Project Clinical Trial Materials must be registered through an easily discoverable existing public route such as clinicaltrials.gov, The EU Clinical Trials Register, or the International Clinical Trials Registry Platform, in accordance with all applicable laws and regulations. The information provided shall follow the current WHO Trial Registration Data Set. The clinical trial ID or registry identifier code/number

shall be included in all publications of clinical trials.

10.4.2 Publication of clinical trial results (including negative results) from Project Clinical Trials and any other clinical trials that utilise any Project Clinical Trial Materials shall be made by the Partner who has been responsible for the applicable Project Clinical Trial Materials or other clinical trial promptly through an easily discoverable existing public route (website or system). Such Partner shall submit clinical trial data from Project Clinical Trials and any other clinical trials that utilise any Project Clinical Trial Materials for publication as soon as reasonably possible but, in any event, within [***] after study completion. During the same time period, such Partner shall make the results available to the national Ministry of Health or equivalent in the countries where Project Clinical Trials are held. Such Partner shall deposit Clinical Trial data in an open sharing platform such as ClinicalStudyDataRequest.com, Vivli Center for Global Clinical Research Data, or an equivalent service.

10.5 **Open Access**. Prior to publishing any manuscripts of any research publications, journal articles, scholarly monologues and book chapters with respect to any Project Clinical Trial published under this Clause 10, the applicable Partner shall submit a copy to CEPI. Each Partner must ensure that a copy of the final manuscript of all research publications, journal articles, scholarly monologues and book chapters with respect to any Project Clinical Trial published under this Clause 10 is deposited into PubMed Central (or Europe PubMed Central) or otherwise made freely available upon acceptance for publication or promptly after the publisher's official date of final publication. Moreover, each Partner shall ensure that all peer-reviewed published research that is funded, in whole or in part, by CEPI shall be published in accordance with the principles of Plan S ("Accelerating the transition to full and immediate Open Access to scientific publications"), a UK and European data sharing initiative for research funded by public grants. Each Partner shall comply with CEPI's reasonable requests to share information in a preprint service such as bioRxiv.

10.6 **Statement of Support in Publications**. All such publications with respect to any Project Clinical Trial shall include a statement that the work was *"supported, in whole or in part, by funding from CEPI"* (or such other words to the same effect regarding other sources of (direct or indirect) funding for the Project as reasonably requested by CEPI, as applicable) and shall credit, where appropriate, the country in which any such clinical trials were performed.

11. INDEPENDENT ASSESSORS

11.1 **Independent Assessors**. During the Term, as required in a Work Package or as otherwise reasonably requested by CEPI, subject to Clause 11.2, each Partner shall cooperate with and provide reasonable assistance to consultants reasonably acceptable to such Partner ("**Assessors**") (which may include but is not limited to the Task Force for Global Health and its Safety Platform for Emergency vACcines (SPEAC) Project), retained in confidence and at CEPI's expense, to consult on development of clinical trial protocols, explore development strategies, and evaluate Project Data and review Project Results, including to use such Project Data to evaluate any Project Vaccine. Each Partner acknowledges that such Assessors may provide CEPI with directly comparable evaluations of similar materials developed under CEPI's portfolio of awarded projects. The results of the analysis, meta-

analysis or other assessments by such Assessor(s) shall be subject to the confidentiality obligations of this Agreement and all non-disclosure agreements or material transfer agreements entered into pursuant to Clause 11.2. CEPI shall promptly provide the Partners with access to the results of any evaluation by an Assessor solely to the extent such assessment directly relates to the Project Results or Project Vaccine. For clarity, CEPI shall not be required to grant access to any information regarding CEPI's portfolio of other awarded projects and shall be entitled to redact such information to the extent it is not obliged to grant access to such information to the Partners in accordance with this Clause.

11.2 **Conditions for Assessor(s) Access.** Prior to any Partner or CEPI disclosing to any Assessor any Project Results or other relevant information or materials with respect to any Project Vaccine under the Work Package(s), such Partner and the Assessor(s) shall, at their own discretion, enter directly into an appropriate agreement between themselves to the extent necessary to facilitate any Assessor's activities under Clause 11.1, such as a non-disclosure agreement or material transfer agreement, and pursuant to such agreement the Assessor(s) shall covenant to comply with the confidentiality terms thereof and use such Project Results and other relevant information or materials solely for the purpose(s) of the applicable assessment(s) and not for any other purpose. CEPI shall, through the JMAG or otherwise, discuss with the Partners protocols and data management related to any Assessor's activities under Clause 11.1.

11.3 **Partner Cooperation**. The Partners shall provide reasonable assistance to CEPI and any designated Assessors to facilitate any Assessor's activities under Clause 11.1 at such times and locations as are reasonably agreeable to by the applicable Partner and CEPI and, to the extent reasonably required for CEPI or the designated Assessor, to evaluate the progress of the funded activities, including:

11.3.1 ensuring that any samples to be transferred or exported by or on behalf of a Partner from a clinical trial site or sample storage site are transferred and/or exported pursuant to the terms and conditions of a material transfer agreement to be entered into between such Partner and the Assessor in a form reasonably acceptable to CEPI, the applicable Partner and the Assessor, in addition to any other applicable laws and regulations; and

11.3.2 cooperating with regard to any data analysis, to the extent relevant under a given Work Package and permitted under applicable laws, regulations, and study site policies, and as reasonably requested by CEPI by:

(i) providing appropriate data or other information generated under any Work Package to CEPI's designated Assessor as CEPI may instruct, including data regarding the results of any of its pre-clinical or clinical trials under any Work Package (duly anonymised and, upon CEPI's request, blinded), and other documents and information from activities under any Work Package such as study protocols, case report forms needed to develop standardised approaches and tools for safety data management;

(ii) considering in good faith whether to provide CEPI's designated Assessor with other data not generated under any Work Package (duly anonymised and, upon CEPI's or the applicable Partner's request, blinded) as CEPI may reasonably request in order to conduct comparative assessments;

(iii) providing CEPI's designated Assessor with clinical trial data generated

under any Work Package (duly anonymised and, at CEPI's request, blinded) for the purposes of signal detection or meta-analyses of safety data (including across product candidates); and

(iv) providing CEPI's designated Assessor a reasonable opportunity to inspect appropriate CMC data generated by or on behalf of a Partner under any Work Package at the applicable facility(ies) designated by such Partner on reasonable notice during ordinary business hours.

Any disclosures by or on behalf of a Partner pursuant to this Clause 11.3 shall be made in the form maintained by or on behalf of such Partner and shall be subject to reasonable redactions to the extent reasonably necessary to protect such Partner's trade secrets or other non-public financially sensitive information (including CMC data). Each Partner may require written obligations of confidentiality, non-disclosure and non-use between CEPI and its designated Assessor in accordance with Clause 18.3.5, such obligations to include that Assessor will not disclose such information, without the applicable Partner's prior written consent.

12. COMPLIANCE

12.1 **Compliance with applicable laws**. Each Partner shall comply, and shall ensure that all of its Sub-contractors comply, with all laws and regulations that are applicable to its activities, operations and use of CEPI funds under the Project.

12.2 **CEPI's Third Party Code and Cost Guidance**. The Third Party Code is a statement of CEPI's values and of the policies, practices and principles applicable to recipients of CEPI funding. CEPI shall notify each Partner of material changes to the Code without undue delay. Neither Partner shall be subject to any changes to the Code or any other applicable policy of CEPI without such Partner's prior written consent; *provided* that: (i) each Partner shall consider in good faith any changes to the Code or other applicable policy that are provided to such Partner in writing and shall not unreasonably withhold, condition or delay its agreement to be bound by any changes to the Code or other applicable policy, and (ii) in the event such Partner withholds, conditions or delays (for more than thirty (30) Business Days after receipt of CEPI's notice) any such consent, CEPI shall have the right to terminate such Partner's involvement in this Agreement pursuant to Clause 19.4.3. CEPI's Cost Guidance provides additional information regarding the treatment of costs.

