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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, 2025
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.)**
20400 Century Blvd Suite 210 Germantown, MD	**20874**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 443 917-0966

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 $13.7 million.

The number of shares outstanding of the registrant's ordinary shares, nominal value £0.000025 per share, as of March 6, 2026: 40,848,893 shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

BARINTHUS BIOTHERAPEUTICS PLC

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2025

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We own the registered trademark BARINTHUS in the United Kingdom ("U.K."), and we have filed applications at the U.K. 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 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 about us and for complying with our disclosure obligations under Regulation FD. 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 transactions with Clywedog Therapeutics, Inc. ("Clywedog") contemplated by the Agreement and Plan of Merger (as amended from time to time, the "Merger Agreement"), dated September 29, 2025, by and among us, Cdog Merger Sub, Inc. and Clywedog (the "Contemplated Transactions"), and expectations regarding the timing and benefits of, and our ability to consummate, the Contemplated Transactions;
- 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"), New Drug Application ("NDA"), and Biologics License Application ("BLA") filings for our current and future product candidates, and final U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), U.K. Medicines and Healthcare products Regulatory Agency ("MHRA"), or other foreign regulatory authority approvals relating to our current and future product candidates;
- our future expectations, plans and prospects, including the estimates of costs that we expect to incur in connection with the restructuring and the timing thereof;
- 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 or similar event;
- the impact of global economic and political developments on our business, including inflationary pressures, volatile interest rates, or intensified disruptions in the global financial markets, the change in the U.S. presidential administration, 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 ability to comply with the continued listing requirement of Nasdaq and 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 majority-owned subsidiaries.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

- Our failure to complete the Contemplated Transactions would have a material adverse effect on our business, results of operations, financial condition and stock price.
- The failure to successfully integrate our business with that of Clywedog in the expected timeframe would adversely affect our future business and financial performance and the value of our stockholders' investment following the Combinations.
- Our shareholders and Clywedog's stockholders may not realize a benefit from the Contemplated Transactions commensurate with the ownership dilution they will experience in connection with the Contemplated Transactions.
- During the period prior to the closing of the Contemplated Transactions, our business is exposed to certain inherent risks due to the effect of the announcement or pendency of the Contemplated Transactions on our business relationships, financial condition, operating results and business.
- Litigation may arise in connection with the Contemplated Transactions, which could be costly, prevent consummation of the Contemplated Transactions, divert management's attention and otherwise materially harm our business.
- We are subject to restrictions on our business activities under the Merger Agreement.
- 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 existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- 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.
- 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 novel approaches to the treatment of diseases, 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.
- 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 expenses, 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.
- The pipeline prioritization and restructuring may be unsuccessful, lead to additional costs, disrupt our operations, create unintended problems in our workforce, or increase litigation, in which case our business could be harmed.
- 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.
- If we were classified as a passive foreign investment company, it could result in adverse U.S. federal income tax consequences to U.S. Holders (as defined below).
- If we fail to regain compliance with the continued listing requirements of Nasdaq Stock Market LLC ("Nasdaq"), our ADSs may be delisted and the price of our ADSs and our ability to access the capital markets could be negatively impacted.
- A variety of risks associated with operating our business internationally could materially adversely affect our business.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel immunotherapeutic drug candidates for treating autoimmune and inflammatory diseases within the immunology and inflammation ("I&I") space. Helping patients and their families is the guiding principle at the heart of Barinthus Bio. We aim to achieve this by developing truly transformational and highly disease-specific immunotherapies.

We are prioritizing the development of a pipeline for I&I indications enabled by our proprietary and highly differentiated platform for promoting immune tolerance, referred to as SNAP-TI, that are designed to guide patient's T cells to reduce inflammation and restore the natural state of immune non-responsiveness to healthy tissue. Our lead candidate, VTP-1000, is designed to restore immune non-responsiveness to gluten in patients with celiac disease, and is currently being assessed in a Phase 1 clinical trial. Based on encouraging preclinical data, we believe that the SNAP-TI platform has the potential to impact multiple other I&I indications.

We are also exploring partnership opportunities for VTP-300, a product candidate to treat chronic hepatitis B ("CHB") that harnesses viral vector platform technologies, consisting of Chimpanzee Adenovirus Oxford ("ChAdOx") and Modified Vaccinia Ankara ("MVA"), which are designed to increase disease-specific CD8+ T cells. VTP-300 is a Phase 2 immunotherapeutic treatment modality that is a component of a treatment regimen to establish functional cure in patients who are chronically infected by the hepatitis B virus.

We believe our core capabilities at the intersection of T cell immunology and immunotherapeutic technology platforms combined with our track record of successfully executing development path activities uniquely position us to navigate towards delivering promising new treatments for patients with autoimmune and inflammatory diseases and building value for shareholders.

Our Approach

We are leveraging the latest understanding of how the immune system's T cells naturally function to control disease. Research has shown that T cells are key to our body’s ability to identify and respond to threats through recognition of antigens. Disease can occur when the T cell response is either inappropriate, as occurs in autoimmunity, or inadequate, as often occurs in chronic viral infections or cancer.

Many autoimmune and inflammatory diseases are characterized by an inappropriate or overactive immune response caused by an imbalance in the T cell population. T effector ("Teff") cells that normally fight infections and cancer can inappropriately attack the body and overwhelm the regulatory T ("Treg") cells that are meant to prevent inflammation. While there has been incredible progress in the treatment options over the last two decades, current therapies still rely heavily on the use of non-specific immunosuppressive agents and supportive therapies. These may efficiently dampen inflammation and slow disease progression, but they often require lifelong treatment and their lack of specificity for the pathogenic mechanism can lead to several, sometimes life-threatening, side effects. Therefore, there remains a need for more targeted, curative therapies that directly address the T cell (Treg/Teff) imbalance underlying many autoimmune and inflammatory diseases. Fortunately, improved understanding of the cause of inflammatory diseases is allowing the identification of the specific antigens that Teff cells are attacking. In autoimmunity, Teff cells recognize and attack tissues harboring self-antigens, such as pancreatic beta islet cell associated antigens in type-1 diabetes. Knowledge of the problematic antigens that the Teff cells are responding to allows for the development of highly specific treatments that only target the T cells involved in the disease and may provide a less aggressive and potentially curative approach.

We aim to directly address the disease process underlying autoimmunity and other inflammatory diseases by developing antigen-specific immune tolerance ("ASIT") therapies based on our proprietary SNAP-TI technology platform. Our approach is to use SNAP-TI to provide the immune system with problematic antigens within an appropriate tolerogenic context that promotes a reduction in Teff cells and increase in Treg cells, aiming to restore the natural state of immune tolerance and control over disease. Properties that differentiate SNAP-TI from other ASIT therapies are the use of synthetic, self-assembling nanoparticles to improve manufacturability of multiple antigen compositions; ability to administer by preferred intramuscular or subcutaneous routes; and use of an immunomodulator that aims to improve the Treg/Teff ratio and prevent unwanted inflammation associated with the treatment.

In 2025, we achieved a number of strategic, operational, and financial objectives, which we believe position us to deliver on our long-term plans:

- In January 2025, we announced a strategic business refocus and restructuring to prioritize immunology and inflammation indications, including the development of VTP-1000 in celiac disease and deprioritization of VTP-300 in CHB until a partner is identified. Partners are also being sought for the other assets that are based upon the viral vector platforms. As part of this refocus, we announced a reduction in workforce of approximately 65% and the expected closure of the U.K. site, focusing future operations at the U.S. site in Germantown, Maryland and extending the cash runway into 2027.

- In May 2025, we presented data from two Phase 2 clinical trials of VTP-300 in CHB at the European Association for the Study of the Liver (“EASL”) Congress 2025 showing VTP-300 induced meaningful and sustained reductions in hepatitis B surface antigen (“HBsAg”). Data from the HBV003 trial, evaluating VTP-300 in combination with low-dose nivolumab (“LDN”) showed in CHB participants with HBsAg levels of <200 IU/mL, meaningful reductions in HBsAg (>1 log decline) occurred soon after dosing on Day 29 in all treatment groups and were maintained to Day 169. In the two best treatment arms HBsAg declines of ≥1 log at Day 169 were observed in 33% (15/45) of participants with HBsAg ≤200 IU/mL at baseline, and 22% (10/45) of participants achieved HBsAg loss at any timepoint with two patients achieving functional cure. In partnership with Arbutus Biopharma, we presented end-of-study data from the Phase 2a clinical trial (IM-PROVE II, AB-729-202) in CHB evaluating the combination of imdusiran (“IDR”), Arbutus’ RNAi therapeutic, followed by VTP-300, with or without LDN. The end of study data show 25% (2/8) of participants with starting baseline HBsAg levels less than 1000 IU/mL receiving the combination of IDR, VTP-300 and LDN achieved functional cure. 3 of 13 participants (23%) receiving IDR+VTP-300+LDN had undetectable HBsAg levels at week 48; all (3/3) of participants with HBsAg loss seroconverted. Treatment with VTP-300 in both studies was generally well-tolerated, with no serious adverse events or treatment discontinuations reported.

- In September 2025, we entered into the Merger Agreement to combine in an all-stock transaction with Clywedog, a private company advancing breakthrough medicines in diabetes. The newly combined company will advance a differentiated portfolio of clinical-stage candidates targeting metabolic and autoimmune diseases, with four clinical data milestones expected within 18 months of the closing of the transaction. Upon the closing of the transaction, the combined company ("Topco") will be renamed “Clywedog Therapeutics Holdings, Inc.” and is expected to trade on the Nasdaq under the new ticker symbol “CLYD.” The transaction is expected to close in the second quarter of 2026.

- In December 2025, we announced an update on the Phase 1 AVALON clinical trial of VTP-1000 for the treatment of celiac disease. The single ascending dose ("SAD") portion of the Phase 1 AVALON trial (NCT06310291) enrolled 18 patients in three placebo-controlled cohorts of ascending doses. VTP-1000 was well tolerated at all dose levels with no treatment-related SAEs. Pharmacological data collected showed a dose-dependent effect.

VTP-1000: Antigen-specific Immune Tolerance Candidate for Celiac Disease

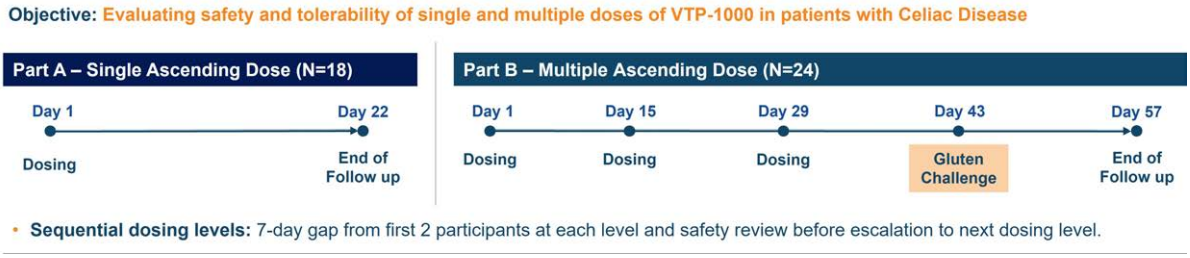
Patients with celiac disease have an unwanted immune response against gluten proteins and can become severely ill following exposure to gluten found in various cereal grains, especially wheat.

VTP-1000 is designed to suppress the unwanted immune response to gluten by restoring a beneficial regulatory T cell to effector T cell 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 that promote tolerance. The immunomodulator is a key component of VTP-1000 and is intended to drive regulatory T cell expansion and prevent pro-inflammatory responses.

Clinical Development

AVALON - Currently enrolling, ongoing Phase 1

The AVALON clinical trial is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-1000. The trial aims to enroll 42 participants with celiac disease and will be conducted in two parts: a randomized double-blind placebo-controlled SAD part, followed by a randomized double-blind placebo-controlled multiple ascending dose ("MAD") part, incorporating a controlled gluten challenge to assess the impact of VTP-1000 administration on patients' exposure to gluten. In the AVALON trial, we are enrolling adults with celiac disease in the two-part trial, as described in the table below.



Part A - SAD Data

In December 2025, we announced an update on the Phase 1 AVALON clinical trial of VTP-1000 for the treatment of celiac disease. The SAD portion of the Phase 1 AVALON trial (NCT06310291) enrolled 18 patients in three placebo-controlled cohorts of ascending doses. VTP-1000 was well tolerated at all dose levels with no treatment-related SAEs. Pharmacological data collected showed a dose-dependent effect.

Future Development

The MAD portion of the trial, which includes a gluten challenge, is currently ongoing, with data expected in the second half of 2026.

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

Our Legacy Infectious Disease and Oncology Pipeline ("Barinthus Legacy Assets"):

In January 2025, we announced a strategic focus on developing a pipeline in I&I, and the deprioritization of our programs in infectious disease and oncology. The following assets shall be referred to collectively as "Barinthus Legacy Assets", and the future clinical development of which will only be advanced by a partner: VTP-300 HBV, VTP-500 MERS, VTP-850 Prostate Cancer.

VTP-300: Our Legacy Hepatitis B Immunotherapy

In 2025, we announced that our Phase 2 Hepatitis B immunotherapy, VTP-300, would only be advanced in the future, with support from a partner. VTP-300 is based on two viral vector platforms (ChAdOx and MVA), each encoding the same antigen sequence based on HBV genotype C antigen sequences, and is designed to stimulate the production of very high levels of Teff cells, such as CD8+ T cells that can recognize viral antigens or tumor antigens.

Patients with chronic hepatitis B infection live with the disease in the absence of symptoms for decades after initial infection. However, as the disease progresses and symptoms occur, it can cause serious health problems, including development of hepatocellular carcinoma or liver cirrhosis, especially if left untreated. There is an urgent need to develop an effective therapeutic strategy for CHB infection as less than 10% of patients achieve a functional cure with existing therapies. Experts agree that achieving functional cure in CHB patients will likely require a combination of agents with complementary mechanisms of action. VTP-300 has been designed to be one of those components by stimulating a highly potent and polyfunctional disease-specific immune response, mostly led by disease-specific effector T-cells.

Clinical Development

VTP-300 has completed three clinical trials to date. Meaningful, durable reductions of HBsAg were seen in patients receiving VTP-300 monotherapy and those receiving VTP-300 followed by a single low dose of nivolumab together with MVA. 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.

In May 2025, we announced primary endpoint data from the Phase 2 HBV003 clinical trial (NCT05343481). The preliminary analysis showed that in CHB participants with hepatitis B surface antigen (“HBsAg”) levels of <200 IU/mL, meaningful reductions in HBsAg (>1 log decline) occurred soon after dosing on Day 29 in all treatment groups and were maintained to Day 169. In the two best treatment arms HBsAg declines of ≥1 log at Day 169 were observed in 33% (15/45) of participants with HBsAg ≤200 IU/mL at baseline, and 22% (10/45) of participants achieved HBsAg loss at any timepoint. 71% of participants (48 of 68) met the criteria for discontinuation of NUC therapy. Treatment with VTP-300 in combination with LDN was generally well-tolerated, with no related serious adverse events reported.

Future Development

We believe that the clinical data to date suggest that VTP-300 contributes to HBsAg loss, and could become part of a regimen that can attain and maintain functional cure. We are actively seeking a partner to take advantage of VTP-300's differentiated ability to achieve sustained HBsAg loss and functional cure in patients with low levels of HBsAg.