12.3 **Partner Responsibilities**. Each Partner:

12.3.1 acknowledges the statement of CEPI's values in Section 1 of the Code;

12.3.2 shall adhere to business practices, ethical principles and legal requirements that are at least substantially similar to those described in Sections 2 to 10 of the Code;

12.3.3 confirms that it has understood and will comply with the provisions of the 'Accurate Records and Documentation' paragraph in Section 10 of the Code;

12.3.4 shall comply with the requirements for reporting compliance concerns and misconduct to CEPI (Sections 4 and 11 of the Code);

12.3.5 shall cooperate as may be reasonably requested by CEPI in the submission of information related to Project activities and expenditures in accordance with the

International Aid Transparency Initiative (Section 12 of the Code);

12.3.6 shall comply with the terms and conditions of this Agreement that are being adopted in furtherance of CEPI's Equitable Access Policy, which is further described in Clause 14 of this Agreement; provided that the Parties acknowledge that the Partner's obligations set forth Clause 14 herein shall be deemed to comply with, and to satisfy any specific performance obligations under, CEPI's Equitable Access Policy;

12.3.7 to the extent applicable to the Project, comply with CEPI's Animals in Research Policy;

12.3.8 to the extent applicable to the Project, rely upon its own reasonable and customary policies and principles so as to comply with, and/or enable CEPI to comply with:
(i) CEPI's Clinical Trials Policy; (ii) CEPI's Managing Conflicts of Interest Policy; (iii) CEPI's Scientific Integrity Policy; (iv) CEPI's Transparency and Confidentiality Policy; and (v) CEPI's Travel and Expenses Policy; and

12.3.9 shall, for any Sub-Contractor not listed in Annex G, comply with the provisions of the Third Party Code related to Sub-Contractors (Section 14 of the Code) and for any Subawardee not listed in the iPDP, comply with the provisions of the Third Party Code related to Sub-Grantees (Section 15 of the Code).

12.4 **Compliance Audit**. During the Term and for a period of [***] after expiration or termination of this Agreement, CEPI, or an auditor appointed by CEPI, shall be entitled not more than once annually to audit each Partner's performance of its compliance obligations under this Agreement, upon reasonable advance notice of at least [***]. Such audits will be conducted during normal operating hours, on a date and at such time as reasonably agreed by CEPI and the audited Partner, in a reasonable manner and in a manner so as to minimise disruption to such Partner's business. Such audits may include requests for documentation concerning such Partner's own costs as well as Subawardees' costs in connection with the Project, and such Partner shall use all reasonable endeavours to provide such documentation to CEPI without undue delay. CEPI shall cause any auditor pursuant to this Clause 12.4 to enter into a reasonably acceptable confidentiality agreement with the audited Partner obligating such auditor to retain all such information in confidence pursuant to such confidentiality agreement.

12.5 **Compliance by Sub-Contractors**. Each Partner shall use all reasonable endeavours to ensure that any Sub-Contractors engaged for the Project conduct any activities pursuant to this Agreement in accordance with the compliance obligations in this Clause 12 in all material respects. If any Partner becomes aware that a Sub-Contractor does not comply with the compliance obligations in this Clause 12 in all material respects, such Partner shall promptly notify CEPI and the Parties will discuss in good faith whether such Sub- Contractor can be brought into compliance within a reasonable time or whether any other actions are necessary to achieve compliance.

13. READY RESERVE OF PROJECT CLINICAL TRIAL MATERIAL

13.1 **Ready Reserve.**

13.1.1 CEPI and a Partner may mutually agree in writing that such Partner shall

undertake the manufacturing, or having manufactured, and maintenance of a Ready Reserve of Project Clinical Trial Material through a Work Package. If at any time a Partner wishes to dispose of the Ready Reserve of Product Clinical Trial Material it is storing, such Partner shall discuss the same with CEPI (including taking into consideration, without limitation, the shelf-life of such materials) and may only dispose of such materials after it has received CEPI's prior written consent (which shall not be unreasonably withheld, conditioned or delayed). Such Ready Reserve of Project Clinical Trial Material may be used: (a) for further clinical trials pursuant to a mutually agreed Work Package, (b) to otherwise advance development of the Project Vaccine, *provided* such Research Reserve of Project Clinical Trial Material is not necessary for activities pursuant to clause (a) at such time, or (c) for emergency use (subject to obtaining all necessary regulatory approvals and consents) in emergency situations based on national or international guidance (such as from WHO) or in such other manner, in each case as may be agreed in the relevant Work Package or otherwise by the Parties in writing.

13.1.2 For the purposes of this Agreement, a "**Ready Reserve of Project Clinical Trial Material**" means an agreed quantity of doses of the Project Vaccine for potential use in a clinical trial. At the Effective Date, Barinthus Bio has agreed that it will, subject to achievement of the relevant Stage Gate, manufacture or have manufactured and store as a Ready Reserve of Project Clinical Trial Material [***] in accordance with GMP and all other requirements and specifications agreed with CEPI. Promptly following achievement of the relevant Stage Gate, Barinthus Bio will submit to CEPI a reasonable budget detailing the reasonable costs of storage and stability testing of the Ready Reserve of Project Clinical Trial Material for approval by CEPI, such approval not to be unreasonably withheld, conditioned or delayed. From time to time, Barinthus Bio shall submit to CEPI revised budgets detailing such costs for approval by CEPI, such approval not to be unreasonably withheld, conditioned or delayed. CEPI shall bear Barinthus Bio's out-of-pocket costs incurred in performing such storage and stability testing, provided that CEPI shall not be required to pay any mark-up or handling charges.

14. EQUITABLE ACCESS.

14.1 **Commitment to Equitable Access**. Each Partner and CEPI confirm their commitment to achieving Equitable Access to the results of all CEPI-supported programmes, whether in an Outbreak, Increased Outbreak Preparation Need, epidemic or pandemic situation, as provided herein with respect to any Project Vaccine in accordance with CEPI's "Equitable Access Policy".

14.2 **Equitable Access Plan.**

14.2.1 The initial plan to support such Equitable Access commitment is set out in Annex E (the "**Equitable Access Plan**"); and the Equitable Access Plan shall be reviewed by the JMAG and/or the Equitable Access Group after it is established in accordance with Clause 14.3 no less than every [***] and shall take

into account, as applicable, changes in COGs over time, production yield and volume and production economics. The Equitable Access Plan shall be updated throughout the Term to reflect such reviews or as otherwise agreed between the Parties. A significantly more detailed Equitable Access Plan shall be agreed promptly after the Equitable Access Group is established. Each Partner will keep CEPI fully and regularly informed of its adherence to the Equitable Access Plan and its progress, or lack thereof, in meeting its objectives.

14.2.2 The Equitable Access Plan shall include a commitment from the Partners to negotiate future purchase, allocation and supply commitments in respect of the Project Vaccine(s), with purchasers in LMICs and UMICs, including with relevant international public health stakeholders such as Gavi, UNICEF and the Pan American Health Organisation.

14.3 **Equitable Access Group**. The Parties will establish an Equitable Access Group that shall meet regularly to monitor the progress of and advance the Partners commitment to Equitable Access. The Equitable Access Group shall coordinate the efforts of the Parties to update the Equitable Access Plan and set out how the Project Vaccine will be used to enable Equitable Access. The rules and frequency of meeting of the Equitable Access Group shall be the same as for the JMAG, unless otherwise agreed by the Parties in writing.

14.4 **Information about Production, Supply, Pricing and Sales**. Upon written request by CEPI, each Partner shall provide reasonable information about its COGs, production, supply, pricing and sales of the Project Vaccine, sufficient to enable CEPI to evaluate whether such activities are consistent with the Partners' obligations under this Agreement.

14.5 **Pricing**. The Parties acknowledge that the price of the Project Vaccine is critical to achieving Equitable Access. Accordingly, the Partners each agree, and shall each procure that its licensees (and any sublicensees) agree, that the pricing of, and any other payments received with respect to, the Project Vaccine shall be as reasonably required to achieve Equitable Access for populations in need of such products, recognising that on-going supply should be commercially sustainable and, in any event, shall reflect the terms agreed in the Equitable Access Plan. Each Partner shall ensure that, and shall procure that its Affiliates, licensees and sublicensees ensure that:

14.5.1 when sold in an LMIC, the price of any Project Vaccine does not exceed [***]; and

14.5.2 when sold in a UMIC, the price of any Project Vaccine does not exceed [***].