Our History and Team

We were founded in May 2016 as a spin-out from a leading institution in the U.K., 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. Our strategic trajectory has grown with the acquisition of Avidea Technologies, Inc. ("Avidea") and the SNAP-TI 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 Altimmune, Celltech, GenVec and Roche.

Our board of directors has extensive expertise in the fields of science, business, and finance and works with our management team on business and scientific development initiatives and strategies.

Our Collaboration and License Agreements

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

In March 2017, Avidea entered into a license agreement (the "March 2017 OUI License Agreement") with Oxford University Innovation ("OUI") 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 6, 2026, 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. In 2025, we paid £59,360 to OUI, representing 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 North America, Inc)

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. The CRADA gave us the option to exclusively license any further inventions made under the CRADA. The CRADA expired on February 23, 2025.

2019 License Agreement with NIH (Barinthus Biotherapeutics North America, Inc)

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-TI and SNAP-CI platforms, 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 6, 2026, 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. In 2025, we paid $45,000 to NIH, representing 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-TI and SNAP-CI platforms, 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.

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 6, 2026, we control a patent portfolio comprising in-licensed and co-owned patent families relating to our key SNAP-TI, SNAP-CI and star polymer technology platforms and product candidates, including one issued U.S. patent, twelve pending U.S. patent applications, seven issued foreign patents, 61 pending foreign patent applications.

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

Our proprietary synthetic SNAP platform is covered by a patent portfolio that includes eight patent families that we co-own and one patent family that we in-license from OUI. As of March 6, 2026, 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 6, 2026, we co-own a patent family that includes one issued U.S. patent, five issued foreign patents, one pending U.S. patent application, one pending European patent application and a further eleven 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 6, 2026, we co-own a patent family that includes one issued foreign patent, one pending U.S. patent application, one pending European patent application and a further five 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 6, 2026, we co-own a patent family that includes one pending U.S. patent application and a further two 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 6, 2026, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further ten 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 6, 2026, we co-own a patent family that includes one pending U.S. patent application, one pending European patent application and a further four 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 6, 2026, 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 licensed exclusive rights in this patent family, which resulted from work carried out under a RCA with the IMC. As of March 6, 2026, we co-own a patent family that includes two pending U.S. patent applications, one pending European patent application and a further nine pending foreign patent applications 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 6, 2026, 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 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.

Product Candidates

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 6, 2026, the patent family includes two pending U.S. patent applications, one pending European patent application and a further nine pending foreign patent applications. 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.”

Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and biological products under the FD&C Act and 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 drugs and 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. Drug and 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 drugs and biological products. The process required by the FDA before a 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 product candidate for its intended purpose;
- preparation of and submission to the FDA of an NDA or 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 NDA or BLA (unless a fee waiver applies);
- a determination by the FDA within 60 days of its receipt of a NDA or 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 investigational product's identity, strength, quality and purity, and of selected clinical trial sites that generated the data in support of the application 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 an NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Before testing any investigational 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 investigational 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 to 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 an NDA or 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 investigational 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 an NDA or BLA requesting approval to market the product for one or more indications. This application 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 an NDA or BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the application 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 an NDA or 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 applications, 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 application. The FDA reviews the NDA or 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 investigational 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 investigational products or 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 product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required.

Before approving an NDA or 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 an NDA or 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") an NDA, BLA or supplement to either for a novel product (*e.g.*, new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

After the FDA evaluates an NDA or 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 application, 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 application in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA or 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 marketing application 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 indication 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 product for the same approved use or 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 approved use or indication, or the same drug or biologic for a different use or indication. Among the other benefits of orphan drug designation are tax credits for qualified clinical testing expenses and a waiver of the NDA or 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 marketing application (NDA or 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 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 drugs and 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 drugs and 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.

Drug and biological product manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws, 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 NDA or 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.

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

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 marketing application (NDA/BLA) plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved 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 NDA or BLA.

Certain of our product candidates are regulated as biologics. 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 12 years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was 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.

A new drug or biological product can also 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 most active moiety and, for drugs, patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection, and, for drugs, patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial, 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 Clinical Trials Regulation (EU) No 536/2014, which replaced the current Clinical Trials Directive 2001/20/EC on January 31, 2022. The Regulation, which is directly applicable in all EU Member States (meaning that no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. The main characteristics of the Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System ("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 (Member States concerned) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State concerned. 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 new 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 European Economic Area (comprising the EU Member States plus Norway, Iceland and Liechtenstein) ("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. 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 European Union 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 marketing application (BLA/NDA) submitted 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 European Union 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 compared 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

Upon receiving marketing authorization in the European Union, innovative medicinal products (reference products), approved on the basis of a complete and independent package of data, generally receive eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity 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. In the European Union 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 MAA. 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 MAA is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

A marketing authorization may be granted to a similar medicinal product to an authorized orphan product during the period of market exclusivity only in very select cases, specifically:

- if it is established that a similar medicinal product is safer, more effective or otherwise clinically superior to the authorized orphan product;
- 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 ("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 accepted onto the PRIME scheme by the EMA in December 2023.

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 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.

All of the aforementioned EU rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the U.K.

The U.K. formally left the EU on January 31, 2020. As a result of the Northern Ireland protocol, following Brexit, the EMA remained responsible for approving novel medicines for supply in Northern Ireland under the EU centralized procedure, and a separate authorization was required to supply the same medicine in Great Britain (England, Wales and Scotland). On February 27, 2023, the U.K. government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework." The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, and the medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the previous system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the U.K. In particular, the MHRA is now responsible for approving all medicinal products destined for the U.K. market (i.e., Great Britain and Northern Ireland), and the EMA no longer has any role in approving medicinal products destined for Northern Ireland under the EU centralized procedure. A single U.K.-wide marketing authorization will be granted by the MHRA for all novel medicinal products to be sold in the U.K., enabling products to be sold in a single pack and under a single authorization throughout the U.K. In addition, the new arrangements require all medicines placed on the U.K. market to be labelled "U.K. only," indicating they are not for sale in the EU. However, although a separate authorization is now required to market medicinal products in the U.K., under an international recognition procedure which was put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of a marketing authorization from the EMA (and certain other regulators) when considering an application for a U.K. marketing authorization. There is now no pre-marketing authorization orphan designation in the U.K. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same, but have been tailored for the U.K. market, i.e., the prevalence of the condition in U.K. (rather than the EU) must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in the U.K.

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 Cybersecurity Laws

We may also be subject to data privacy and cybersecurity laws in the U.S. and various jurisdictions around the world in which we operate or process personally identifiable information ("personal information" or "personal data"). In addition to HIPAA U.S. federal enforcement agencies, such as the Federal Trade Commission (the "FTC") require businesses to take appropriate steps to keep consumers' personal information secure. In addition, numerous U.S. states have enacted laws that govern the privacy and security of health information and other personal information, some of which may be more stringent than HIPAA and which differ from each other in significant ways thus complicating compliance efforts. For example, the California Consumer Privacy Act (the "CCPA") establishes certain requirements for data use, sharing and transparency, and provides California residents the ability to limit the sharing of their personal information. Similarly comprehensive laws have passed in a number of states. Certain states have passed or proposed more targeted privacy laws that focus on the privacy of health and medical information, such as Washington's My Health My Data Act, which has a private right of action that may increase potential damages for noncompliance. Connecticut and Nevada have also passed similar laws regulating consumer health data. Such laws are continuously evolving and are likely to 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. 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.

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 U.K. is subject to the EU General Data Protection Regulation ("EU GDPR") (with regards to the EEA) and the U.K. General Data Protection Regulation ("U.K. GDPR") (with regards to the U.K.), as well as applicable data protection laws in effect in the Member States of the EEA and in the U.K. (including the U.K. Data Protection Act 2018). In this Annual Report, "GDPR" refers to both the EU GDPR and the U.K. 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 special categories of personal data (such as health data), implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, conducting data protection impact assessments for high risk processing 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 U.K. 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 is 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, as they are enacted, would require significant additional 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.

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 or more rare disease designation and for which the only approved indications are for rare diseases or conditions. The effects of the IRA on our business and the healthcare industry in general are not yet known.

- In addition, the One Big Beautiful Bill Act of 2025 imposed significant reductions in Medicaid funding, additional work requirements for certain Medicaid beneficiaries and more frequent eligibility redeterminations. These changes are expected to place increased pressure on state Medicaid budgets and could reduce enrollment, utilization and reimbursement levels for prescription drugs, including our products, which could adversely affect our business.

The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products.

On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation ("MFN") price targets to manufacturers and propose a rulemaking plan to impose MFN pricing if "significant progress" is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. The executive order further states that the Administration will take additional action (for example, examining whether marketing approvals should be modified or rescinded or considering individual drug importation waiver authorities) should manufacturers fail to offer American consumers the MFN lowest price. In July 2025, President Trump sent letters to certain pharmaceutical companies demanding that these companies extend MFN pricing to Medicaid and newly launched drugs as well as move to direct-to-consumer models priced at MFN pricing, and soliciting binding commitments by September 29, 2025. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions fOr U.S. Medicaid ("GENEROUS") Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

Further legislative and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

Individual States in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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

Employees and Human Capital Resources

As of December 31, 2025, we had 14 full-time and part-time employees, of which 4 were located in the U.K., and 10 located in the United States. As of December 31, 2025, 57% of our workforce and 43% of our leadership (at Director level and above) were female. In addition, 14% of our workforce were racially or ethnically diverse. Of our full and part-time employees, 2 have Ph.D. or M.D. degrees, and 6 are engaged in research and clinical development activities.

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. We focus on hiring and retaining qualified candidates by promoting a supportive and inclusive working environment for all. We believe that fostering a workforce with a wide range of experiences and backgrounds 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 remains of paramount importance to us. We have a Health and Safety Committee that focuses on implementing policies and training programs to enhance workplace safety.

Carbon emissions

We have calculated the emissions for the year ended December 31, 2025 and 2024 in tons of carbon dioxide equivalent (“tCO2e”). The carbon emissions for our company for the years ended December 31, 2025 and 2024 are as follows:

	December 31, 2025		December 31, 2024	
Scope	**tCO2e**	**% Total emissions**	**tCO2e**	**% Total emissions**
Scope 1	5.41	1%	6.23	2%
Scope 2	442.94	99%	391.91	98%
Total	**448.35**	**100%**	**398.14**	**100%**

For clarity, Scope 1 emissions are direct emissions produced from activities owned or controlled by Barinthus Bio. Scope 2 emissions are indirect emissions related to the generation of the electricity consumed and purchased by Barinthus Bio. 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 "U.K. Government GHG Conversion Factors for Company Reporting (2025)” guidance were applied to estimate emissions. Electricity usage at our leased facilities in the United States and U.K. 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 an increase in utilities

from activity in the U.S. laboratory and office, offset by a reduction in activity in the U.K. laboratory and office following the reduction in workforce with the wind down of the facility during the year.

We have elected not to include the voluntary disclosure for Scope 3 emissions.

For the year ended December 31, 2025, the split of emissions by geography is as follows:

Scope	Location	tCO2e	% Total emissions	
Scope 1	U.K.	0.78	0.2%	[1]
	U.S.	4.63	1.0%	
Scope 2	U.K.	60.27	13.4%	
	U.S.	382.67	85.4%	
Total		**448.35**	**100%**	

[1] Indicates amount less than one percent.

We consider 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, 2025, and 2024 are as follows:

	December 31, 2025		December 31, 2024	
Ratio	tCO2e /employee	Average employees	tCO2e /employee	Average employees
Intensity ratio	9.09	49	3.24	123

The tons of carbon dioxide per employee has increased year on year, primarily as a result of our increased activity in the United States, notwithstanding the reduction in the number of employees that occurred during the year across both sites.

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 titled "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 the Contemplated Transactions with Clywedog

Our failure to complete the Contemplated Transactions would have a material adverse effect on our business, results of operations, financial condition and stock price.

Completion of the Contemplated Transactions is subject to the satisfaction of various conditions, including (i) the effectiveness of a registration statement to register shares of common stock, $0.0001 par value per share, of Topco (the "Topco Common Stock"), to be issued in connection with the Combinations; (ii) the absence of any law or order that enjoins, prevents, prohibits, or makes illegal the consummation of the Contemplated Transactions; (iii) approvals by our shareholders of the Scheme Transaction and certain related matters, and sanction by the Court of the Scheme Transaction; (iv) approval by Clywedog's stockholders of the Merger Agreement, the Merger and Contemplated Transactions; (v) the approval for listing by Nasdaq of the shares of Topco Common Stock issuable in the Combinations; (vi) certain consents, clearances and expirations or terminations of waiting periods under applicable antitrust laws; (vii) the absence of a material adverse effect with respect to either party; (viii) the completion of the Self-Tender Offer to the extent that Topco elects to commence the Self-Tender Offer; (ix) minimum cash requirements for each party; and (xi) subject to certain materiality and material adverse effect qualifiers, the accuracy of the representatives and warranties of the parties contained in the Merger Agreement and the compliance by each party with the covenants contained in the Merger Agreement. As of the date of this report, the transaction is expected to close in the second quarter of 2026, subject to the satisfaction or waiver of these conditions. There is no assurance that all of the various conditions will be satisfied or waived, or that the Contemplated Transactions will be completed on the proposed terms, within the expected timeframe, or at all.

The Contemplated Transactions may be delayed, and may ultimately not be completed, due to a number of factors, including the following:

- We may fail to obtain the approval of the Scheme Transaction by our shareholders. Despite our board of directors having carefully and thoroughly considered a variety of strategic options and having determined that such strategic options either were unavailable to the Company, or would not provide value to shareholders greater than the value that would be provided in the Contemplated Transactions, we may be unable to secure the requisite approval of our shareholders.

- We may fail to obtain regulatory approvals from various governmental entities (or conditions, limitations or restrictions may be imposed on such approvals). We cannot provide any assurance that we will not face regulatory hurdles, blocks or delays with respect to the Contemplated Transactions. Material delays in obtaining any required approvals may result in the termination of the Contemplated Transactions, as either party may terminate the Contemplated Transactions if the Contemplated Transactions is not consummated by September 30, 2026, subject to certain extensions as further described in the Merger Agreement.

- Potential shareholder litigation and other legal and regulatory proceedings may delay or prevent the Contemplated Transactions.

- The parties may fail to satisfy one or more of the conditions to the completion of the Contemplated Transactions.

Additional risks if the Contemplated Transactions are not completed include:

- to the extent the current market price of our ADSs reflects an assumption that the Contemplated Transactions will be completed, the price of our ADSs could decrease; and

- investor confidence could decline, stockholder litigation could be brought against us, relationships with existing and prospective customers, distributors, retailers, service providers, investors, lenders and other business partners may be adversely impacted, we may be unable to retain key personnel, and profitability may be adversely impacted due to costs incurred in connection with the Contemplated Transactions.

The failure to successfully integrate our business with that of Clywedog in the expected timeframe would adversely affect our future business and financial performance and the value of our stockholders' investment following the Combinations.

The combination of two independent companies is a complex, costly and time-consuming process. As a result, Topco will be required to devote significant management attention and resources to integrate our business practices and operations with those of Clywedog. The integration process may disrupt the business of either or both of the companies and, if implemented ineffectively, could preclude realization of the full benefits expected by us and our shareholders from the Contemplated Transactions. The failure of Topco to meet the challenges involved in successfully integrating our operations with those of Clywedog or otherwise to realize the anticipated benefits of the Contemplated Transactions could cause an interruption of the activities of Topco and could seriously harm its results of operations. In addition, the overall integration of the two companies may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships and diversion of management's attention, and may cause Topco's stock price to decline. The difficulties of combining our operations with those of Clywedog include, among others:

- managing a significantly larger company;
- coordinating geographically separate organizations, including extensive international operations;
- the potential diversion of management's focus and resources from other strategic opportunities and from operational matters;
- performance shortfalls at one or both of the companies as a result of the diversion of management's attention caused by completing the Combinations and integrating the companies' operations;
- aligning and executing the strategy of the combined companies;
- retaining existing business relationships and executing new strategic or commercial relationships;
- maintaining employee morale and retaining key management and other employees;
- the disruption of, or the loss of momentum in, each company's ongoing business or inconsistencies in standards, controls, systems, procedures and policies;
- integrating two unique business cultures, which may prove to be incompatible;
- the possibility of faulty assumptions underlying expectations regarding the integration process;
- consolidating corporate and administrative infrastructures and eliminating duplicative operations;
- integrating IT, communications and other systems;
- changes in applicable laws and regulations;
- managing tax costs or inefficiencies associated with integrating the operations of each company;
- unforeseen expenses or delays associated with the Contemplated Transactions; and
- taking actions that may be required in connection with obtaining regulatory approvals.

Many of these factors will be outside of our control and any one of them could result in increased costs and diversion of management's time and energy, which could materially impact our business, financial condition and results of operations

as Topco. In addition, even if our operations are integrated successfully with those of Clywedog, Topco may not realize the full benefits of the Contemplated Transactions, including the synergies, cost savings or growth opportunities that we and our shareholders expect. These benefits may not be achieved within the anticipated timeframe, or at all. As a result, we cannot assure our shareholders that the Contemplated Transactions will be completed successfully, that the integration will be accomplished within the expected timeframe, or that Topco will realize the full benefits anticipated from the Contemplated Transactions, any of which could adversely affect the value of our shareholders' investment.

Our shareholders and Clywedog's stockholders may not realize a benefit from the Contemplated Transactions commensurate with the ownership dilution they will experience in connection with the Contemplated Transactions.

If Topco is unable to realize the full strategic and financial benefits currently anticipated from the Contemplated Transactions, our shareholders and Clywedog's stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent Topco is able to realize only part of the strategic and financial benefits currently anticipated from the Contemplated Transactions.

Our shareholders and Clywedog's stockholders will generally have a reduced ownership and voting interest in, and will exercise less influence over the management of, Topco following the completion of the Contemplated Transactions as compared to their current ownership and voting interests in the respective companies.

After the completion of the Contemplated Transactions, our current shareholders and the current stockholders of Clywedog will generally own a smaller percentage of Topco than their ownership of their respective companies prior to the Contemplated Transactions. Immediately after the Contemplated Transactions, our shareholders as of immediately prior to the Scheme Transaction are expected to own approximately 34% of the outstanding shares of Topco and former Clywedog stockholders are expected to own approximately 66% of the outstanding shares of Topco.

During the period prior to the closing of the Contemplated Transactions, our business is exposed to certain inherent risks due to the effect of the announcement or pendency of the Contemplated Transactions on our business relationships, financial condition, operating results and business.

Inherent risks to our business during the period prior to the closing of the Contemplated Transactions that may adversely affect our business relationships, financial condition, operating results and business include:

- the possibility of disruption to our business and operations, including diversion of management attention and resources;
- the inability to attract and retain key personnel, and the possibility that our current employees could be distracted, and their productivity decline as a result, due to uncertainty regarding the Contemplated Transactions;
- the inability to pursue alternative business opportunities or make changes to our business pending the completion of the Contemplated Transactions, and other restrictions on our ability to conduct our business included in the Merger Agreement;
- our inability to solicit other acquisition proposals during the pendency of the Contemplated Transactions;
- the amount of the costs, fees, expenses and charges related to the Contemplated Transactions and the Contemplated Transactions; and
- other developments beyond our control, including, but not limited to, changes in domestic or global economic conditions that may affect the timing or success of the Contemplated Transactions.

Litigation may arise in connection with the Contemplated Transactions, which could be costly, prevent consummation of the Contemplated Transactions, divert management's attention and otherwise materially harm our business.

Regardless of the outcome of any future litigation related to the Contemplated Transactions, such litigation may be time-consuming and expensive and may distract our management from running the day-to-day operations of our business. The litigation costs and diversion of management's attention and resources to address the claims and counterclaims in any litigation related to the Contemplated Transactions may materially adversely affect our business, financial condition and

operating results, including by decreasing our cash reserves for related expenses. If the Contemplated Transactions are not consummated, for any reason, litigation could be filed in connection with the failure to consummate the Contemplated Transactions. Any litigation related to the Contemplated Transactions may result in negative publicity or an unfavorable impression of our company, which could adversely affect the price of our common stock, impair our ability to recruit or retain employees, damage our relationships with our clients, or otherwise materially harm our operations and financial performance.

We are subject to restrictions on our business activities under the Merger Agreement.

While the Merger Agreement is in effect, we are generally required to conduct our business in the ordinary course consistent with past practice, and are restricted from taking certain actions without Clywedog's prior consent, which is not to be unreasonably withheld, conditioned or delayed. These limitations include, among other things, certain restrictions on our ability to amend our organizational documents, acquire other businesses and assets, dispose of our assets, make investments, repurchase, reclassify or issue securities, make loans, pay dividends, incur indebtedness, make capital expenditures, enter into, amend or terminate certain contracts, change accounting policies or procedures, initiate or settle certain litigation, change tax classifications and elections, or take certain actions relating to intellectual property.

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 product 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. Currently, we have no products approved for commercial sale and are not generating 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 (royalties/milestone payments) arising from AstraZeneca sales of Vaxzevria and our agreement with OUI, as amended (the "OUI License Agreement"). In December 2025, we delivered written notice to OUI to terminate the OUI License Agreement. The OUI License Agreement will remain in effect during the three-month notice period and terminated on March 2, 2026 in accordance with its terms. For the years ending December 31, 2025 and 2024, we incurred net losses of $66.5 million and $61.2 million, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $304.1 million and $237.7 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:

- 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 personnel;
- conduct preclinical studies and clinical trials for our current and future product candidates based on our proprietary synthetic platform, SNAP-TI 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 through a selected partner;
- acquire or in-license other product candidates and technologies for development and commercialization; 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 unless and until such losses are eliminated by revenue.

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 current 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 in our clinical trials;
- our ability to complete INDs, 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 immune modulators, monoclonal antibodies, CRISPR editing, or other small molecules, RNA, DNA, nanoparticle, peptide, protein, other 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 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 possibility that immune tolerance with our SNAP-TI platform may not translate into clinical benefit; and
- the increased costs and complexities associated with manufacturing.

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 existing 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;
- risks and uncertainties arising from disagreements or other relationship-related matters with the other party to such a transaction; and
- a failure 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, 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 synthetic platform, SNAP-TI, 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, 2025, our cash, cash equivalents and restricted cash were $71.9 million. Based on our current business plan, our management believes that we have sufficient cash and other financial resources to support our operations for at least the next 12 months, 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 existing 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 existing 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 current 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 existing 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 third parties to develop and market our 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 platforms and our product candidates developed using our platforms. Preclinical studies, clinical trials and additional research and development activities will require substantial funds to complete. We expect the research and development expenses for our programs to increase in parallel with the 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 launch, 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, cash equivalents and restricted cash of $71.9 million as of December 31, 2025. Our future capital requirements will 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;
- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements;
- the costs of future commercialization activities, including product launch, product sales, marketing, manufacturing and distribution, for any of our current and future product candidates for which we receive marketing approval;
- the timing, receipt and amount of commercial sales revenues, milestones or royalties or other income from, our future products, should any of our product candidates receive marketing approval;
- 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; and
- the emergence and success or otherwise of competing autoimmune disease therapies and other market developments.

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, maintain optimal 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 national and international 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.

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 the global 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 or the life sciences 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 or life sciences 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 or life sciences 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.

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 candidate VTP-1000, 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 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, the demonstration of effectiveness to pricing and reimbursement authorities, the obtaining of sufficient manufacturing supply of product for both clinical development and commercial sales, the building of a commercial organization, and substantial investment in significant marketing efforts for product launch. 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;
- successful launch of our product candidates, if and when approved to generate product sales;

- 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.

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 the disease areas that we focus on;
- 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, 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. 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, this 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 becomes 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 are 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 is 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.

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 autoimmunity, 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 promote immune tolerance for suppressing unwanted inflammation. 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. 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 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.

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, 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. Results of our clinical 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 and if an approval is granted for an indication, the regulatory authority may require us to include a warning in the patient information leaflet. 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 for a clinical trial, or the ability of enrolled participants to complete their participation in a clinical trial or result in potential product liability claims, particularly if they have not been described in the patient information leaflet. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff.

Risks Related to Our Approach

The market opportunities for certain of our 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.

Immunotherapies for treating patients with autoimmune and other inflammatory diseases are sometimes staged based on disease severity or may be 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. Our product candidate VTP-1000 based on SNAP-TI is at an early stage of development and there is currently uncertainty as to how the may fit into existing treatment paradigms. We expect to seek approval of VTP-1000 as a first line therapy, but FDA or other regulatory authorities may disagree with this plan, and we may need to seek approval for use as a second or later line of therapy.

Our projections of both the number of people who have the disease that we are targeting, as well as the subset of people with these conditions 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 conditions. 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 field of immunotherapeutics 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 nanoparticle-based antigen-delivery platforms. Adverse events in clinical trials of VTP-1000, 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 immunotherapeutics 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 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.

VTP-1000 utilizes SNAP-TI to induce immune tolerance. Adverse developments in clinical trials of other immunotherapy products that promote antigen-specific immune tolerance, may result in a disproportionately negative effect for our platform, as compared to other products within the I&I field that do not rely on antigen-specific immune tolerance. 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 all medicinal 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, which is a risk that applies to all medicinal product development.

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 because of the risks inherent in conducting clinical trials. 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 milestone payments and 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 based on SNAP-TI will compete against alternative or more conventional approaches, including anti-inflammatory compounds, monoclonal antibodies against cytokines or other pathways, immune cell depletion regimens (*e.g.*, antibodies, CAR-T cells and T cell engagers) immunomodulatory small molecules, transgenic T cells, genetic therapies and other antigen-specific immune tolerance therapies based on proteins, DNA, RNA and peptides 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 and drugs 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. For example, 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.

As is the case with all investigational biologics and drugs, including novel immunotherapeutics such as those based on our SNAP-TI platform, 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 and others in the medical community.

The use of novel immunotherapeutics, such as our SNAP-TI product candidate to target the treatment and prevention of autoimmune diseases is a recent development and may not become broadly accepted by physicians, patients, hospitals 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 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 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 nanoparticle-based therapeutics and public perception of other nanoparticle-based therapeutics;
- the prevalence and severity of any side effects for other antigen-specific immune tolerance therapies or those utilizing rapamycin and public perception of other antigen-specific immune tolerance therapies and those utilizing rapamycin;
- 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 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 based approaches, serious adverse events or deaths in other clinical trials involving immunotherapeutic 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 do not know 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.

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 MAAs. 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 manufacture 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 synthetic 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.

Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances we, our collaborators or other third parties on which we rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or if the previously proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted.

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 BLA or NDA 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;
- Inadequate funding for the FDA, the SEC and other government agencies, including from prolonged 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 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 trial 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. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

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. For example, 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. In addition, U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes.

Even if we were to obtain a 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 indication. Even after an orphan drug is approved, the FDA can subsequently approve a second drug candidate for the same indication 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 manufacture of 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, 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, including the potential for sponsors under FDA draft guidance issued in 2024 to demonstrate interchangeability without conducting so-called "switching" studies and the potential for sponsors under FDA draft guidance issued in 2025 to demonstrate biosimilarity without conducting comparative efficacy studies. Although the FDA has yet to finalize these draft guidance documents, these or similar efforts may increase the risk of competition for our biologic product candidates, if approved.

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, European Commission or MHRA approval for our current or future product candidates that we may identify and pursue in the United States, the European Union or the U.K.***, we may never obtain approval to commercialize any such product candidates outside of those jurisdictions.***

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, European Commission or MHRA approval, in addition to country-specific risks and challenges. 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.

Our U.K. incorporated and tax resident entities are subject to U.K. corporation tax. 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, 2025, we had cumulative carryforward tax losses of approximately $160.4 million (December 31, 2024: $101.7 million). Subject to any relevant criteria and restrictions (including those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half of our ordinary shares and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits, 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. From 2025, we benefit from the applicable United Kingdom research and development tax credit regime which is the merged scheme Research & Development expenditure credit ("RDEC") and enhanced R&D intensive support ("ERIS") that replaces the old RDEC and small and medium-sized enterprise ("SME") schemes for accounting periods beginning on or after April 1, 2024. For expenditure under the merged scheme, the rate of Research and Development expenditure credit is 20%, which is the same as the rate under the old RDEC scheme for expenditure incurred on or after April 1, 2023. For loss-makers and small profit-makers, a lower rate of notional tax restriction (currently 19%) applies at payment. The amount of the Pay As You Earn ("PAYE") cap for claims under both the merged scheme and ERIS is £20,000 plus 300% of the company's relevant PAYE and National Insurance contributions liabilities. The PAYE cap (where applicable) will limit the amount of payable credit that can be received in the accounting period under consideration. Any excess over the cap will be carried forward and treated as an amount of Research and Development expenditure credit to which the company will be entitled for the next accounting period. Based on prior claims and the split of qualifying spend it is expected that the PAYE cap is unlikely to affect the net benefit. Furthermore, legislation included in Finance Act 2024 restricts the extent to which payments to contractors for R&D, and externally provided workers can qualify for R&D relief where R&D activity takes place outside the U.K., which may restrict the ability to include cost incurred on externally provided workers based in the U.S.

A large portion 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 based on the eligibility criteria. Unsurrendered U.K. 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 U.K. taxable profits. There was no tax loss restriction applied to the R&D tax credits in the U.K. for the years ending December 31, 2025 and 2024.

Under both the current RDEC scheme and the historic SME scheme (which we relevant to us in prior tax years), a company qualifies as an R&D intensive business if R&D expenditure constitutes at least 30% of total expenditure.
From the analysis performed, we have not and do not currently expect to claim under the loss-making R&D intensive scheme criteria primarily due to the proportion of total relevant expenditure occurring outside the U.K.

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 U.K. tax authority, His Majesty's Revenue and Customs ("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 U.K. 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 a letter citing such failure to comply and public posting of such letter and redacted company response, which could damage the company's reputation. 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 titled “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.

Without appropriation of funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. 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 other events that may otherwise affect the FDA's ability to perform routine function. 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.

Disruptions and personnel turnover, including as a result of leadership changes, staff reductions or otherwise, at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing also could result in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

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. In addition, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, 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.