14.6 **Public Health Licence**. Subject to the terms of this Agreement, each Partner hereby grants (and shall ensure that each Subawardee grants) to CEPI a non-exclusive, worldwide, irrevocable, fully paid up, royalty free license under such Partner's Enabling Rights that is necessary or reasonably useful to develop, manufacture, and commercialise the Project Vaccine in order to achieve Equitable Access during the Term and for [***] thereafter (the "**Public Health License**"), on the condition that CEPI may only

exercise the Public Health License in the event that:

14.6.1 CEPI is not in material breach of its obligations under this Agreement; and

14.6.2 one or more of the triggers set out in Clause 14.7 has occurred with respect to such Partner.

The Public Health License shall be sub-licensable to one or more third parties. Notwithstanding the foregoing, CEPI acknowledges and agrees that each Partner's obligations to any Third Party Collaborators may limit the availability or the scope of a Partner's sublicensees, and as such, if required by CEPI, such Partner shall use reasonable efforts to facilitate the necessary arrangements between CEPI and any Third Party Collaborators, as contemplated in Clause 3.4. Any sublicence of the Public Health License shall be in writing and CEPI shall require that each sublicensee complies with the terms of the Public Health Licence.

14.7 **Public Health Licence Triggers**. Consistent with Clause 14.6, CEPI shall have the right to exercise the Public Health Licence with respect to a Partner, in the event that any one or more of the following events occurs with respect to such Partner:

14.7.1 [***]
14.7.2 [***]
14.7.3 Such Partner is in material breach of this Agreement or the Equitable Access Plan and has not cured such breach [***]; or

14.7.4 The Agreement is terminated by CEPI pursuant to Clause 19.3 (Termination by CEPI for Default or Insolvency) or Clauses 19.4.5 (failure to satisfy payment criteria), 19.4.6 (Financial Irregularity) or 19.4.7 (reputation impact).

14.8 **Effects of Exercise of the Public Health Licence**. Upon exercise of the Public Health Licence by CEPI and provision of written notice to the Partners, the Partner in respect of which the Public Health Licence has been exercised shall promptly:

14.8.1 provide CEPI with an up-to-date written list of all its Enabling Rights; and

14.8.2 promptly and diligently make available to CEPI all guidance, information, materials and assistance reasonably required to accomplish any Project activities that were to be performed by such Partner, and which guidance, information, materials and assistance are identified by CEPI. Such transfer shall be: (i) in the event the Public Health Licence is exercised by CEPI pursuant to Clause 14.7.1 or Clause 14.7.2 at CEPI's reasonable cost; or (ii) in the event the Public Health Licence is exercised by CEPI pursuant to Clause 14.7.3 or Clause 14.7.4 at such Partner's cost.

14.9 **Effects of Termination of Barinthus Bio Licence Agreement**. In addition to the foregoing, in the event that the licence agreement between Oxford University Innovation Limited, a private limited company registered in England and Wales with company number 02199542 and with its registered office address at University Offices, Wellington Square, Oxford, OX1 2JD ("**OUI**") and Barinthus Bio dated 4th March 2016 (the "**Barinthus Bio Licence Agreement**") is terminated, then Oxford shall, and shall procure that OUI shall, immediately upon such termination, grant to CEPI a non-exclusive, worldwide, irrevocable, fully paid up, royalty free license under all rights previously licensed to Barinthus Bio pursuant to the Barinthus Bio Licence Agreement that are necessary or reasonably useful to develop, manufacture, and commercialise the Project Vaccine in order to achieve Equitable Access during the Term and for twenty (20) years thereafter.

15. COMMERCIAL BENEFITS

15.1 **Barinthus Bio**

15.1.1 Barinthus Bio shall pay to CEPI the following percentage of each of Net Sales and Net Income received during the Royalty Term: [***]

15.1.2 Barinthus Bio shall pay CEPI the following percentages of Net Revenue:

[***].

15.1.3 Barinthus Bio shall pay to CEPI [***] of any PRV Proceeds received during the Royalty Term.

15.1.4 Barinthus Bio shall promptly notify CEPI, in writing, of any Commercial Benefits arising from the Project Vaccine, including details of all Net Income, Net Sales and Net Revenue received, on which payments are due hereunder. Once the foregoing notification has been provided, Barinthus Bio shall, from then on, submit to CEPI within [***], a written report setting out the details of (i) the price at which Barinthus Bio and its Affiliates sell Project Vaccines in LMICs or UMICs, including COGs for such Project Vaccines ("**Selling Price**"), and (ii) all Net Income, Net Sales and Net Revenue received by Barinthus Bio [***] and the associated payment due to CEPI under Clause 15.1.1. CEPI will invoice Barinthus Bio for the payments due to CEPI under Clause 15.1.1 on the Net Income, Net Sales and Net Revenue reported by Barinthus Bio and Barinthus Bio will pay such amounts to CEPI within [***] following receipt of such invoice.

15.1.5 All payments made under this Clause 15 shall be payable in US dollars and be made by wire transfer in immediately available funds to a bank and account designated in writing by CEPI, unless otherwise specified in writing by CEPI.

15.1.6 If any Net Income or Net Revenue is received as non-cash consideration, Barinthus Bio shall, at Barinthus Bio's discretion, either: (i) transfer a percentage of such non-cash consideration into the name of CEPI to satisfy Barinthus Bio's obligation under Clause 15.1.1; or (ii) transfer cash to CEPI calculated based on applying the applicable percentage set out in Clause 15.1 to the cash value of such Net Income or Net Revenue at the time such non-cash consideration was received by Barinthus Bio, with either Party having the right to refer the determination of the cash value of such non-cash consideration to a mutually agreed independent expert for determination if the Parties do not agree on such cash value.

15.1.7 **Financial Records and Audits**. Barinthus Bio shall keep, and shall require its Affiliates to keep, accurate records pertaining to all Net Income, Net Sales and Net Revenue received by Barinthus Bio and its Affiliates. If requested by CEPI, and at CEPI's reasonable cost, once annually upon reasonable prior notice, Barinthus Bio agrees to an external audit firm appointed by CEPI, reasonably acceptable to Barinthus Bio, conducting an audit with respect to all amounts owed to CEPI pursuant to this Agreement, including in respect of the calculation of Net Income, Net Sales and Net Revenue and associated payments to CEPI, in accordance with ISA800 and/or ISA805 and like standards and provide CEPI with an audit report. Such inspections shall be conducted during normal operating hours, on advance notice of at least [***] on dates and at such times as reasonably agreed by CEPI and Barinthus Bio, in a reasonable manner and in a manner to minimise disruption to Barinthus Bio's activities. The receiving Party shall treat all information subject to review under this Clause 15.1.7 in accordance with the confidentiality provisions of Clause 18. CEPI shall cause any auditor pursuant to this Clause 15.1.7 to enter into a reasonably acceptable confidentiality agreement with Barinthus Bio obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement. CEPI shall disclose to Barinthus Bio the audit report, and, to the extent that it is in CEPI's possession, any calculations and workings underlying it, and shall give Barinthus Bio an opportunity to discuss the report with CEPI and the audit firm. Absent manifest error or fraud, the audit report shall be binding on both Parties. Barinthus Bio promptly pay any shortfall to CEPI, and CEPI shall promptly repay any overpayment, and if the report finds an underpayment by

Barinthus Bio of more than [***] Barinthus Bio shall pay the reasonable fees and expenses charged by the audit firm. Otherwise the costs of the audit firm shall be payable by CEPI. If either Party challenges the audit report on the basis of manifest error or fraud, the matter shall be dealt with under Clause 20 (Resolving Differences).