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 cybersecurity 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 data protection, privacy, and cybersecurity 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 U.K., and/or (ii) carried out in the context of the activities of our establishments in the EEA or U.K., is subject to the GDPR, as well as other national data protection legislation in force in relevant EEA member states and the U.K., (including the U.K. Data Protection Act 2018).

The GDPR is wide-ranging in scope and impose numerous obligations on companies that process personal data, including special requirements in respect of the processing of special categories of personal data (such as health 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 requires different informed consent practices and more detailed notices for clinical trial participants and investigators than apply to clinical trials conducted in the United States. We are required to apply GDPR standards to any clinical trials that recruit participants in the EEA and U.K. as well as any clinical trials that our EEA and U.K. established businesses carry out anywhere in the world.

The GDPR imposes strict rules on the transfer of personal data to countries outside the EEA and U.K., 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 U.K. 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 U.K. is regarded as a third country under the EU GDPR, the European Commission issued a decision recognizing the U.K. as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the U.K. remain unrestricted. Personal data transfers from the U.K. to the EEA remain free flowing by virtue of a U.K. 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 U.K., 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 is 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 U.K.'s data protection regime is independent from but aligned to the EU's data protection regime. However following the U.K.'s departure from the European Union ("Brexit"), there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these territories. For example, the U.K. Data (Use and Access) Act 2025 ("U.K. Act"), now in force, further alters the similarities between the U.K. and EEA data protection regimes. In December 2025, the European Commission adopted a decision determining that the UK continues to provide a level of data protection that is "essentially equivalent" to the EU standards and extended the validity of the UK adequacy decision for six years, through December 2031. While this renewal reduces immediate adequacy concerns, uncertainty remains regarding how UK data protection laws will evolve in the medium to longer term. This lack of clarity on future U.K. 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 U.K. and EEA. In addition, EEA Member States have adopted national laws to implement the GDPR that may partially deviate from the GDPR. Further, the competent authorities in the EEA Member States interpret GDPR obligations slightly differently from country to country (particularly in relation to the processing of health data) and therefore we do not expect to operate in a uniform legal landscape in the EEA.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified

cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

In the U.S., 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 FTC Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. For example, 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 applies to certain sensitive personal information and created a new state agency vested with authority to implement and enforce the CCPA. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may lead to increased litigation. U.S. states are constantly amending existing laws, requiring attention to frequently changing regulatory requirements, which 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 with them. We are conducting a clinical trial in California, where the CCPA includes only a partial exemption for certain clinical trial data, and we may be subject to privacy compliance obligations on our business that raise new risks for potential fines and class actions.

Numerous other U.S. state privacy laws have been enacted that 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. State laws feature several key differences in scope, application, and enforcement, that collectively 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.

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, cybersecurity, data security and data breaches. Many of these laws require businesses to notify cybersecurity incidents and data breaches to applicable regulators and/or data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of artificial intelligence ("AI") and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict.

We may use and integrate AI into our business processes both in our own development and implementation of AI and through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In Europe, the European Union began implementing the Artificial Intelligence Act (the "AI Act") on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high-risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on judicial interpretations and forthcoming legislative amendments, and non-compliance can lead to significant fines.

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 U.K., 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 U.K.) 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. Under the GDPR, 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, legislatures and consumer protection agencies.

The risk of our being found in violation of these laws is increased by their fact that the interpretation and enforcement 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.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U.S. policy occurred and since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. For example, in September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of active pharmaceutical ingredients and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. Any direct tariffs, if imposed on pharmaceutical products, may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical contract manufacturing organizations, and a delay in our development timelines. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

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. 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. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party (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 fields of infectious disease, I&I 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 programs 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. 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.

For biologics, separate non-patent exclusivity under the BPCIA may apply. The FDA cannot make approval of a biosimilar effective until 12 years after the reference product's first licensure, but policy changes could affect the scope or duration of this exclusivity, and competitors may nonetheless pursue full BLAs. As a result, even with patents and any extensions, competition from biosimilars or other biologics could occur earlier than anticipated.

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 was fully ratified and came into being 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. 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. 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

The pipeline prioritization and restructuring may be unsuccessful, lead to additional costs, disrupt our operations, create unintended problems in our workforce, or increase litigation risk, in which case our business could be harmed.

On June 12, 2024, we announced plans to prioritize our pipeline to focus on the development of VTP-300 in CHB and VTP-1000 in celiac disease, including a workforce reduction of approximately 25%. On January 10, 2025, we announced a restructuring plan that aims to prioritize our immune tolerance research and development programs, including a reduction in workforce. As of December 31, 2025, we had 14 full-time and part-time employees.

Despite our efforts, the pipeline prioritization and restructuring may be unsuccessful, lead to additional costs, disrupt our operations, create unintended problems in our workforce, and increase litigation risk, which could harm our business and results of operations. We may incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the pipeline prioritization and restructuring. We may not realize, in full or in part, the anticipated benefits and savings from the pipeline prioritization and restructuring due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the pipeline prioritization and restructuring, our operating results and financial condition would be adversely affected. Moreover, our decision to focus on the development of VTP-1000 in celiac disease may cause us to fail to capitalize on viable commercial products or profitable market opportunities or limit the opportunities we are able to pursue.

In addition, we may need to undertake additional workforce reductions or restructuring activities in the future. Furthermore, the pipeline prioritization and restructuring could yield unanticipated consequences, such as increased difficulties in our day-to-day operations, the loss of institutional knowledge and expertise, attrition beyond planned workforce reductions, reduced employee morale, and difficulty attracting and retaining qualified management, scientific, and other personnel critical to our business. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. If employees who were not affected by the workforce reduction pursue alternative employment, we may need to seek contractor support, which could harm our productivity and add unplanned expense. The implementation of the workforce restructuring could also lead to litigation brought by or on behalf of our former employees.

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 may experience changes in key leadership or key positions in the future. The departure of key leadership personnel can result in loss of significant knowledge and experience from the company. This loss of knowledge and experience can be mitigated through successful hiring and transition, but there can be no assurance that we will be successful in such efforts. Attracting and retaining qualified senior leadership may be more challenging under adverse business conditions. Failure to attract and retain the right talent, or to smoothly manage the transition of responsibilities resulting from such turnover, would affect our ability to meet our challenges and may cause us to miss performance objectives or financial targets.

We conduct our operations at our facilities in Germantown, Maryland. This region is the 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.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.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 notice periods specified in their employment agreements. 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, 2025, we had 14 full-time and part-time employees. As our development and commercialization plans and strategies develop, 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, including cybersecurity incidents and data breaches. 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 insider employees or vendors, hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, including ransomware, denial-of-service, social engineering fraud, including phishing attacks, data breaches, or other means to threaten data security, confidentiality, integrity and availability, and may be enhanced or facilitated by Artificial Intelligence (AI). Further, attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems from malicious third-parties or insider threats may incorporate widely varying and frequently changing tactics, which may be enhanced or facilitated by AI. 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 or data 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.

Like other companies in our industry, we, and our third party vendors, have experienced and will continue to experience threats and cybersecurity incidents relating to our information technology systems and infrastructure. 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 notifications and disclosures, 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 cybersecurity or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

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. In the past, global financial crises have 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 (including tariffs that have been or may in the future be imposed by the United States or other countries), trade protection measures, trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), 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 U.K. 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 geopolitical 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 geopolitical 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 U.K. 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 U.K. In addition, uncertainty exists as to whether the courts of England and Wales would entertain original actions brought in the U.K. 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 U.K. 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, pounds sterling, AUS dollars and the euro. Further potential future revenue may be derived 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 4 in the notes to our annual financial statements appearing elsewhere in this Annual Report for a description of foreign exchange risks.

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 6, 2026, our executive officers, directors, and 5% shareholders beneficially owned approximately 46% 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;
- 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.

If we fail to regain compliance with the continued listing requirements of Nasdaq, our ADSs may be delisted and the price of our ADSs and our ability to access the capital markets could be negatively impacted.

On December 30, 2025, we received a deficiency letter from Nasdaq indicating that, for the last 30 consecutive business days, the bid price for our ADSs had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market, referred to as the minimum bid price rule. In accordance with Nasdaq Listing Rules, we have an

initial period of 180 calendar days, or until June 29, 2026, to regain compliance with the minimum bid price rule. If we do not regain compliance with the minimum bid price rule by June 29, 2026, we may be eligible for an additional 180 calendar day compliance period. We intend to monitor the closing bid price of our ADSs and may, if appropriate, consider available options to regain compliance with the minimum bid price rule.

There are many factors that may adversely affect our ADS' minimum bid price, including those described throughout this section titled "Item 1A. Risk Factors." Many of these factors are outside of our control. As a result, we may not be able to sustain compliance with the minimum bid price rule in the long term. Any potential delisting of our ADSs from the Nasdaq would likely result in decreased liquidity and increased volatility for our ADSs and would adversely affect our ability to raise additional capital or to enter into strategic transactions. Any potential delisting of our ADSs from the Nasdaq would also make it more difficult for holders of our ADSs to sell our ADSs in the public market.

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 $1.235 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 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., we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on foreign reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations 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. In addition, after we no longer qualify as an emerging growth company, we expect to incur additional legal, accounting and other expenses.

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 those 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 and Wales, we will only be able to make a distribution if the amount of our net assets is not less than the aggregate of our called-up share capital and undistributable reserves and if, and to the extent that, the distribution does not reduce the amount of those assets to less than that aggregate.

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 U.K. 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 U.K. (or the Channel Islands or the Isle of Man).

We believe that our place of central management and control is not in the U.K. (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 U.K.), the Takeover Code may apply to us in the future.

The Takeover Panel has confirmed that, from February 3, 2027, the location of the Company's place of central management and control will no longer be relevant in determining whether the Takeover Code applies to the Company. From February 3, 2027, the Takeover Code will only apply to the Company in the event that our securities are quoted on a UK regulated market (or U.K. multilateral trading facility or certain exchanges in the Channel Islands or the Isle of Man).

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 U.K. 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 U.K., 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 U.K. 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. For example, the One Big Beautiful Bill Act (the "OBBBA") was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our ordinary shares or ADSs. We are evaluating the elections available under the OBBBA. Based on our current assessment, we do not expect the changes to Section 174 under the OBBBA to have a material impact on our financial position or results of operations. For example, under Section 174 of the Internal Revenue Code of 1986, as amended (the "Code"), in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. 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.

We believe we were a passive foreign investment company ("PFIC"), for prior taxable years and we may be a PFIC in the current or future taxable years, which could result in adverse U.S. federal income tax consequences to U.S. Holders.

Under the Code, we will be a 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 the 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, 2025 and expect to remain a PFIC for our current taxable year (or the portion of our current taxable year ending on or prior to the consummation of the Scheme Transaction, as applicable). 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 are 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 (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" 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 applicable law for taxable years ending before January 1, 2026, 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. Each Ten Percent Shareholder of a CFC is also required to include in income such Ten Percent Shareholder's share of "global intangible low-taxed income" (for tax years beginning after December 31, 2017 and prior to January 1, 2026) and "net CFC tested income" (for tax years beginning after December 31, 2025) with respect to such CFC. 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 (1) the value of all classes of stock of such corporation or (2) the 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 2025, and (prior to the consummation of the Scheme Transaction) we do not expect to be a CFC in 2026. 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 for the treatment of immunetolerance.

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 U.K.'s withdrawal from the European Union could increase the regulatory burden of product development and authorization in the U.K. and European Union.

The U.K. formally left the European Union on 31 January 2020 (commonly referred to as Brexit). The European Union and the U.K. have concluded a trade and cooperation agreement ("TCA") which has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of the U.K. and European Union pharmaceutical regulations. As a result, a separate application must be made to conduct a clinical trial in the U.K. as well as the European Union and a separate U.K. marketing authorization is required to commercialize a medicinal product in the U.K. as well as the European Union. Obtaining such regulatory approvals is a lengthy and expensive process and this therefore adds time and expense to the conduct of our business in both the U.K. and European Union. In addition, the U.K. is seeking to reform aspects of the medicines legislation following its departure from the European Union. For example, on December 12, 2024, the U.K. government introduced a legislative proposal that, if implemented, will replace the current regulatory framework for clinical trials in the U.K. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials and the development of medicinal products in the U.K. and/or European Union, our development plans may be impacted. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects will 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 that has been

integrated into our overall risk management process; it 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 an incident response plan to guide us in responding to cybersecurity incidents, and have conducted tabletop exercises to test the plan. We also take steps to protect against business interruption and conduct annual restoration testing for major systems. In addition, we use a risk-based approach to assessing cybersecurity risks from certain critical 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 Manager of Operations and IT Systems, who reports directly to senior management on matters regarding cybersecurity, as appropriate, and is supported by third-party vendors. Together, our senior management and Manager of Operations and IT Systems 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 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.

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

We lease and occupy approximately 19,700 square feet of state-of-the-art wet laboratory and office space in Germantown, Maryland, United States. We also lease approximately 31,000 square feet of office and laboratory space on the Harwell Science and Innovation Campus, Harwell, Oxfordshire, U.K. We are currently marketing the Harwell facility for sublease for the remainder of the lease term.

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 6, 2026, there was one holder of record of our ordinary shares, nominal value £0.000025 per share, and 39 holders of record of our ADSs. The closing sale price per ADS on the Nasdaq Global Market on March 6, 2026 was $0.60.

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 U.K. Tax Considerations

The following discussion is limited to a general guide to current U.K. tax law and HM Revenue & Customs, or HMRC, published guidance (which is not binding) applying as at the date of this Annual Report (both of which are subject to change at any time, possibly with retrospective effect) relating to the ownership and disposition of ordinary shares, or such shares represented by ADSs. Each shareholder should however seek individual tax advice as specific rules may apply in certain circumstances. The U.K. tax consequences discussed below do not constitute legal or tax advice and do not reflect a complete analysis or listing of all the possible U.K. tax consequences that may be relevant to holders of our ordinary shares or ADSs. It is written on the basis that we do not (and will not) directly or indirectly derive 75% or more of its qualifying asset value from U.K. land, and that we are and will remain solely resident in the U.K. for tax purposes and will therefore be subject to the U.K. tax regime and not the U.S. tax regime.

Except to the extent that the position of non-U.K. resident persons is expressly referred to, this guide relates only to persons who are resident for tax purposes solely in the U.K. and do not have a permanent establishment, branch or agency (or equivalent) in any other jurisdiction with which the holding of our ordinary shares or ADSs is connected, who are absolute beneficial owners of our ordinary shares or ADSs (and do not hold our ordinary shares or ADSs through an Individual Savings Account or a Self-Invested Personal Pension or any other wrapper or similar product) (a "U.K. Holder").

This guide may not relate to certain classes of U.K. Holders, such as (but not limited to):

- persons who are connected with us;
- financial institutions;
- insurance companies;
- charities or tax-exempt organizations;
- collective investment schemes;
- pension schemes;
- market makers, intermediaries, brokers or dealers in securities or persons who hold ordinary shares or ADSs otherwise than as an investment; and

- persons who have (or are deemed to have) acquired their ordinary shares or ADSs by virtue of an office or employment or who are or have been our officers or employees or any of our affiliates.

The decision of the First-tier Tribunal (Tax Chamber) in HSBC Holdings PLC and The Bank of New York Mellon Corporation v HMRC (2012) cast some doubt on whether a holder of a depositary receipt is the beneficial owner of the underlying shares. However, based on published HMRC guidance we would expect that HMRC will regard a holder of ADSs as holding the beneficial interest in the underlying shares and therefore these paragraphs assume that a holder of ADSs is the beneficial owner of the underlying ordinary shares and any dividends paid in respect of the underlying ordinary shares (where the dividends are regarded for U.K. purposes as that person's own income) for U.K. direct tax purposes.

Chargeable Gains

A disposal or deemed disposal of ordinary shares or ADSs by a U.K. 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 U.K. capital gains tax (for individuals) and corporation tax on chargeable gains (for corporation tax payers).

If an individual U.K. Holder who is subject to U.K. income tax at either the higher or the additional rate is liable to U.K. capital gains tax on the disposal of ordinary shares or ADSs, the current applicable rate will be 24% (for the tax year 2025/2026). For an individual U.K. Holder who is subject to U.K. income tax at the basic rate and liable to U.K. capital gains tax on such disposal, the current applicable rate would be 18% (for the tax year 2025/2026), save to the extent that any capital gains when aggregated with the U.K. Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the capital gains tax rate currently applicable to the excess would be 24% (for the tax year 2025/2026).

If a corporate U.K. Holder is or becomes liable to U.K. corporation tax on the disposal (or deemed disposal) of ordinary shares or ADSs, the main rate of U.K. 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 2025/2026 tax year).

Any chargeable gain (or allowable loss) will generally be calculated by reference to the consideration received for the disposal of the ADSs less the allowable cost to the U.K. Holder of acquiring such ADSs.

If you are not resident in the U.K. for U.K. tax purposes (or, in the case of an individual, not temporarily non-resident), you should not normally be liable for U.K. 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 U.K. 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 U.K. for U.K. 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 U.K. (or upon ceasing to be regarded as resident outside the U.K. for the purposes of any relevant double taxation treaty) for U.K. capital gains tax despite the fact that the individual may not be resident in the U.K. at the time of the disposal.

Taxation of Dividends

Under U.K. law, there is no withholding tax on dividends paid on the ordinary shares or ADSs.

An individual U.K. Holder may, depending on his or her particular circumstances, be subject to U.K. tax on dividends received from us. An individual holder of ADSs who is not resident for tax purposes in the U.K. should not be chargeable to U.K. 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 U.K. through a branch or agency to which the ADSs are attributable. There are certain exceptions for trading in the U.K. through independent agents, such as some brokers and investment managers.

Dividend income is treated as the top slice of the total income chargeable to U.K. income tax for an individual U.K. Holder. An individual U.K. Holder who receives a dividend in the 2025/2026 tax year will be entitled to a dividend tax-free allowance of £500. 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% for the tax year 2025/2026 (rising to 10.75% for the tax year 2026/2027) to the

extent the excess amount falls within the basic rate band, 33.75% for the tax year 2025/2026 (rising to 35.75% for the tax year 2026/2027) to the extent the excess amount falls within the higher rate band and 39.35% (for the tax years 2025/2026 and 2026/2027) 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 U.K. should not be chargeable to U.K. corporation tax on dividends received from us unless it carries on (whether solely or in partnership) a trade in the U.K. through a permanent establishment to which the ADSs are attributable.

Corporate U.K. Holders should not be subject to U.K. corporation tax on any dividend received from 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 U.K. Holder elects for an otherwise exempt dividend to be taxable, U.K. corporation tax will be chargeable on the amount of any dividends (at the current rate of 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 2025/2026 tax years).

Stamp Duty and Stamp Duty Reserve Tax

The discussion below relates to the holders of our ordinary shares or ADSs wherever resident, however it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries.

Stamp duty and/or stamp duty reserve tax ("SDRT") are imposed in the U.K. on certain transfers of securities (including shares in companies which, like us, are incorporated in the U.K.) 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.

Issue of Ordinary Shares

Under current U.K. tax law (and except in relation to depositary receipt systems and clearance services (as to which see below), no U.K. SDRT (or, where effected by a written instrument, U.K. stamp duty) should generally be payable in respect of an issue of ordinary shares (including ordinary shares underlying our ADSs).

Transfer of 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.

Clearance Services and Depositary Receipts

An unconditional agreement to issue 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) should not attract the higher rate of 1.5% U.K. stamp duty or U.K. SDRT (which we refer to as the 1.5% Charge). Furthermore, subject to the below, no 1.5% Charge should arise in respect of a transfer of ordinary shares to a clearance service or a depositary receipt system where the transfer is carried out in the course of "capital-raising arrangements", being arrangements pursuant to which the relevant ordinary shares are issued by the company for the purpose of raising new capital. Where any ordinary shares are subject to restriction that has the effect of preventing the transfer of such ordinary shares into a clearance service or depositary receipt system in the course of capital-raising arrangements, such ordinary shares must be transferred as soon as reasonably practicable after the time at which the restriction ceases to have effect in order to prevent the 1.5% Charge from applying.
Where a clearance service has made and maintained an election under section 97A of the U.K. Finance Act 1986, or a section 97A election no 1.5% Charge will apply on any transfer of ordinary shares to that clearance service. 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 U.K. stamp duty or U.K. SDRT charge in any circumstances.

Issue of ADSs

No U.K. stamp duty or SDRT should be payable on the issue of ADSs in the Company.

Transfers of ADSs within a clearance system

No U.K. 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.

Issuance or Transfers of ADSs

On the basis of current published HMRC guidance, ADSs are not regarded as stock or a marketable security for the purposes of U.K. stamp duty or a chargeable security for the purposes of U.K. SDRT and, as such, no U.K. 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.

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 "Special 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 focused on developing novel immunotherapeutic drug candidates for treating autoimmune and inflammatory diseases within the immunology and inflammation ("I&I") space. Helping patients and their families is the guiding principle at the heart of Barinthus Bio. We aim to achieve this by developing truly transformational and highly disease-specific immunotherapies.

We are prioritizing the development of a pipeline for I&I indications enabled by our proprietary and highly differentiated platform for promoting immune tolerance, referred to as SNAP-TI, that are designed to guide patient's T cells to reduce inflammation and restore the natural state of immune non-responsiveness to healthy tissue. Our lead candidate, VTP-1000, is designed to restore immune non-responsiveness to gluten in patients with celiac disease, and is currently being assessed

in a Phase 1 clinical trial. Based on encouraging preclinical data, we believe that the SNAP-TI platform has the potential to impact multiple other I&I indications.

We are also exploring partnership opportunities for VTP-300, a product candidate to treat CHB that harnesses viral vector platform technologies, consisting of ChAdOx and MVA; which are designed to increase disease-specific CD8+ T cells. VTP-300 is a Phase 2 immunotherapeutic treatment modality that is a component of a treatment regimen to establish functional cure in patients who are chronically infected by the hepatitis B virus.

We believe our core capabilities at the intersection of T cell immunology and immunotherapeutic technology platforms combined with our track record of successfully executing development path activities uniquely position us to navigate towards delivering promising new treatments for patients with autoimmune and inflammatory diseases and building value for shareholders.

In September 2025, we entered into the Merger Agreement to combine in an all-stock transaction with Clywedog. The newly combined company will advance a differentiated portfolio of clinical-stage candidates targeting metabolic and autoimmune diseases, with four clinical data milestones expected within 18 months of the closing of the transaction. Upon the closing of the transaction, the combined company will be renamed "Clywedog Therapeutics Holdings, Inc." and is expected to trade on the Nasdaq under the new ticker symbol "CLYD." The transaction is expected to close in the second quarter of 2026, supported by existing cash and additional investments by OrbiMed and TPAV, LLC, both existing shareholders in Clywedog, and new investors.

We have incurred net losses in each annual and interim reporting period since 2023. For the years ending December 31, 2025 and 2024, we incurred net losses of $66.5 million and $61.2 million, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $304.1 million and $237.7 million, respectively, and we do not currently expect 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, 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 or partnerships, 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 current standalone research and development plans, we expect that our existing cash, cash equivalents, restricted cash and other financial resources will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. 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.

Recent Developments

Merger Agreement Amendment

In February 2026, we announced we have entered into an amendment to the Merger Agreement with Clywedog to update the exchange ratio framework to provide additional flexibility in finalizing the transaction terms and to revise certain minimum cash requirements to reflect anticipated transaction timing. All other material terms remain unchanged.

Nasdaq Listing Rule Compliance

On January 6, 2026, we announced we received a letter from the Nasdaq indicating that the closing bid price of our ADSs, each representing one ordinary share of the Company, was below $1.00 per share for 30 consecutive business days, and that, therefore, we are not in compliance with Nasdaq Listing Rule 5450(a)(1), which is the minimum bid price requirement for continued listing on the Nasdaq Global Market. The notice from Nasdaq has no immediate effect on the listing of the ADSs, and the ADSs will continue to be listed on the Nasdaq Global Market under the symbol "BRNS." Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have automatically been afforded a 180-calendar day period, or until June 29, 2026, to regain compliance with the minimum bid price requirement. The continued listing standard will be met if the closing bid price of the ADSs is at least $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day period. If we are not in compliance by June 29, 2026, we may be afforded a second 180-calendar day period to regain compliance if it meets certain requirements. We intend to monitor the closing bid price of the ADSs and are currently evaluating our options for regaining compliance, which could include a reverse stock split of the ADSs.

Impact of International Conflict

In respect of the international conflicts in Gaza, Ukraine and Iran, we have no operations or suppliers based in Israel, Gaza, Ukraine, Belarus, Russia or Iran, and as a result, as of the date of this Annual Report on Form 10-K, we believe the impact on our business, operations and financial condition will be minimal.

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. Inflationary pressures, volatile interest rates, 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. In March, 2022, we were notified by OUI of the commencement of payments to us arising from AstraZeneca's commercial sales of Vaxzevria. In May 2024, AstraZeneca announced the initiation of withdrawal of marketing authorization for Vaxzevria in Europe as demand had declined. In October 2024, we were informed of additional amounts due to the Company from Oxford University Innovation Limited (OUI) in relation to the Company's share of royalties received by OUI as a result of prior commercial sales of Vaxzevria by AstraZeneca. As a result there was no revenue for the year ending December 31, 2025 (year ended December 31, 2024 $15.0 million), representing the amounts we have been notified of as due by OUI to date. We do not expect to receive any further payments relating to future commercial sales of Vaxzevria and, if such payments are due, 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 and 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 a next-generation adenoviral vector, acquiring new technology platforms including SNAP-TI and SNAP-CI, conducting preclinical studies, developing various manufacturing processes, and advancing our clinical programs. Research and development activities account for a large portion of our operating expenses, and product candidates in later stages of development generally have higher development costs than those in earlier stages, due to larger and more complex clinical trials, manufacturing scale-up and an increase in research and development headcount to oversee these activities. We are currently seeking partners to fund or collaborate on certain of our programs, including VTP-300 and VTP-850, which we do not intend to develop beyond the completion of the ongoing trials, as applicable. We expect research and development expenses to increase in the future as we progress our program through the next stage of development. 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 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, impairment of property and equipment and right-of-use assets, foreign exchange gains and losses on our cash balances, other central non-research costs and changes in the fair value of contingent consideration. When determining the 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. Our general and administrative expenses would continue to increase in the future if we expand our operating activities and if we seek to manufacture and/or commercialize any of our current and future product candidates. These costs will increase if 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 and the SEC, directors' and officers' liability insurance premiums and investor relations activities.

Other Operating Income

Other operating income includes grant income from an agreement (the "CEPI Funding Agreement") with the Coalition for Epidemic Preparedness Innovations ("CEPI") pursuant to which CEPI will provide funding to us to advance the development of VTP-500, a vaccine candidate against MERS. When there is reasonable assurance that we 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 we recognize expenses for the related costs for which the grants are intended to compensate. Payments received in advance of incurring reimbursable expenses are recorded as deferred income. Any remaining unused amounts of the cash payments received on the balance sheets will be disclosed as restricted cash in the notes of the consolidated financial statements. Minimal future activity is expected in relation to the VTP-500 program following the strategic decision to prioritize pipeline assets in the I&I space.

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.

Interest Expense

Interest expense results primarily from the asset retirement obligation discounted over the length of the relevant lease.

Research and Development Incentives

Research and development incentives contain payments receivable from the U.K. government related to corporation tax relief for qualifying expenditure on research and development projects in the U.K. We account for such relief received as other income.

Qualifying expenditures largely comprise employment costs for research staff, consumables, outsourced contract research organization costs, externally provided workers and utilities costs incurred as part of research projects. 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.

For 2025, we benefit from the applicable U.K. research and development tax credit regime which is the merged scheme Research & Development expenditure credit ("RDEC") and enhanced R&D intensive support ("ERIS") that replaces the old RDEC and small and medium-sized enterprise ("SME") schemes for accounting periods beginning on or after April 1, 2024. For expenditure under the merged scheme, the rate of Research and Development expenditure credit is 20%, which is the same as the rate under the old RDEC scheme for expenditure incurred on or after April 1, 2023. For loss-makers and small profit-makers, a lower rate of notional tax restriction (currently 19%) applies at payment. The amount of the Pay As You Earn ("PAYE") cap for claims under both the merged scheme and ERIS is £20,000 plus 300% of the company's relevant PAYE and National Insurance contributions liabilities. The PAYE cap (where applicable) will limit the amount of payable credit that can be received in the accounting period under consideration. Any excess over the cap will be carried forward and treated as an amount of Research and Development expenditure credit to which the company will be entitled for the next accounting period. Based on prior claims and the split of qualifying spend it is expected that the PAYE cap is unlikely to affect the net benefit. Furthermore, legislation included in Finance Act 2024 restricts the extent to which

payments to contractors for R&D and externally provided workers can qualify for R&D relief where R&D activity takes place outside the U.K., which may restrict the ability to include cost incurred on externally provided workers based in the U.S.

For 2024, we benefited from the applicable U.K. 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. Under the SME Program, we were able to surrender some of our trading losses that arise from qualifying research and development activities for a cash rebate of up to 18.6% of such qualifying research and development expenditure, as the SME additional deduction is 86% and the SME credit rate is 10%.

Under both the merged RDEC scheme and the SME program, a company qualifies as an R&D intensive business if R&D expenditure constitutes at least 30% of total expenditure. From the analysis performed, we have not and do not expect to claim under the loss-making R&D intensive scheme criteria primarily due to the proportion of total relevant expenditure occurring outside the U.K.

In future years, we may not be able to continue to claim research and development tax credits under the U.K. research and development tax credit regime if we no longer qualify based on the eligibility criteria. Unsurrendered U.K. 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 U.K. taxable profits. There was no tax loss restriction applied to the R&D tax credits in the U.K. for the years ended December 31, 2025 and 2024.

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 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 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 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.

Long-lived Assets

We review 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.

Intangible assets

In September 2025, we announced that we have entered into the Merger Agreement to combine in an all-stock transaction with Clywedog. The indicative offer price was below the fair value of our net assets expected at completion and below prior valuations utilized in our most recent impairment assessments, thereby constituting an impairment triggering event. As a result, we recorded a total impairment charge for acquired development technology intangible assets of $4.7 million during the quarter ended September 30, 2025. The determination of the fair value of our net assets expected at completion, is a non-recurring fair value measurement. Subsequently, we reviewed for additional indicators of impairment and did not identify any additional impairment triggers nor was any additional impairment expense recorded.