15.1.8 **Selling Price and COGs Audit**. Barinthus Bio shall keep, and shall require its Affiliates and manufacturers (as applicable) to keep, accurate records pertaining to the Selling Price and the calculation of COGs in respect of the Project Vaccine in order to demonstrate Barinthus Bio's compliance with its obligations under Clause 14.5. If requested by CEPI, and at CEPI's reasonable cost, Barinthus Bio shall provide to CEPI all such records and any supporting documentation reasonably requested by CEPI for review by CEPI or an external audit firm appointed by CEPI, reasonably acceptable to Barinthus Bio. If requested by CEPI or Barinthus Bio, Barinthus Bio and CEPI and any such audit firm shall meet to discuss the Selling Price and such calculation. Such review shall take place no more than once annually. CEPI shall treat all information subject to review under this Clause 15.1.8 in accordance with the confidentiality provisions of Clause 18. CEPI shall cause any audit firm receiving information pursuant to this Clause 15.1.8 to enter into a reasonably acceptable confidentiality agreement with Barinthus Bio obligating such firm to retain all such information in confidence pursuant to such confidentiality agreement. CEPI shall disclose to Barinthus Bio the results of any such review, and, to the extent it is in CEPI's possession, any calculations and workings underlying those results, and shall give Barinthus Bio an opportunity to discuss the results of the review with CEPI and the audit firm. Absent manifest error or fraud, if the audit report concludes that there has been an error in the calculation of the Selling Price, this shall be binding on both Parties and [***]. For the avoidance of doubt, any remedies set out in this Clause 15.1.8 are in addition to all other remedies available to CEPI, whether under this Agreement, at law or in equity.. If either Party challenges the audit report, on the basis of manifest error or fraud, the matter shall be dealt with under Clause 20 (Resolving Differences).

15.2 **Oxford**

15.2.1 Oxford will promptly notify CEPI of any Commercial Benefits it receives. Promptly after receipt of such notification, Oxford and CEPI shall enter into a revenue share agreement detailing the share of Commercial Benefits that will be allocated to CEPI.

15.2.2 The share of Commercial Benefits received by CEPI shall be proportionate to the added value of CEPI's funding under this Agreement, taking into account all relevant factors, including the amount of funding by CEPI and the results of such funding. Without prejudice to the foregoing, CEPI does not require a share of Commercial Benefits received from the exploitation of the Project Results for the

benefit of LMICs, including technology transfer to manufacturers or service providers who are engaged specifically to assist in making vaccines available to LMICs.

15.3 **Tax**

15.3.1 Payments under this Agreement are to be made without withholding for or on account of any tax unless required by law, in which case, any such tax withheld shall be treated as having been paid by the paying Party to the recipient Party for all purposes under this Agreement, and the paying Party shall duly account for such tax withheld to the relevant tax authority and provide reasonable evidence of this to the recipient Party. The paying Party will notify the recipient Party in writing as soon as reasonably practicable once it becomes aware it has an obligation to so withhold, and the Parties will cooperate with respect to reasonable requests by that recipient Party to secure a reduction in the rate of, or eliminate, applicable withholding tax or to permit that recipient Party to obtain a repayment of, or credit for, tax withheld. [***].

16. REPRESENTATIONS AND WARRANTIES

16.1 **Partner Warranties**. Each Partner warrants that the following statements are true and correct as of the Effective Date:

16.1.1 it has the full power and authority to enter into and assume its obligations under this Agreement;

16.1.2 this Agreement has been duly executed by it and is legally binding and enforceable on it in accordance with its terms, except to the extent that enforcement of the rights and remedies created hereby is subject to: (i) bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors; or (ii) laws governing specific performance, injunctive relief and other equitable remedies;

16.1.3 it is in material compliance with all statutes, regulations, directives and requirements of any governmental entity related to the conduct of the Project hereunder;

16.1.4 it has disclosed in writing to CEPI any actual commitments or obligations to provide to third parties Project Vaccine doses;

16.1.5 its actions or obligations under any Work Package will not infringe, misappropriate or violate any Third Party Intellectual Property, privacy or publicity rights;

16.1.6 the execution of this Agreement does not conflict with the terms or conditions of any written agreement, instrument or understanding to which it is a party; or violate any applicable law or regulation of any court, governmental body or administrative agency having jurisdiction over such Partner;

16.1.7 neither such Partner nor any agreed Subawardees, if any, nor any officer or employee of the foregoing has been debarred or is subject to debarment under 21
U.S.C. 335(a) or under similar provision by a Regulatory Authority or funding agency anywhere in the world;

16.1.8 all financial and other information with respect to the Project Vaccine submitted to CEPI by such Partner in relation to this Agreement is true, complete and accurate in all material respects;

16.1.9 it is not:

(i) a Restricted Party;

(ii) in breach of Sanctions from a Sanctions Authority; or

(iii) subject to or involved in any complaint, claim, proceeding, formal notice, investigation or other action by any regulatory or enforcement authority or third party concerning any Sanctions from a Sanctions Authority;

16.1.10 none of the funds provided under this Agreement (whether via a sub-contract or otherwise) are used in any way directly or indirectly to provide support, resources or assets to a Restricted Party, provided, however, that it shall not be a breach of this Agreement to supply vaccines, including the Project Vaccine, to a Restricted Party, provided that such supply of vaccines is exempt from any applicable Sanctions; and

16.1.11 the Barinthus Bio Licence Agreement is in full force and effect; the version of the Barinthus Bio Licence Agreement provided to CEPI is complete and accurate in all respects and has not been amended, varied, or terminated (whether in whole or in part); no party has received a notice from any other party seeking to terminate the Barinthus Bio Licence Agreement; and Barinthus Bio is not aware of any material breach of the Barinthus Bio Licence Agreement by any other party to it, nor is Oxford aware of any material breach of the Barinthus Bio Licence by Barinthus Bio.

16.2 **Partner Representations**. During the Term of this Agreement, each Partner shall:

16.2.1 notify CEPI promptly in writing in the event that any of the warranties it has given under Clause 16.1 would no longer be true and correct were they repeated at the time that such Partner requests any disbursement of Project funds in accordance with Clause 3.5; and

16.2.2 notify CEPI promptly if it becomes aware that any actions are reasonably likely to be taken or have already been taken by the government of any country in which such Partner conducts Project activities that may adversely affect such Partner's commitments in this Agreement, including Equitable Access. For clarity, such government actions may relate, for example, to the exercise of eminent domain or sovereign rights over Project Vaccine doses.

16.3 **CEPI Warranties**. CEPI warrants that the following statements are true and correct to its reasonable knowledge and belief, in so far as they relate to the Project, as of the Effective Date:

16.3.1 it has the full power and authority to enter into and assume its obligations under

this Agreement;

16.3.2 it is in material compliance with all statutes, regulations, directives and requirements of any governmental entity related to the conduct of such Project and the funding of same hereunder;

16.3.3 it has disclosed in writing to the Partners any actual commitments or obligations to provide to third parties Project Vaccine doses;

16.3.4 so far as it is aware, its actions or obligations under this Agreement will not infringe, misappropriate or violate any Third Party Intellectual Property, privacy or publicity rights;

16.3.5 it is not:

(i) a Restricted Party;

(ii) in breach of Sanctions from a Sanctions Authority; or

(iii) subject to or involved in any complaint, claim, proceeding, formal notice, investigation or other action by any regulatory or enforcement authority or third party concerning any Sanctions from a Sanctions Authority; and

16.3.6 it has not granted rights to any third party in respect of Project Results (other than in accordance with the terms of this Agreement).

16.4 **No Other Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NO PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

17. INSURANCE, LIABILITY AND INDEMNIFICATION

17.1 **Insurance**. Each Partner shall maintain insurance that is reasonable and customary with respect to the activities, risks, and potential omissions relevant to the Project, including clinical trial liability insurance coverage, in accordance with generally accepted industry standards and as required by law during the Term and for [***] thereafter. Each Partner shall provide CEPI with a certificate confirming such insurance upon request. In the event that the Public Health License becomes exercisable and CEPI exercises such rights, CEPI shall maintain comparable insurance protection.

17.2 **Indemnification for Third Party Claims**.

17.2.1 Each Partner shall indemnify CEPI and its Affiliates and its and their respective officers, directors, employees and third party consultants, auditors and Assessors engaged by CEPI for the purposes of this Agreement (the "**CEPI Indemnitees**"), from and against any and all claims, damages, and liabilities asserted against such persons by third parties (including claims for negligence) to the extent resulting from (i) such Partner's, or its Affiliate's or Subawardee's activities under this Agreement, (ii) the research, development, manufacture, supply,

commercialisation, disposal or use by or on behalf of such Partner, its third party licensees, Subawardees and its Affiliates, including all customers and end users thereof, of the Project Vaccine, Project Intellectual Property or any Project Results; or (iii) any claim that the use of such Partner's Intellectual Property in relation to the Project Vaccine infringes the intellectual property rights of any third party, except to the extent such claim, damage or liability is caused by breach of any term or condition of this Agreement by, or the negligence or intentional misconduct of, any CEPI Indemnitees.

17.2.2 In the event that the Public Health License becomes exercisable and CEPI exercises such rights, CEPI shall grant an indemnity to the Partner(s) in respect of which the Public Health Licence has been granted on the same terms as the indemnity set out in this Clause 17.2, which shall apply to CEPI *mutatis mutandis*.

17.2.3 **Conduct of Responses to Third Party Claims**. The indemnified party shall use all reasonable endeavours to inform the indemnifying Party promptly of any circumstances that are likely to give rise to a third party claim which may be covered by Clause 17.2.1 together with copies of all relevant documents, correspondence and records. The indemnified party shall not take any material action in respect of any third party claim which is covered by Clause 17.2.1 without the consent of the indemnifying party, including any settlement of any such third party claim, *provided* such consent is not unreasonably conditioned, withheld or delayed. The indemnifying party shall have the right to assume control of defence of the claim and shall keep the indemnified party reasonably informed of the progress of all relevant third party claims which are covered by Clause 17.2.1 and shall consult with the indemnified party on the nature of any defence to be advanced in advance. The indemnified party may have its counsel participate in (but not control) the defence of a claim, at the indemnified party's own expense.

17.2.4 **Exclusions**. No Party shall be liable to any other Party for any loss of profits, loss of opportunity, loss of contract or bargain (in each case, whether direct or indirect damages); or indirect, incidental, consequential, special, punitive or exemplary losses or damages, whether in contract, warranty, negligence, tort, strict liability, indemnity, contribution or otherwise, arising out of or in connection with this Agreement.

17.3 **Liability Cap**. Subject to Clause 17.4, CEPI's maximum liability in aggregate arising out of, or in connection with, this Agreement shall not exceed [***]. Notwithstanding the foregoing, if CEPI has exercised the Public Health License, or if CEPI is in breach of the confidentiality obligations in Clause 18, CEPI's maximum liability in aggregate to Partner shall not exceed [***]. Subject to Clause 17.4, the maximum liability of each Partner to any other Party in aggregate arising out of, or in connection with, this Agreement shall not exceed [***]

17.4 **Exclusions from Liability Cap**. Notwithstanding the foregoing, nothing in this Agreement shall limit the liability of any Party in respect of: (i) personal injury or death arising out of that Party's negligence or intentional misconduct; (ii) fraud or fraudulent misrepresentation or intentional misconduct, (iii) any Party's obligations under Clause
17.2 or, (iv) any Party's obligation to make payments to any other Party, subject to any applicable rights to withhold, condition, delay or otherwise not pay as permitted under this Agreement.

18. CONFIDENTIALITY

18.1 **Confidential Information**.

18.1.1 "**Confidential Information**" means information disclosed by one Party to another Party or its Affiliates or designees (including, for clarity, any information disclosed by or on behalf of a Partner (i) to CEPI pursuant to Clause 3, (ii) to any Assessor pursuant to Clause 11 and any information disclosed by or on behalf of a Partner to any auditor pursuant to this Agreement) under or in connection with this Agreement, whether prior to, on, or after the Effective Date. For avoidance of doubt, the Project Results and Project Intellectual Property shall be deemed the Confidential Information of the Partner that first created, invented or generated such Project Results or Project Intellectual Property.

18.1.2 Each Party undertakes that it shall keep confidential and not disclose another Party's Confidential Information to any person other than: (i) to a Party, (ii) any Affiliate of a Party or such Party's or its Affiliates' employees, officers, agents, contractors, consultants and legal and accounting advisers, who have a need to know such Confidential Information to achieve the specific purpose under this Agreement for which such Confidential Information was disclosed (or for which such Confidential Information was permitted to be created by the person or entity deemed to be the recipient of the same) and are subject to customary confidentiality terms, or (iii) as permitted in Clause 18.3. The obligations of confidentiality, non-use and non-disclosure under this Clause 18.1 shall be in full force and effect during the Term of this Agreement and until [***] after its expiry or termination. In the event that at any time a Partner wishes to disclose to CEPI any Confidential Information that is subject to obligations to a third party under any agreement between such Partner or any of its Affiliates and a third party (or to which such Partner or any of its Affiliates is otherwise subject), it shall have the right to condition such disclosure on CEPI's agreement to comply with any additional confidentiality or non-use obligations owed to such third party(ies). In such event, the relevant Partner shall notify CEPI that such Confidential Information would be subject to such additional confidentiality or non-use obligations, and CEPI and such Partner shall discuss and agree whether such Confidential Information will be disclosed by such Partner. In the event that CEPI elects to receive such Confidential Information, CEPI and the relevant Partner shall work together to enter into a written agreement setting out such additional

confidentiality and non-use obligations hereunder. Each Party shall take commercially reasonable precautions to protect against unauthorised use or unauthorised disclosure of another Party's Confidential Information. For clarity, Project Results may be disclosed and utilised by the Parties as expressly set out in this Agreement.

18.1.3 Notwithstanding Clause 18.1.2 or any term or condition of this Agreement to the contrary, any information produced by Assessors pursuant to Clause 11 using any Confidential Information of a Partner shall be deemed Confidential Information of such Partner.

18.2 **Confidentiality Limitations**. Confidential Information shall not include:

18.2.1 information already known to the receiving Party and which is not subject to pre- existing obligations of confidentiality;

18.2.2 information that is independently developed by the receiving Party without access to or the use of or access to another Party's Confidential Information;

18.2.3 information that is or becomes part of the public domain other than by unauthorised disclosure by receiving Party or any of its Affiliates or any designee or other person to which the receiving Party has disclosed such information; and

18.2.4 information properly obtained by the receiving Party from a source that is not bound by a confidentiality obligation to the disclosing Party.

18.3 **Permitted Disclosures**. Notwithstanding Clause 18.1, the receiving Party may disclose Confidential Information of a disclosing Party:

18.3.1 as permitted by and in accordance with Clause 18.6, to the U.S. Securities and Exchange Commission or any national securities exchange in any relevant jurisdiction (each a "securities regulator" for purposes of Clause 18.6);

18.3.2 in response to a valid order of a court of competent jurisdiction or other governmental authority or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by applicable law (other than to a securities regulator); provided that to the extent legally permissible the receiving Party will first give written notice to the disclosing Party and give the disclosing Party a reasonable opportunity to (i) quash any such order; (ii) obtain a protective order or confidential treatment requiring that the Confidential Information that is the subject of such order or applicable law (A) be held in confidence by the recipient and (B) be used only for the purposes for which the order was issued or as required by applicable law; and (iii) propose redactions to such Confidential Information; and provided, further, that any Confidential Information disclosed in response to any such order or applicable law will be limited to that information which is required or reasonably deemed to be required to be disclosed in response thereto;

18.3.3 by a Partner, as the receiving Party, to a Regulatory Authority, as reasonably required or useful in connection with any filing, submission or communication with respect to the Project Vaccine;

18.3.4 to the limited extent that is required to be disclosed by a competent legal authority or which is required to be disclosed pursuant to a request under the Freedom of

information Act 2000, the Freedom of Information (Scotland) Act 2002, Environmental Information Regulations 2004 or Environmental Information (Scotland) Regulations 2004; provided that, where it is free to do so, the receiving Party shall give notice of such disclosure to the disclosing Party as soon as reasonably practicable; and

18.3.5 (i) in the case of CEPI, to a Regulatory Authority and to CEPI's funders and Assessors, and (ii) in the case of a Partner as the receiving Party, (1) to any actual or potential collaborators, partners, investors, funders, lawyers, bankers, advisors, (sub)licensees, (sub)contractors or Subawardees in connection with the development, manufacture or commercialization of the Project Vaccine, or (2) otherwise to the extent necessary or useful for such Partner to exercise its rights or perform its obligations hereunder; provided that, in each case ((i) and (ii)), prior to any such disclosure, each disclosee will be bound by written obligations of confidentiality, non- disclosure and non-use no less restrictive than the obligations set forth in this Clause 18; and provided, further, that the receiving Party will remain responsible for any failure by any such disclosee to treat such Confidential Information as required under this Clause 18.