Contingent Consideration

We recognize 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. 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, 2025 and 2024

The following table sets forth the significant components of our results of operations (in thousands):

	Year ended December 31, 2025	Year ended December 31, 2024	Change
License revenue	$ —	$ 14,969	$ (14,969)
Operating expenses:			
Research and development	25,564	42,236	(16,672)
General and administrative	40,830	29,670	11,160
Impairment of intangible assets	4,667	—	4,667
Goodwill impairment	—	12,209	(12,209)
Total operating expenses	71,061	84,115	(13,054)
Other operating income	506	1,176	(670)
Loss from operations	(70,555)	(67,970)	(2,585)
Other income/(expense):			
Interest income	1,957	2,678	(721)
Interest expense	(51)	(53)	2
Research and development incentives	2,000	3,983	(1,983)
Other income	16	135	(119)
Total other income, net	3,922	6,743	(2,821)
Loss before income tax	(66,633)	(61,227)	(5,406)
Tax benefit	175	44	131
Net loss	$ (66,458)	$ (61,183)	$ (5,275)

Revenue

For the year ended December 31, 2025 and 2024, our revenue consisted of nil and $15.0 million, respectively from the OUI License Agreement Amendment with respect to amounts owed to us by OUI for the commercial sales of Vaxzevria. In 2024, AstraZeneca announced it had made the strategic decision to initiate the withdrawal of marketing authorization for Vaxzevria within Europe, citing decline in demand as the reason for the decision. We do not expect to receive any further payments relating to future commercial sales of Vaxzevria and, if such payments are due, that we will be notified of such payments in a timely manner.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

	Year ended December 31, 2025	Year ended December 31, 2024	Change
Direct research and development expenses by program:			
VTP-1000 Celiac	$ 6,063	$ 5,486	$ 577
Barinthus legacy assets[1]	8,531	18,223	(9,692)
Total direct research and development expenses	$ 14,594	$ 23,709	$ (9,115)
Indirect research and development expenses:			
Personnel-related (including share-based compensation)	8,413	15,867	(7,454)
Facility related	1,370	1,249	121
Other indirect costs	1,187	1,411	(224)
Total indirect research and development expenses	10,970	18,527	(7,557)
Total research and development expenses	$ 25,564	$ 42,236	$ (16,672)

[1] In January 2025, we announced a strategic focus on developing a pipeline in I&I, and the deprioritization of our programs in infectious disease and oncology. The following programs were previously presented separately and have been grouped collectively as "Barinthus Legacy Assets" for both years presented: VTP-300 HBV, VTP-850 Prostate Cancer, VTP-200 HPV, VTP-600 NSCLC, VTP-500 MERS and other and earlier stage programs.

Our research and development expenses for the years ended December 31, 2025 and 2024 were $25.6 million and $42.2 million, respectively, and consisted of direct and indirect research and development expenses.

Direct expenses for the years ended December 31, 2025 and 2024 were $14.6 million and $23.7 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 $9.1 million decrease, $9.7 million pertains to a net decrease in spend across Barinthus legacy asset infectious disease and oncology programs as the ongoing trials reached clinical completion and following the strategic decision to partner these programs for future development. This decrease is partially offset by a $0.6 million increase in spend on VTP-1000 for the ongoing Phase 1 AVALON clinical trial.

Indirect research and development expenses for the years ended December 31, 2025 and 2024 were $11.0 million and $18.5 million, respectively. Of the $7.6 million decrease, $7.5 million relates to the reduction in headcount and the associated reduction in personnel-related expense (including share-based compensation).

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2025 and 2024 were $40.8 million and $29.7 million, respectively. The increase of $11.1 million relates primarily to a $12.0 million change in foreign exchange gains and losses (from a gain of $2.4 million for the year ended December 31, 2024 to a loss of $9.6 million for the year ended December 31, 2025), as well as an increase of $6.5 million in professional fees attributable to increased strategic activity.

These increases are partially offset by a $2.6 million net reduction in depreciation and amortization reflecting the $5.3 million impairment charge recorded in the year ended December 31, 2024 in relation to the U.K. operating lease right-of-use assets and property and equipment. For the year ended December 31, 2025, depreciation includes a $1.1 million impairment charge in relation to U.S. right-of-use assets and leasehold improvements and $1.6 m accelerated depreciation due to a decrease in the estimated useful lives of the U.K. right of use and fixed assets.

Personnel-related expenses decreased $2.8 million due to the reduction in headcount and the associated reduction in personnel-related expense (including share-based compensation). Other general and administrative costs decreased $1.4 million which is attributable to reduced travel expenses, reduced communications expenses, lower insurance premiums and other reductions in facility-related expenses.

Impairment of intangible assets expense

For the years ended December 31, 2025 and 2024, impairment of intangible assets expense was $4.7 million and nil million, respectively. This increase relates to the impairment assessment performed during the third quarter of 2025, following an impairment triggering event identified in relation to us entering a definitive merger agreement to combine in an all-stock merger transaction with Clywedog. See Note 7 for further details.

Goodwill Impairment Expense

For the years ended December 31, 2025 and 2024, goodwill impairment expense was nil and $12.2 million, respectively. The decrease relates to the impairment assessment performed during the fourth quarter of 2024, based on the expected utilization of Company assets and external market conditions.

Interest Income

For the years ended December 31, 2025 and 2024, interest income was $2.0 million and $2.7 million respectively, which primarily resulted from the reduction in interest rates and the reduction in cash amounts on short-term cash deposits held by Barinthus Biotherapeutics (UK) Limited.

Research and Development Incentives

For the years ended December 31, 2025 and 2024, research and development incentives were $2.0 million and $4.0 million, respectively. Such research and development incentives relate to corporation tax relief on research and development project incentive programs in the U.K. The decrease of $2.0 million is primarily due to a decrease in qualifying R&D activities related to the strategic decision to stop development of the viral vector programs beyond the completion of the ongoing clinical trials in the U.K. and reduced R&D recovery rate under the new merged scheme for 2025.

Tax benefit

For the years ended December 31, 2025 and 2024, the tax benefit was $0.18 million and $0.04 million respectively, which primarily relates to movements in deferred tax.

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 upfront royalty and milestone payments from OUI in connection with the OUI License Agreement Amendment for Vaxzevria. Through December 31, 2025, we have received gross proceeds of approximately $330.1 million from the issuance of our ordinary and preferred shares and convertible loan notes. As of December 31, 2025, we had cash, cash equivalents and restricted cash of $71.9 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 initial public offering of our ordinary shares on Nasdaq.
- Between April 2022 and November 2024, we received $59.5 million of cash from OUI for the commercial sales of Vaxzevria.
- Between December 2022 and December 31, 2024, we raised net proceeds of $5.1 million from the issuance of 2,558,586 shares represented by ADSs through “at-the-market” offerings under the sales agreement with Jefferies LLC ("Jefferies").

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 immunotherapy platforms and our product 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.

On September 29, 2025, we entered into the Merger Agreement providing for our combination with Clywedog. We have agreed to various covenants and agreements, including, among others, agreements to conduct our business in the ordinary course of business between the execution of the Merger Agreement and the closing of the Combinations. Outside of certain limited exceptions, we may not take certain actions without Clywedog's consent, including (i) acquiring businesses and disposing of significant assets, (ii) incurring expenditures above specified thresholds; (iii) incurring additional debt outside the ordinary course of business, (iv) issuing additional securities, or (v) repurchasing ordinary shares or ADSs.

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, 2025	Year ended December 31, 2024
Net cash used in operating activities	$ (47,979)	$ (28,940)
Net cash provided by/(used in) investing activities	416	(892)
Net cash provided by financing activities	2	2,163
Effect of exchange rates on cash, cash equivalents and restricted cash	7,013	(2,021)
Net decrease in cash, cash equivalents and restricted cash	$ (40,548)	$ (29,690)

Cash Used in Operating Activities

During the year ended December 31, 2025, net cash used in operating activities was $48.0 million, primarily resulting from our net loss of $66.5 million, adjusted by depreciation and amortization expense of $5.8 million, long-lived asset impairment charge of $5.8 million, unrealized foreign exchange loss of $3.7 million, non-cash lease expenses of $3.3 million, share based compensation of $0.5 million and changes in our operating assets and liabilities, net of $0.4 million primarily related to a $6.4 million decrease in research and development incentives receivable, a $6.0 million decrease in accounts payable and accrued expenses, a $2.0 million decrease in operating lease liabilities, a $1.7 million decrease in prepaid expenses, and a $0.5 million decrease in deferred income.

During the year ended December 31, 2024, net cash used in operating activities was $28.9 million, primarily resulting from our net loss of $61.2 million, adjusted by goodwill impairment expense of $12.2 million, depreciation and amortization of $5.8 million, an impairment charge of $5.3 million, share based compensation of $4.7 million, non-cash lease expenses of $1.4 million and changes in our operating assets and liabilities, net of $2.6 million primarily related to a $3.6 million decrease in prepaid expenses, a $1.8 million decrease in operating lease liabilities, a $1.7 million increase in deferred income, a $1.4 million increase in accounts payable and accrued expenses and a $2.3 million increase in research and development incentives receivable.

Net Cash Provided By / (Used In) Investing Activities

During the years ended December 31, 2025 and 2024, cash provided by/(used) in investing activities was $0.4 million and $(0.9) million, respectively. For the year ended December 31, 2025, these amounts primarily related to proceeds received upon the sale of U.K. laboratory equipment. For the year ended December 31, 2024, these amounts primarily related to lab and office equipment purchases in both our U.K. and U.S. facilities.

Net Cash Provided by Financing Activities

During the year ended December 31, 2025 cash provided by financing activities related only to net proceeds from the issuance of ordinary shares in the form of ADSs through stock option exercises. During the year ended December 31, 2024, cash provided by financing activities of $2.2 million primarily related to net proceeds received from the issuance of ordinary shares in the form of ADSs through the "at-the-market" sales agreement with Jefferies LLC.

Effect of Exchange Rates on Cash, Cash Equivalents and Restricted Cash

During the years ended December 31, 2025 and 2024, the effect of foreign exchange on cash, cash equivalents and restricted cash was a $7.0 million gain and $2.0 million loss 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, except for 2022 when we were profitable. We have negative operating cash flows for the periods ending December 31, 2025 and 2024. As of December 31, 2025, we had an accumulated deficit of $304.1 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 if, and 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 personnel;
- conduct preclinical studies and clinical trials for our current and future product candidates based on our proprietary synthetic and biologic platforms, including SNAP-TI;
- 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 through a selected partner;
- acquire or in-license other product candidates and technologies for development and commercialization;
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company; and
- incur additional legal, advisory, accounting, tax and other expenses in operating our business, including the additional costs associated with completing the Contemplated Transactions.

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 unless and until such losses are eliminated by revenue.

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.

Since our foundation, we have invested a significant portion of our efforts and financial resources in research and development activities for our viral vector platform (ChAdOx and MVA), acquisition of additional complementary platforms such as SNAP-TI, development of new technologies, 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 timing, outcome and terms of the Contemplated Transactions currently in progress as well as associated transaction and advisory costs;
- 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 current and any future collaboration partners;
- our ability to establish, maintain or terminate collaborations, strategic licensing or other arrangements and the financial terms of such agreements;
- the costs of future commercialization activities, including product launch, product sales, marketing, manufacturing and distribution, for any of our current and future product candidates for which we receive marketing approval;
- the timing, receipt and amount of commercial sales, revenues, milestones or royalties or other income from our future products, 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; and
- the emergence and success or otherwise of competing autoimmune or 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 current standalone research and development plans, we expect that our existing cash, cash equivalents, restricted cash and other financial resources will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. 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.

We may require substantial additional financing in the future to meet any such unanticipated factors, including if the Contemplated Transactions are not consummated timely or at all. 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 programs, future commercialization efforts, other operational plans 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, plant 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, 2025. See section entitled “Business - Our Collaboration and License Agreements.

Emerging Growth Company Status

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended, or 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 Vaccitech Oncology Limited, is the pound sterling. The functional currency of our wholly owned foreign subsidiaries, Barinthus Biotherapeutics North America, Inc., Beacon Topco, Inc. and Cdog Merger Sub, Inc., is the United States dollar. The functional currency of our wholly owned foreign subsidiary, Barinthus Biotherapeutics Pty Limited, is the Australian dollar. The functional currency of our wholly owned foreign subsidiary, Barinthus Biotherapeutics Switzerland GmbH, is the Swiss franc. Our cash, cash equivalents and restricted cash as of December 31, 2025 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 U.K. and face exposure to changes in the exchange ratio of the United States dollar and the pound sterling arising from expenses and payables from our U.K. operations that are settled in pound sterling. For the year ended December 31, 2025, an average 10% weakening in the United States dollar relative to the pound sterling would have resulted in a material change to our current and projected expenses denominated in pound sterling for the year ended December 31, 2025.

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, cash equivalents and restricted cash of $71.9 million as of December 31, 2025, which were primarily held as account balances with banks in the U.K. and United States. 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.

Item 8. 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 principal executive officer and principal 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, 2025.

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 principal executive officer and principal financial officer, has concluded that, as of such date, our disclosure controls and procedures were effective.

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, 2025, 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, 2025, based on criteria in Internal Control-Integrated Framework (2013) issued by the COSO.

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

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2025 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Plans

None of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the three months ended December 31, 2025 covered by this Annual Report.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

The following table sets forth certain information about our current directors and executive officers as of the date of this Annual Report:

Name	Age	Present Position	Year Elected to Present Position
William Enright	63	Chief Executive Officer and Director	2019
Leon Hooftman	68	Chief Medical Officer	2024
Robin Wright	61	Chairman of the Board of Directors	2018
Alex Hammacher	45	Non-Executive Director	2020
Pierre A. Morgon, PharmD	63	Non-Executive Director	2018
Anne M. Phillips, MD	72	Non-Executive Director	2021
Karen T. Dawes	74	Non-Executive Director	2021
Joseph C. Scheeren	70	Non-Executive Director	2021

William Enright has been our Chief Executive Officer and a member of our board of directors since August 2019. From June 2008 to November 2018, Mr. Enright served as the Chief Executive, President and Director of Altimmune, Inc. ("Altimmune"), a biopharmaceutical company. Prior to joining Altimmune, Inc., Mr. Enright held various positions at GenVec, Inc. (acquired by Precigen, Inc.), leaving as Head of Business Development. He currently serves on the Board of Directors and Chair of the Compensation Committee of BullFrog AI, Inc. Mr. Enright brings a breadth of experiences in a variety of positions within the life science/biotech industry, including time as a consultant, a bench scientist and 12 years with Life Technologies, Inc. (acquired by Thermo-Fisher), working in various senior level licensing, business management, manufacturing and research roles. Mr. Enright holds a MA and BS in Biology from SUNY at Buffalo and a MS in Business Management from Johns Hopkins University. We believe that Mr. Enright is qualified to serve on our board of directors because of his considerable management experience in the biopharmaceutical industry.

Leon Hooftman has been our Chief Medical Officer since June 2024. Dr. Hooftman held Chief Medical Officer roles at several biotechnology companies, including ISA Pharmaceuticals from May 2018 to June 2024, Polyphor AG from September 2014 to May 2018, Synthon BV from October 2011 to August 2014 and Chroma Therapeutics from October 2004 to January 2011. Prior to that, he served as the Head of Clinical Development at Celltech, from December 2002 until its acquisition by UCB in October 2004. Earlier in his career, Dr. Hooftman held various senior management positions at Roche from May 1995 to December 2002. Dr. Hooftman holds a M.D. from Utrecht State University (Netherlands) and performed his specialist training in Cambridge and London (UK).