18.4 **Permitted Uses**. Notwithstanding Clause 18.1 or any other term or condition of this Agreement, Confidential Information of a Partner shall be used by CEPI or any third party to which CEPI discloses any such Confidential Information (for clarity, which third party disclosure shall be made in accordance with Clause 18.3) solely to fulfil CEPI's obligations and exercise CEPI's rights in accordance with this Agreement in connection with the Project, and shall not be disclosed to any third party who engages in the same or similar business, including development of same or similar products except as agreed otherwise by the Parties in writing.

18.5 **Notice of Breach**. Each Party shall promptly notify the other Parties of any breach or unauthorized disclosure with respect to another Party's Confidential Information of which it becomes aware.

18.6 **Securities Filings; Disclosure under Applicable Law.** Each Party acknowledges and agrees that each other Party shall have the right to submit this Agreement to, or file this Agreement with, the securities regulators or to other governmental persons or entities, if required by applicable law, and if a Party submits this Agreement to, or files this Agreement with, any securities regulator or other person or entity as required by applicable law, to the extent practicable in a given timeline and as permitted under applicable law, such Party shall consult with the other Parties with respect to the preparation and submission of a confidential treatment request for this Agreement. Notwithstanding the foregoing, if a Party seeks to make a disclosure as required by a securities regulator or other person or entity as required by applicable law as set forth in this Clause 18.6 and any other Party provides comments in accordance with this Clause 18.6, the Party seeking to make such disclosure or its counsel, as the case may be, will reasonably consider such comments, to the extent permitted under and consistent with applicable law.

19. TERM AND TERMINATION

19.1 **Term**. This Agreement shall commence on the Effective Date identified in the Agreement Summary and, unless earlier terminated pursuant to this Clause 19, shall continue in full

force and effect until the fifth (5th) anniversary of the Effective Date ("**Initial Term**"). Following expiry of the Initial Term, the Parties may agree to extend this Agreement for a period of up to twenty four (24) months unless all activities set out in all Work Packages, including any additional Work Packages, have been completed (the "**Term**").

19.2 **Termination by Either Partner for Default or Insolvency**. A Partner (the "**Terminating Partner**") shall be entitled, in its sole discretion, to terminate its involvement in this Agreement by giving written notice of termination to the other Partner and to CEPI, effective immediately, if any other Party:

19.2.1 materially breaches this Agreement, where such breach is material in respect of the Terminating Partner's rights under this Agreement, and either fails to cure such material breach within a cure period of [***] after notice from the Terminating Partner or such longer time if agreed in writing or if prompt and reasonable steps to cure such material breach are undertaken when the breach is not reasonably capable of cure with [***] and such diligent efforts are maintained until cure is achieved, provided cure is achieved within [***] after the notification of breach;

19.2.2 (a) makes an assignment for the benefit of its creditors, (b) files or resolves to file for protection under bankruptcy, insolvency, reorganisation, restructuring or business rescue laws anywhere in the world (except for the purpose of solvent amalgamation, reorganisation or restructuring), (c) appoints or suffers the appointment of a receiver, administrative receiver, bailiff or trustee or analogous appointment over substantially all of its property, (d) proposes or implements a scheme of arrangement, company voluntary arrangement or other agreement of composition, compromise or extension of its debts, (e) proposes or is a party to any dissolution or liquidation or ceases continuation of substantially all of its business, (f) is subject to any filing of an application or a petition under any bankruptcy, insolvency, reorganisation, restructuring or business rescue laws anywhere in the world (except for the purpose of solvent amalgamation, reorganisation or restructuring), or has any such application or petition filed against it that, in any such case, is not discharged, within fourteen (14) days of the filing thereof; or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course; or

19.2.3 violates any applicable Sanctions, anti-bribery, anti-corruption or anti- competitive laws and regulations or commits any illegal business practices.

19.3 **Termination by CEPI for Default or Insolvency**. CEPI shall be entitled, in its sole discretion, to terminate either Partner's involvement in this Agreement, or this Agreement in its entirety, by giving written notice of termination to the other Parties, effective immediately, if a Partner:

19.3.1 materially breaches this Agreement and either fails to cure such material breach within a cure period of thirty (30) Business Days after notice from CEPI or such longer time if agreed in writing; or

19.3.2 (a) makes an assignment for the benefit of its creditors, (b) files or resolves to file for protection under bankruptcy, insolvency, reorganisation, restructuring or business rescue laws anywhere in the world (except for the purpose of solvent amalgamation, reorganisation or restructuring), (c) appoints or suffers the

appointment of a receiver, administrative receiver, bailiff or trustee or analogous appointment over substantially all of its property, (d) proposes or implements a scheme of arrangement, company voluntary arrangement or other agreement of composition, compromise or extension of its debts, (e) proposes or is a party to any dissolution or liquidation or ceases continuation of substantially all of its business, (f) is subject to any filing of an application or a petition under any bankruptcy, insolvency, reorganisation, restructuring or business rescue laws anywhere in the world (except for the purpose of solvent amalgamation, reorganisation or restructuring), or has any such application or petition filed against it that, in any such case, is not discharged, within fourteen (14) days of the filing thereof; or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course; or

19.3.3 violates any applicable Sanctions, anti-bribery, anti-corruption or anti- competitive laws and regulations or commits any illegal business practices.

19.4 **Other Termination by CEPI**. CEPI shall be entitled, in its sole discretion, to terminate either Partner's involvement in this Agreement, this Agreement in its entirety, or any Work Package, by providing written notice of termination to the other Parties, if:

19.4.1 CEPI notifies a Partner that there are material safety, regulatory, scientific misconduct or ethical issues associated with continuing the Project, as reasonably determined by CEPI and the Partner either fails to end or cure such issue within a period of [***] after notice from CEPI or such longer time if agreed in writing;

19.4.2 the Stage Gate Review Committee determines that a Stage Gate was not completed by the Stage Gate Deadline pursuant to Clause 2.6 [***];

19.4.3 a Partner withholds, conditions or delays its consent to the material changes to the Code or other applicable policy pursuant to Clause 12.2;

19.4.4 CEPI reasonably determines that a Partner is unable to discharge its obligations under this Agreement, for example if key personnel or technology resources which are essential for the successful completion of all Projects become unavailable to Partner, and Partner does not reasonably alleviate CEPI's concerns within a cure period of [***] or such longer time as may be agreed by the Parties in writing;

19.4.5 CEPI delays or conditions a payment in accordance with Clause 3.6, or a Partner has failed to satisfy the payment requirements set out in Clause 3.5, and a Partner fails to resolve any such impediments to payment or address CEPI's concerns to CEPI's reasonable satisfaction, within a cure period of [***] or such longer time as may be agreed by the Parties in writing or [***];

19.4.6 a Partner has committed fraud or a Financial Irregularity. For purposes of this Agreement, "**Financial Irregularity**" includes any and all kinds of corruption,

including bribery, nepotism and illegal gratuities; misappropriation of cash, inventory and all other kinds of assets; and making fraudulent financial and non- financial statements to CEPI; or

19.4.7 upon notice in writing if CEPI reasonably believes that a Partner's or its Affiliate's tax affairs would have a material adverse impact on CEPI's reputation.