Robin Wright has served as our chairman since October 2018 and a member of our board of directors since August 2018. Mr. Wright has extensive senior level experience as a Chief Financial Officer of public companies in both the pharmaceutical and biotechnology industries. Mr. Wright has served as the Chief Financial Officer of MiNa Therapeutics since January 2021. From September 2020 to October 2020, Mr. Wright was our interim Chief Financial Officer. From September 2015 to May 2020, Mr. Wright was the Chief Financial Officer of Pharming Group N.V., a biopharmaceutical company. Mr. Wright holds a BA degree in Chemistry from Oxford University and is a Fellow of the Institute of Chartered Accountants in England and Wales in the UK. We believe Mr. Wright is qualified to serve on our board of directors because of his extensive management experience and financial expertise in the life sciences industry.

Alex Hammacher has been a member of our board of directors since January 2020. Dr. Hammacher is Head of Strategic Operations & Corporate Finance at Oxford Sciences Enterprises, a venture capital firm partnered with Oxford University, a position he has held since October 2019. Prior to joining Oxford Sciences Enterprises, Dr. Hammacher held positions of increasing seniority at Lazard, an investment banking firm, from October 2015 to October 2019, most recently as Director of Healthcare Investment Banking, and UBS, an investment banking firm, from July 2007 to September 2015. Dr. Hammacher received a BA and BM BCh from Oxford University. We believe Dr. Hammacher is qualified to serve on our board of directors because of his extensive investment experience in the life sciences industry.

Pierre A. Morgon has been a member of our board of directors since January 2018. Dr. Morgon is Chief Executive Officer of MRGN Advisors, an investment strategy advisor, a position he has held since January 2015. Dr. Morgon was Regional Partner for Switzerland at Mérieux Equity Partners, an investment firm, a position he has held since October 2014, and is currently a senior advisor to the firm. Dr. Morgon is also Chief Business Officer at Nuvamid, a position he has held from January 2024 to August 2025, Executive Vice President Portfolio Strategy and Supranational Affairs at CanSino Biologics until February 2024, Chief Business Officer at PLL Therapeutics since January 2025, Venture Partner at Rocket Bio Capital since June 2025 and Director at AlMorphous Health since November 2025. Dr. Morgon is also chair of the board of directors of Health Technologies Holding (HTH) Srl, a position he held from June 2020 to April 2025, chair of the board of directors of MYCB1, a position he has held since July 2020, chair of the board of directors of Eurocine Vaccines, a position he has held since May 2019, chair of the board of directors of Kupando GmbH, a position he held from December 2021 to April 2025, and a member of the board of directors of UNIVERCELLS, a position he has held since July 2018, and a member of the board of Amoéba SA, a position held since June 2021, and a member of the board of directors of CanSinoBio Switzerland, a position he has held since May 2022, and a member of the board of directors of Limula, a position he has held since July 2022. Dr. Morgon also served as a member of the board of directors of Alma Biotherapeutics from 2017 to 2018, chair of the board of directors of Virometix AG from January 2017 to November 2019, and chair of the board of directors of Theradiag from 2017 to March 2023. Pierre has over 35 years of experience in the global life science industry, especially with specialty care, vaccines and immunotherapy, at the helm of international operations, in C-level positions at global level in multinational corporations and as CEO of start-up companies. He is a lecturer in several MBA programs and in life science conferences, and at the Mass Challenge incubator in Switzerland where he is also a mentor for start-up life sciences companies. He holds a Doctorate of Pharmacy, a Master in Business Law and an MBA. He is also an alumnus of INSEAD and IMD. We believe Dr. Morgon is qualified to serve on our board of directors due to his extensive experience as a director of life sciences companies.

Anne M. Phillips has been a member of our board of directors since February 2021. Dr. Phillips was a Senior Vice President of Clinical, Medical & Regulatory Affairs, North America Operations, for Novo Nordisk Inc., leading the drug development, clinical operations, medical, regulatory, health economics and outcomes research, and safety teams, a position she held from 2011 to 2022. Prior to joining Novo Nordisk, Dr. Phillips held positions of increasing seniority at GlaxoSmithKline from 1998 to 2010, most recently as Vice President, Medicine Development Leader. Dr. Phillips also served on the board of directors of Trevena Corporation, a biopharmaceutical company, a position she held from 2014 to 2024. Dr. Phillips also served as a member of the board of directors of Carmot Therapeutics, a private biopharmaceutical company, from 2022 to 2023. Dr. Phillips also served as a member of the board of directors of AMAG Pharmaceuticals, Inc., a pharmaceutical company, from 2019 to 2020, and Biotechnology Innovation Organization, a biotechnology trade organization, from 2017 to 2018. Dr. Phillips currently serves on the board of directors of Sagimet Biosciences since August 2024, as well as on the board of directors of vTv Therapeutics since March 2024. Dr. Phillips received a BSc in Zoology from the University of Western Ontario and an MD from the University of Toronto. She completed postgraduate training in Internal Medicine, Medical Microbiology and Infectious Diseases. We believe Dr. Phillips is qualified to serve on our board of directors because of her extensive expertise in the life sciences industry.

Karen T. Dawes has been a member of our board of directors since February 2021. Ms. Dawes is the President of Knowledgeable Decisions, LLC, biopharma pharmaceutical consulting firm focusing on development and commercial/corporate strategy, a position she has held since 2003. Ms. Dawes served from 1999 to 2003 as Senior Vice President and U.S. Business Group Head for Bayer Corporation's U.S. Pharmaceuticals Group. Prior to joining Bayer, she was Senior Vice President, Global Strategic Marketing, at Wyeth LLC, a pharmaceutical company (formerly known as American Home Products). Ms. Dawes also served as Vice President, Chief Commercial Officer, for Genetics Institute, Inc. Ms. Dawes began her pharmaceuticals industry career at Pfizer, Inc. where, from 1984 to 1994, she held a number of marketing positions, serving most recently as Vice President, Marketing of the Pratt Division. Ms. Dawes also serves on the boards of directors of one publicly traded company, Repligen Corporation, one privately-held company, JPA Health, and one not-for-profit organization, Medicines 360. Ms. Dawes received a BA and an MA from Simmons College in English Literature and an MBA from Harvard University. We believe Ms. Dawes is qualified to serve on our board of directors because of her extensive experience with biopharmaceutical companies as well as her considerable background in the development and commercialization of pharmaceutical products.

Joseph C. Scheeren has been a member of our board of directors since March 2021. Dr. Scheeren is also the founder and president of Scheeren HealthCare LLC, a consulting company specializing in pharmaceutical development and regulatory affairs, and has held these positions since August 2021. Dr. Scheeren serves as the co-chair of the Scientific Advisory Board of Fosun Shanghai Pharmaceuticals in Shanghai since February 2023 and is a member of the International Advisory Board of the French Clinical Research Infrastructure Network in France. He is also on the Supervisory Board of Connect 4 Children Stiechting ("C4C S"), a Dutch non-profit organization since May 2023. Dr. Scheeren served as President and Chief Executive Officer of Critical Path Institute, ("C-Path"), a non-profit organization, from April 2019 to March 2021.

Prior to joining C-Path, Dr. Scheeren served in various senior roles at Bayer AG, a global pharmaceutical company, for 15 years, including serving as Senior Vice President, Senior Advisor to Research and Development from January 2018 to December 2018 and Senior Vice President, Head of Global Regulatory Affairs, Pharmaceuticals and Consumer Health from January 2015 to December 2017. He previously also held numerous executive positions at Aventis Pharmaceuticals, Roussel UCLAF, Ares Serono and Les Laboratoires Servier. Dr. Scheeren has served as an advisor to PathBiotech LLC from June 2021 until October 2023. Dr. Scheeren currently serves as a director on several boards of non- profit organizations, is an adjunct Professor of Regulatory Science at Peking University, Beijing, and was a lecturer at Yale University. Dr Scheeren earned his PharmD, MSc and BS degrees at the University of Leiden, Leiden, the Netherlands, School of Pharmacy. We believe Dr. Scheeren is qualified to serve on our board of directors because of his global expertise in research and development and regulatory affairs in the pharmaceutical industry.

There are no material legal proceedings to which any of our directors is a party adverse to us or any of our subsidiaries or in which any such person has a material interest adverse to us or our subsidiary.

Board of Directors Composition

Our board of directors seeks director candidates who represent a mix of backgrounds and experiences that will enhance the quality of our board of directors' deliberations and decisions. Such candidates are expected to have substantial experience with one or more publicly traded national or multinational companies or have achieved a high level of distinction in their chosen field.

Structure of our Board of Directors

The leadership structure of our board of directors separates the positions of chief executive officer and chairman of the board in order to ensure independent leadership of the Board. Our Board believes that this separation is appropriate for the Company at this time because it allows for a division of responsibilities, with our chief executive officer focused on leading the Company while the chairman can focus on leading the Board in overseeing management, and for a sharing of ideas between individuals having different perspectives.

Independence of our Board of Directors

Our board of directors has determined that Robin Wright, Pierre A. Morgon, Anne M. Phillips, Karen T. Dawes and Joseph C. Sheeren are each independent within the meaning of the director independence standards of Nasdaq. Furthermore, our board of directors has determined that all of the members of our audit committee, compensation committee, and nominating and corporate governance committee are independent within the meaning of the director independence standards of Nasdaq and the rules of the SEC applicable to each such committee.

Our board of directors has determined that Alex Hammacher and William Enright are not independent within the meaning of director independence standards of Nasdaq.

Family Relationships and Adverse Proceedings

There are no family relationships between any of our directors or executive officers. Neither we nor any of our subsidiaries are party to any material proceedings to which any of our directors, officers, affiliates, 5% or more shareholders, or any of their respective associates are a party. We do not believe that any of our directors, officers, affiliates, 5% or more shareholders, or any of their respective associates are adverse to us or any of our subsidiaries or have a material interest that is adverse to us or any of our subsidiaries.

Code of Business Conduct and Ethics

The Company has 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.

The Company intends 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.

Board Oversight of Risk Management

Our management is primarily responsible for assessing and managing risk, while our board of directors is responsible for overseeing management's execution of its responsibilities. Our board of directors is supported by its committees in fulfillment of this responsibility. For example, our audit committee focuses on our overall financial risk by evaluating our internal controls and disclosure policies as well as ensuring the integrity of our financial statements and periodic reports. The audit committee also oversees the Company's information security and technology risks, including the Company's information security and related risk management programs. Our compensation committee strives to create incentives that encourage an appropriate level of risk-taking consistent with our business strategy. Our nominating and corporate governance committee ensures that our governance policies and procedures are appropriate in light of the risks we face.

Committees of our Board of Directors

Our board of directors has three standing committees: the audit committee, the compensation committee and the nominating and corporate governance committee. The charters for each of these committees can be found on our website at www.barinthusbio.com, under the "Corporate Governance" subsection of the "Investors" section. Each such committee reviews its respective charter at least annually.

Name	Audit	Compensation	Nominating and Corporate Governance
William Enright			
Robin Wright	*	X	
Alex Hammacher			
Pierre A. Morgon. ParmD	X		*
Anne M. Phillips, MD		*	
Karen T. Dawes	X		X
Joseph C. Sheeren		X	X

*denotes committee chairperson.

Audit Committee

Our audit committee is currently composed of Karen T. Dawes, Pierre A. Morgon and Robin Wright, and is chaired by Mr. Wright. Our board of directors has determined that each member of the audit committee meets the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the applicable Nasdaq rules. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq listing rules. Our board of directors has determined that Mr. Wright is an "audit committee financial expert" within the meaning of SEC regulations and the applicable Nasdaq rules. The audit committee held 5 meetings during 2025. The audit committee's responsibilities include:

- recommending the appointment of the independent auditor to the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board of directors on at least an annual basis;
- reviewing the adequacy of our internal controls with management and any remediation plan associated with any significant control deficiencies or material weaknesses;
- reviewing and discussing with management and our independent registered public accounting firm our financial statements and our financial reporting process;
- reviewing, approving or ratifying any related party transactions; and
- determining whether the Company is required to prepare a financial restatement.

Compensation Committee

Our compensation committee is currently composed of Anne M. Phillips, Robin Wright and Joseph C. Scheeren, and is chaired by Dr. Phillips. Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable Nasdaq rules. Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. The compensation committee held 3 meetings during 2025. The compensation committee's responsibilities include:

- annually reviewing and approving the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation determine and approve the Chief Executive Officer's compensation;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and recommending to the board of directors our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing our compensation committee report if and when required by SEC rules;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," if and when required, to be included in our annual proxy statement;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters; and
- adopting and administering a compensation recovery policy.

Our board of directors has delegated to the compensation committee the authority to determine the compensation for all of our executive officers. Non-executive director compensation is recommended by our compensation committee to the board of directors for approval. Our Chief Executive Officer may participate in general discussions with our compensation committee and board of directors about these compensation matters but he does not participate in discussions during which his individual compensation is being considered and approved.

In 2025, the compensation committee retained the services of the Rewards Solutions practice at Aon plc ("Aon"), an independent compensation consultant, to assist the compensation committee with respect to compensation actions in 2025 with the goal of ensuring that our compensation arrangements for our Chief Executive Officer, our other senior executive officers and our non-executive directors were competitive. Aon provided data from comparable publicly traded biotechnology companies and otherwise assisted the compensation committee in its design of competitive compensation for our Chief Executive Officer, senior executives and non-executive directors. The compensation committee expects to continue to use compensation consultants to assist the compensation committee in determining competitive levels of executive and non-executive compensation and specific design elements of our executive compensation program and non-executive directors' compensation program. After review and consultation with Aon, the compensation committee determined that Aon is independent and that there is no conflict of interest resulting from retaining Aon in 2025. In reaching these conclusions, our compensation committee considered the factors set forth in the SEC rules and the applicable Nasdaq rules.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is composed of Pierre A. Morgon, Karen T. Dawes and Joseph C. Scheeren, which is chaired by Dr. Morgon. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined under the applicable Nasdaq rules. The nominating and corporate governance committee held 1 meeting during 2025. The nominating and corporate governance committee's responsibilities include:

- determining selection criteria and appointment procedures for directors;
- recommending nominees for election to our board of directors and appointment to its committees;
- assessing the functioning of our board of directors and executive officers and reporting the results of such assessment to the board of directors;

- developing corporate governance guidelines and any other governance policies;
- reviewing and discussing with management of the Company's key human resource management strategies and programs; and
- establishing the Company's policies and procedures regrading on succession planning and continuing education of employees.

The nominating and corporate governance committee considers candidates for board of directors membership suggested by its members and the Chief Executive Officer. Additionally, in selecting nominees for directors, the nominating and corporate governance committee will review candidates recommended by shareholders in the same manner and using the same general criteria as candidates recruited by the committee and/or recommended by our board of directors.

Our board of directors is responsible for filling vacancies on our board of directors and for nominating candidates for election by our shareholders each year in the class of directors whose term expires at the relevant annual general meeting. The board of directors delegates the selection and nomination process to the nominating and corporate governance committee, with the expectation that other members of the board of directors, and of management, will be requested to take part in the process as appropriate.