19.5 **Other Termination by mutual agreement**. The Partners and CEPI may terminate this Agreement by mutual written agreement.

19.6 **Payments After Certain Terminations**. If this Agreement as a whole, or the involvement of any Partner, is terminated by a Partner pursuant to Clause 19.2.1 to 19.2.3 (material breach, insolvency or breach of sanctions), as a result of the breach or insolvency of CEPI; terminated by the Parties pursuant to Clause 19.5 (mutual termination); or is terminated by CEPI pursuant to Clause 19.4.1 to 19.4.3 (issues precluding continuation of the Project, required termination by CEPI, or non-acceptance of material changes to the Code), then CEPI shall reimburse such Partner(s) for all reasonably incurred out-of-pocket expenses through termination and any non-cancellable out-of-pocket expenses relating to Project activities that were included in the terminated Work Package(s) and/or authorised in writing by CEPI, and that arise through termination and after the termination date, solely to the extent they are not otherwise covered by CEPI funding provided prior to the date of termination and *provided* always that the relevant Partner uses all reasonable endeavours to minimise and mitigate any such expenses.

19.7 **Additional Effects of Termination**. Irrespective of the grounds for termination of the Agreement (if this Agreement is terminated as a whole, then the following shall apply to all Work Packages and Partners, and if this Agreement is terminated only with respect to a particular Partner or a particular Work Package, then the following shall apply solely to such terminated Partner or Work Package):

19.7.1 CEPI shall not be required to make any further payments to the terminated Partner(s) and/or in respect of the terminated Work Package(s), other than as specified in this Clause 19;

19.7.2 each terminated Partner shall return any CEPI funds relating to the Project, or terminated Work Packages, as the case may be, within [***] from the date of termination that are unspent, if any, after deducting reimbursement to such terminated Partner for all reasonably incurred out-of- pocket expenses incurred prior to the termination date and any non-cancellable out-of-pocket expenses relating to the Project activities that were included in any terminated Work Package(s) and/or authorised in writing by CEPI and that arise before or after the date of termination, *provided* always that such Partner uses all reasonable endeavours to minimise and mitigate any such expenses;

19.7.3 each Party shall return or destroy (and certify the destruction of), as requested by any other Party, the Confidential Information of such requesting Party relating to the terminated elements of this Agreement, except that: (i) CEPI may retain the Project Results subject to the limitations on use thereof provided in this Agreement and obligations of confidentiality set out in Clause 18, and (ii) each Party may keep one (1) copy of such Confidential Information for monitoring compliance with this Agreement. Neither Party shall be required to delete copies of Confidential Information stored on automatic electronic backup systems; and

19.7.4 if there is an on-going clinical trial which is to be terminated, unless agreed otherwise by the Parties in writing or otherwise required by institutional review boards, ethics committee, or relevant regulatory authorities under applicable laws, CEPI shall not be required to make any further payments to a Partner under this Agreement or any Work Package other than as specified in this Clause 19; *provided* that in the event that the Partner responsible for such clinical trial elects (in its sole discretion) to wind-down the clinical trial as a result of such termination, such Partner shall do so in an orderly fashion, with due regard for patient safety and the rights of any participating subjects; *provided, further,* that the expenses of winding down or (to the extent required by applicable law or patient safety and rights) completing such clinical trial shall be reimbursed by CEPI subject to Clause 19.6 or Clause 19.7, as applicable.

19.8 **Repayment of Funds for Financial Irregularity**. Notwithstanding Clauses 19.6 and 19.7, where termination is due to any Financial Irregularity, the relevant Partner shall repay to CEPI the amount of funds related to such Financial Irregularity activity within [***] of the notice of termination and CEPI shall not be required to make any payments to such Partner pursuant to Clauses 19.6 and 19.7 unless and until such repayment has occurred in full.

19.9 **Survival of Rights and Identified Clauses**. Termination of this Agreement shall be without prejudice to the rights and duties of the Parties accrued prior to termination or expiry of the Agreement. The following Clauses shall continue to be enforceable notwit standing termination or expiry: 1, 3.4, 3.13, 3.14, 3.15, 4.1, 4.3, 4.4, 6, 8, 10, 12.4, 14, 15, 16.4, 17, 18, 19.6, 19.7, 19.8, 19.9, 20 and 21.

20. RESOLVING DIFFERENCES

20.1 **Resolution by the Joint Oversight Committee**. The Partners and CEPI shall cooperate in good faith to attempt to resolve differences and disputes at the JMAG.

20.2 **Escalation to Senior Management of the Parties**. Any difference or dispute that cannot be resolved by the JMAG shall be submitted to the Parties' respective Chief Executive Officers or designees for resolution. If the Parties remain unable to resolve such dispute within [***] (or such additional time as mutually agreed in writing), then the Parties irrevocably submit to arbitration for its resolution upon referral of such dispute by a Party pursuant to Clause 20.3.

20.3 **Arbitration**. Any controversy, dispute, or claim arising out of or relating to this Agreement, or the breach thereof, shall be determined by binding arbitration (including any question regarding its existence, validity or termination or this Agreement), and be referred to and finally resolved under the Rules of the London Court of International Arbitration, which Rules are incorporated by reference into this Clause 20.3. The number of arbitrators shall be three (3). The seat, or legal place, of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English. Notwithstanding the foregoing, any Party may seek specific performance, interim or final injunctive relief or any other relief of similar nature or effect in any court of competent jurisdiction. This Clause shall be governed by and construed in accordance with the law of England and Wales without giving effect to any choice of law or conflict of law provisions

or rules that would cause the application of the laws of any other jurisdiction.

21. MISCELLANEOUS

21.1 **Relationship of the Parties**. Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute any Party the agent of any other Party, or authorise any Party to make or enter into any commitments for or on behalf of another Party. No Party shall be held liable for or incur liability in respect of the acts or defaults of any other Party.

21.2 **Announcements and Use of Names**. No Party shall issue any press release, public statement or public announcement with respect to this Agreement without the prior written consent of the other Parties. Subject to Clause 18.6, no Party shall use the name or trademarks of another Party or its Affiliates in any press release, public statement or publication in connection with this Agreement without the named Party's prior express written consent. After the initial announcement, or as required by law, either Party may disclose a description of the Project, the names of each Party and its Project Lead, and the amount of the CEPI funding without the prior consent of the other Parties.

21.3 **Assignment.**

21.3.1 No Party shall, without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed, assign its rights or obligations under this Agreement to any third party, except that CEPI may do so to an organisation of equivalent charitable mission and technical capabilities.

21.3.2 Save as otherwise permitted under this Agreement, neither Partner shall assign, license or encumber its rights in the Project Intellectual Property, Project Results or any Intellectual Property controlled by such Partner, in each case to the extent that they relate to the Project Vaccine, including all Enabling Rights, without the consent of CEPI, such consent not to be unreasonably withheld or delayed, and as a condition of giving such consent CEPI may require that such assignment, or license is made subject to the terms of this Agreement, and that any encumbrance is subject and subordinate to CEPI's rights under this Agreement. In the event of a change of control of a Partner, or any Partner is otherwise acquired, then such Partner shall ensure that any such acquirer is made aware of the terms of this Agreement and shall remain bound by and subject to the terms of this Agreement in all respects.

21.3.3 Notwithstanding the restriction set out in Clause 21.3.2, CEPI understands that Barinthus Bio is considering [***]. Barinthus Bio shall keep CEPI updated with regards to any plans it may have [***]. In the event that Barinthus Bio does [***] it will notify CEPI in writing [***] and CEPI and Barinthus Bio shall discuss, in good faith, the appropriate terms pursuant to which CEPI may give its consent pursuant to Clauses 21.3.1 and 21.3.2 [***].

21.3.4 This Agreement will be binding upon, inure solely to the benefit of, and be enforceable by each Party and their respective permitted successors and assigns.

21.4 **Notice**. Any notice to be given pursuant to this Agreement shall be in writing in the English language and shall be delivered by overnight courier, by registered, recorded delivery or certified mail (postage prepaid) or email to the address (or email address) of the recipient Party provided in the Agreement Summary or such other address (or email address) as a Party may from time to time designate by notice in writing. Any notice given pursuant to this Clause shall be deemed to have been received on the day of receipt, *provided* receipt occurs on a Business Day of the recipient Party or otherwise on the next following Business Day of the recipient.

21.5 **Entire Agreement**. This Agreement (including the Agreement Summary and its Annexes) constitutes the entire agreement and understanding between the Parties relating to its subject matter and together they supersede and replace all prior arrangements, whether written or oral, between the Parties relating to the subject matter of this Agreement.

21.6 **Amendments to this Agreement**. No variation, amendment, modification or supplement to this Agreement, including its Annexes, shall be valid unless and until it is made in writing and signed by a duly authorised representative of each Party.

21.7 **Order of Precedence**. If there is any conflict between the provisions of this Agreement, and the Third Party Code or any Work Package, then the provisions of this Agreement shall prevail. Subject to the foregoing sentence, if there is any conflict between the provisions of a Work Package and the Third Party Code, the provisions of the Third Party Code to the extent described in the Third Party Code Declaration Letter shall prevail. If there is an inconsistency between any provision in this Agreement and the corresponding provision in the [***] then, as between [***] the terms of the [***] shall prevail.

21.8 **Force Majeure**. A Party shall not be deemed to have defaulted under or to be in breach of this Agreement for failure or delay in fulfilling material obligations when such failure or delay is directly caused by an event outside of their reasonable control, including acts of war, insurrections, acts of terrorism, acts of God, epidemics, pandemics, quarantines or delays in acting or failure to act by any of CEPI's funders, in each case other than in respect of an Outbreak (collectively a "**Force Majeure Event**"). Each Party shall inform the other Parties promptly and in writing of any Force Majeure Event and the Parties shall seek to agree on the appropriate course of action under the circumstances. In the event that any delay or failure to fulfil material obligations occurs or is likely to occur due to the Outbreak, the affected Party shall promptly notify the other Parties and the Parties shall discuss in good faith any reasonable and appropriate actions in order to minimize and mitigate the effects of such delay or failure.

21.9 **No Rights for Third Parties**. A person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act of 1999 or otherwise to enforce or to enjoy the benefit of any term of this Agreement.

21.10 **Equitable Relief.** Each Party acknowledges and agrees that the restrictions set forth in Clauses 5 (IP), 14 (Equitable Access) and 18 (Confidentiality) are reasonable and necessary to protect the legitimate interests of the other Parties and that such other Parties would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Clauses may result in irreparable injury to one or more such other Parties for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Clauses, the non-breaching Party(ies) shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, or specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party(ies) may be entitled in law or equity.

21.11 **No Waiver**. A Party shall not be deemed to have waived any of its rights or remedies under this Agreement unless the waiver is expressly made in writing and signed by a duly authorised representative of that Party.

21.12 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party, including the doctrine commonly known as *contra proferentem,* shall not apply.

21.13 **Business Day Requirements**. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

21.14 **Further Assurances**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

21.15 **Counterparts and Electronic Signing**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. No counterpart shall be effective until each

Party has executed at least one counterpart. Additionally, this Agreement may be signed electronically by exchanging signed PDF versions or by using an electronic signature platform which meets the European Union requirements for valid electronic signatures (such as DocuSign®).

21.16 **Choice of Law**. This Agreement shall be governed by and construed in accordance with, and any dispute or claim arising out of or in connection with it or its subject matter (including non-contractual disputes or claims) shall be governed by, the laws of England and Wales without giving effect to any choice of law or conflict of law provisions or rules that would cause the application of the laws of any other jurisdiction.

21.17 **Severability**. If any provision or part-provision of this Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of this Agreement.

21.18 **Interpretation**. In this Agreement:

21.18.1 any headings in this Agreement shall not affect the interpretation of this Agreement;

21.18.2 unless the context otherwise requires, reference to the singular includes the plural and vice versa, any reference to a person includes a body corporate and words importing one gender include both genders;

21.18.3 a reference to a statute or statutory provision is (unless otherwise stated) a reference to the applicable UK or other country's statute as it is in force for the time being, taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it;

21.18.4 where the words "include(s)" or "including" are used in this Agreement, they are deemed to have the words "without limitation" following them, and are illustrative and shall not limit the sense of the words preceding them;

21.18.5 the word "or" shall have its inclusive sense (and/or), and no contrary inference shall be drawn from the use of "or" in certain phrases and the use of "and/or" in other phrases; and

21.18.6 "third party(ies)" shall not be construed to include Affiliate(s) of either Party.

Annex B: Team Charter

[***]

Annex C: Integrated Product Development Plan and Work Package(s)

[***]

Annex D: Budget for Work Packages

[***]

ANNEX E: Equitable Access Plan

EA Provisions	Details
Price	• Commitment to CEPI Equitable Access Policy Supplier to offer price not exceeding [***] for public markets in LMICs and (Low- and Middle-Income Countries) and price no higher than [***] for UMICs
	• Principles agreed for COGS determination with access to be provided for an independent audit if required
	• [***]
Clinical Development	• [***]
	• Aligning on clinical development and regulatory submission strategy to enable product licensure/commercialization in endemic countries
Intellectual Property	• Agreement on Public Health License inclusion
Shared Risk/Benefit	• Parties have agreed to an commercial benefits mechanism listed in section 15
Data Sharing & Transparency	• Agreement on project data being shared by the awardee and CEPI openly with broader community to inform public health response
	• Commitment to open access to data, results and publication arising from CEPI funding
	• Clinical trial data and results publicly disclosed as per CEPI's clinical trial policy
Availability & Supply	• Develop a product, technology with a Target Product Profile (TPP) suitable for LMICs
	• Partner to develop a regulatory licensure and supply plan for LMICs for CEPI feedback
	• CEPI to assess need to support technology transfer to additional LMICs. Barinthus to provide the background IP, project licenses, data, dossier etc. without any cost.

Annex F: List of UMICs, HICs and LMICs as at the Effective Date

[***]

Annex G: Sub-Contractors

[***]

Annex H: COGs

[***]

Annex I: Third Party Code, Cost Guidance and Transparency and Confidentiality Policy

[***]

Annex J – Stage Gates

[***]

Annex K – Template Technical Report
[***]

Annex L – List of CEPI Affiliates as at the Effective Date

[***]

Annex M – CEPI's Clinical Trial Policy

[***]

Exhibit 21.1

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
Barinthus Biotherapeutics Pty Limited (formerly Vaccitech Australia Pty Limited)	Australia
Vaccitech Oncology Limited	England and Wales
Barinthus Biotherapeutics (UK) Limited (formerly Vaccitech (UK) Limited)	England and Wales
Barinthus Biotherapeutics North America, Inc. (formerly Vaccitech North America, Inc.)	Delaware
Barinthus Biotherapeutics Italia S.R.L. (formerly Vaccitech Italia S.R.L.)	Italy
Barinthus Biotherapeutics Switzerland GmbH (formerly Vaccitech Switzerland GmbH)	Switzerland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-255664, 333-263844 and 333-270815) and Form S-3 (Nos. 333-265763 and 333-266724) of Barinthus Biotherapeutics plc of our report dated March 20, 2024 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
PricewaterhouseCoopers LLP, 3 Forbury Place, 23 Forbury Road, Reading, Berkshire, RG1 3JH
T: +44 (0) 118 959 7111, F: +44 (0) 1189 383 020, www.pwc.co.uk
Reading, United Kingdom
March 20, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William Enright, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 of Barinthus Biotherapeutics plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The 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.

Date: March 20, 2024

By: /s/ William Enright

William Enright
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gemma Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 of Barinthus Biotherapeutics plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The 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

Date: March 20, 2024

By: /s/ Gemma Brown

Gemma Brown
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS 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 Barinthus Biotherapeutics plc (the "Company") on Form 10-K for the fiscal year ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his or her knowledge 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.

Date: March 20, 2024

By: /s/ William Enright
William Enright
Chief Executive Officer

Date: March 20, 2024

By: /s/ Gemma Brown
Gemma Brown
Chief Financial Officer