Board and Committee Meetings Attendance

The full board of directors met 11 times during 2025. During 2025, each member of our board of directors attended in person or participated in 75% or more of the aggregate of (i) the total number of meetings of our board of directors (held during the period for which such person has been a director), and (ii) the total number of meetings held by all committees of the board of directors on which such person served (during the periods that such person served). Directors are encouraged to attend the annual meeting of stockholders. Last year, we held an annual meeting of stockholders on June 10, 2025, at which all of our directors were present.

Insider Trading Policy and Prohibition on Hedging and/or Pledging Securities

Our board of directors adopted our insider trading policy governing transactions in our securities by our executive officers, directors, employees and certain designated consultants, that the Company believes it is reasonably designed to promote compliance within insider trading laws, rules and regulations, and any listing standards applicable to the Company.

Certain transactions in our securities (such as purchases and sales of publicly traded put and call options, and short sales) create a heightened compliance risk or could create the appearance of misalignment between management and stockholders. In addition, securities held in a margin account or pledged as collateral may be sold without consent if the owner fails to meet a margin call or defaults on the loan, thus creating the risk that a sale may occur at a time when an officer or director is aware of material, non-public information or otherwise is not permitted to trade in Company securities. Our insider trading policy allows our directors, officers, vice-president level or above employees, and members of the finance department involved in periodic financial reporting to pledge our securities as collateral for a loan (or modify an existing pledge) only if the pledge has been approved by the audit committee.

It is the Company's policy to comply with applicable insider trading laws, rules and regulations, and any exchange listing standards when engaging in transactions in Company securities.

Rule 10b5-1 Trading Plan Policy

We have adopted a Rule 10b5-1 trading plan policy, which permits our officers, directors, employees and certain other persons to enter into trading plans complying with Rule 10b5-1 under the Exchange Act. Generally, under these trading plans, the individual relinquishes control over the transactions once the trading plan is put into place and can only put such plans into place while the individual is not in possession of material non-public information. Accordingly, sales under these plans may occur at any time, including possibly before, simultaneously with, or immediately after significant events involving our company.

Compensation Recovery Policy

Our Board adopted a Compensation Recovery Policy effective as of October 2, 2023 and adopted an Amended and Restated Compensation Recovery Policy effective June 21, 2023 in compliance with the Nasdaq listing rules, which requires recovery from executive officers of incentive-based compensation that is earned, granted or vested based on the

achievement of a financial reporting measure in the event of that we are required to restate our previously issued financial statements due to our material noncompliance with any financial reporting requirement under securities laws. The recoverable compensation includes any compensation received after the effective date of the Compensation Recovery Policy and in the three-year fiscal period preceding the date we were required to prepare the accounting restatement that is in excess of the amount that would have been earned, paid or vested had it been calculated based on the restated financial statements. Recovery is required regardless of fault or a covered officer's role in the financial reporting process.

Item 11. Executive Compensation

Director Compensation

The table below shows all compensation earned by or paid to our non-executive directors during 2025. William Enright, our Chief Executive Officer, does not receive any compensation for his services as a director and, consequently, is not included in this table. The compensation received by William Enright during 2025 is set forth in the heading "Named Executive Compensation".

Name	Fees Paid in Cash ($)[1]	Option Awards ($)[1][2]	Total ($)
Alex Hammacher[3]	$42,182	$17,295	$59,477
Pierre A. Morgon[4]	$61,295	$17,295	$78,590
Robin Wright[5]	$92,272	$17,295	$109,567
Anne M. Phillips[6]	$55,363	$17,295	$72,658
Joseph C. Scheeren[7]	$54,045	$17,295	$71,340
Karen T. Dawes[8]	$56,022	$17,295	$73,317

(1) The amounts reported have been converted from pounds sterling to U.S. dollars using the average exchange rate for 2025 of £0.7586 to $1.00.
(2) Amounts shown reflect the grant date fair value of stock option awards granted during 2025. The grant date fair value was computed in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification Topic 718 ("ASC Topic 718"), Compensation — Stock Compensation, disregarding the effect of estimated forfeitures related to service-based vesting. The assumptions used in calculating the grant date fair value of the shares are set forth in Note 14 of "Notes to Consolidated Financial Statements." These amounts reflect the accounting cost for the stock options and do not correspond to the actual economic value that may be received by the director upon exercise of the stock options.
(3) As of December 31, 2025, Dr. Hammacher held unexercised options to purchase 111,819 shares.
(4) As of December 31, 2025, Dr. Morgon held unexercised options to purchase 132,213 shares.
(5) As of December 31, 2025, Mr. Wright held unexercised options to purchase 132,213 shares.
(6) As of December 31, 2025, Dr. Phillips held unexercised options to purchase 111,819 shares.
(7) As of December 31, 2025, Dr. Scheeren held unexercised options to purchase 111,819 shares.
(8) As of December 31, 2025, Ms. Dawes held unexercised options to purchase 111,819 shares.

Non-Executive Director Compensation Program

We compensate our non-executive directors with a cash retainers and equity awards. The amount of each component of such director cash compensation may change from year to year and is generally established by the compensation committee in conjunction with the Board, and presented at our annual general meeting of shareholders for the period. The annual retainers in effect for services during 2025 are as follows:

Annual Retainer for Board Membership		
Annual service on the Board of Directors	£	32,000
Additional compensation for service as non-executive Chair of the Board of Directors	£	20,000
Additional Annual Retainer for Committee Membership		
Annual service as Chair of the Audit Committee	£	13,000
Annual service as member of the Audit Committee (other than Chair)	£	6,500
Annual service as Chair of the Compensation Committee	£	10,000
Annual service as member of the Compensation Committee (other than Chair)	£	5,000
Annual service as Chair of the Nomination and Corporate Governance Committee	£	8,000
Annual service as member of the Nomination and Corporate Governance Committee (other than Chair)	£	4,000

Our policy provides that, upon initial election to our board of directors, each non-executive director will be granted an option to purchase a number of ordinary shares equal to 0.10% of the outstanding ordinary shares as of the date of grant (the "Initial Grant"). Furthermore, on the date of each of our annual meeting of shareholders, each non-executive director who will continue as a non-executive director following such meeting will be granted an option to purchase a number of ordinary shares equal to 0.05% of the outstanding ordinary shares as of the date of grant (the "Annual Grant"). The Annual Grant will vest in full on the earlier of (i) the one-year anniversary of the grant date or (ii) the next annual meeting of shareholders, subject to continued service as a director through the applicable vesting date. The Initial Grant will vest in 36 equal monthly installments, subject to continued service as a director through the applicable vesting date. Such awards are subject to full accelerated vesting upon the sale of the Company.

Employee directors will receive no additional compensation for their service as a director.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our Board of Directors or any committee thereof.

Compensation Committee Interlocks and Insider Participation

Dr. Phillips, Mr. Wright, and Dr. Scheeren served as members of our compensation committee during the year ended December 31, 2025. None of the members of our compensation committee is, or has been at any time, one of our officers or employees. None of our executive officers currently serves, or has served in the past fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

Named Executive Officer Compensation

The following table sets forth information concerning the compensation of our named executive officers for the years ended December 31, 2025 and 2024:

Name and Principal Position	Year	Salary ($)	Stock Awards ($)[1]	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total ($)
William Enright	2025	653,432	—	512,245	—	47,986	1,213,663
Chief Executive Officer	2024	634,400	—	1,376,573	304,512	47,474	2,362,959
Leon Hooftman[4]	2025	441,259	540,487	119,524	—	36,329	1,137,599
Chief Medical Officer	—	—	—	—	—	—	—
Geoffrey Lynn[5]	2025	301,795	—	—	—	268,257	570,052
Former Chief Scientific Officer	—	—	—	—	—	—	—
Gemma Jones[6]	2025	136,216	—	—	—	632,774	768,990
Former Chief Financial Officer	2024	357,875	—	605,510	120,246	23,294	1,106,925

(1) The amounts reported reflect the grant date fair value of restricted share unit awards and option awards granted in 2025 and 2024 in accordance with ASC Topic 718, disregarding the effect of estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant date fair value of the shares are set forth in the Note 14. These amounts do not correspond to the actual value that may be recognized by the named executive officers upon vesting of the applicable awards.
(2) The amounts reported for 2024 represent the annual bonuses paid in February 2025 for the year ended December 31, 2024.
(3) The amounts reported for Mr. Enright 401(k) matching contributions and health insurance coverage. The amounts reported for Dr. Hooftman consist of pension contributions and health insurance. The amounts reported for Dr. Lynn consist of 401(k) matching contributions and health insurance coverage, $146,667 in severance compensation, $11,846 of unused vacation and $69,167 of consulting fees. The 2025 amounts reported for Mrs. Jones consist of pension contributions, health insurance, $261,678 in severance compensation, $17,808 of unused vacation and $349,245 of consulting fees. The 2024 amounts reported for Mrs. Jones consist of pension contributions and healthcare. The amounts reported for Mrs. Jones and Dr. Hooftman have been converted from pounds sterling to U.S. dollars using the average exchange rate for 2024 of 0.7824 to $1.00 and 2025 of £0.7586 to $1.00.
(4) The amounts reported have been converted from pounds sterling to U.S. dollars using the average exchange rate for 2025 of £0.7586 to $1.00. Dr. Hooftman was not a named executive officer for 2024.
(5) Dr. Lynn was not a named executive officer for 2024. Dr. Lynn’s employment terminated effective as of September 5, 2025.
(6) The amounts reported have been converted from pounds sterling to U.S. dollars using the average exchange rate for 2024 of 0.7824 to $1.00 and 2025 of £0.7586 to $1.00. Mrs. Jones' employment terminated effective as of April 30, 2025. She transitioned to a consultant after her termination date and serves as Chief Financial Officer.

Narrative to the Summary Compensation Table

Base Salaries

For the fiscal year ending December 31, 2025, the base salaries for Mr. Enright and Dr. Hooftman were $653,432 and £334,750 ($441,259 using the average exchange rate for 2025 of £0.7586 to $1.00), respectively. At the time of Dr. Lynn's date of termination on September 5, 2025, his base salary was $440,000. At the time of Mrs. Jones' date of termination on April 30, 2025, her base salary was £310,000 ($408,648 using the average exchange rate for 2025 of £0.7586 to $1.00).

Annual Cash Bonuses

Subject to the attainment of certain company and individual performance goals, the Board may approve discretionary bonuses based on a percentage of the executive’s base salary. For the fiscal year ended December 31, 2025, each named executive officer was eligible to earn an annual cash bonus calculated as a percentage of each executive’s base salary and based on the achievement of corporate performance metrics. The corporate performance metrics were not satisfied and no annual cash bonus was awarded for the fiscal year ended December 31, 2025.

Long-Term Equity Incentives

Although we do not yet have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our shareholders. In addition, we believe that equity grants promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and may grant equity incentive awards to them from time to time. Equity awards granted during fiscal year 2025 are set forth below in the Outstanding Equity Awards at Fiscal Year-End table.

Employment Agreements with Our Named Executive Officers

William Enright. We entered into a new employment agreement with Mr. Enright effective upon the closing of our IPO in May 2021. Pursuant to this employment agreement, Mr. Enright agreed to continue to serve as our chief executive officer. Mr. Enright shall be entitled to an annual base salary, subject to periodic increase (but not decrease), target annual bonus opportunity and employee benefits. Under Mr. Enright's new employment agreement, in the event that Mr. Enright's employment is terminated by us without "cause" or Mr. Enright resigns for "good reason" (as such terms are defined in the employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor), he will be entitled to receive (i) an amount equal to 12 months of his base salary, payable over the 12 month period following his termination, (ii) if his termination occurs following completion of a calendar year but prior to payment of an annual bonus, payment of such annual bonus, and (iii) if Mr. Enright is participating in our group health plans immediately prior to his termination and elects COBRA health continuation, continuation of such group health coverage at the same rate as if he were an active employee, until the earliest of (A) the 12 month anniversary of his termination; (B) his eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of his continuation rights under COBRA. The employment agreement also provides that, in lieu of the payments and benefits described above, in the event that Mr. Enright's employment is terminated by us without cause or Mr. Enright resigns for good reason, in either case within 12 months following a "change in control" (as defined in the employment agreement), subject to the execution and effectiveness of a general release of claims in our favor, he will be entitled to receive (i) a lump sum cash payment equal to 1.5 times the sum of his then-current base salary (or his base salary in effect immediately prior to the change in control, if higher) plus his annual target bonus for the then-current year (or the annual target bonus in effect immediately prior to the change in control, if higher), and (ii) if Mr. Enright is participating in our group health plans immediately prior to his termination and elects COBRA health continuation, continuation of such group health coverage at the same rate as if he were an active employee, until the earliest of (A) the 18 month anniversary of his termination; (B) his eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of his continuation rights under COBRA. Mr. Enright's new employment agreement further provides that in the event Mr. Enright's employment is terminated by us without cause or Mr. Enright resigns for good reason, in either case within 12 months following a change in control, then any outstanding time-based equity awards shall immediately accelerate and become fully vested and exercisable or nonforfeitable on the date of termination.

Mr. Enright is also subject to an agreement relating to confidentiality, assignment of inventions, and a twelve-month nonsolicitation and noncompetition covenant.

Dr. Leon Hooftman. We entered into an employment agreement with Dr. Hooftman on February 21, 2024. Pursuant to this employment agreement, Dr. Hooftman agreed to serve as our chief medical officer. Dr. Hooftman is entitled to an annual base salary, subject to periodic review, target annual bonus opportunity and employee benefits. Dr. Hooftman's employment agreement contains standard confidentiality provisions which survive termination and also twelve-month non-competition and non-solicitation restrictive covenants.

Dr. Geoffrey Lynn. We entered into an employment agreement with Dr. Lynn effective as of December 1, 2024. Pursuant to this employment agreement, Dr. Lynn agreed to serve as our chief scientific officer. Dr. Lynn was entitled to an annual base salary, subject to periodic review, target annual bonus opportunity and employee benefits. Dr. Lynn's employment had no specified term but could be terminated at will by either party. Under Dr. Lynn's employment agreement, in the event that Dr. Lynn's employment was terminated by us without "cause" or Dr. Lynn resigned for "good reason" (as such terms are defined in the employment agreement), subject to the execution and effectiveness of a separation agreement, including a general release of claims in our favor), he would have been entitled to receive (i) an amount equal to 6 months of his base salary, payable over 9 months commencing within 60 days after his date of termination and (ii) subject to Dr. Lynn's copayment of premium amounts at the applicable active employees' rate and proper election to receive COBRA health continuation, continuation of such group health coverage at the same rate as if he were an active employee, until the earliest of (A) the 6 month anniversary of his termination; (B) his eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of his continuation rights under COBRA; provided, however, that if we determined that we

cannot pay such amounts to the group health plan provider or the COBRA provider without potentially violating applicable law, then we would convert such payments to payroll payments directly to Dr. Lynn for the time period specified above. The employment agreement also provided that, in lieu of the payments and benefits described above, in the event that Dr. Lynn's employment was terminated by us without cause or Dr. Lynn resigned for good reason, in either case within 12 months following a "change in control" (as defined in the employment agreement), subject to the execution and effectiveness of a general release of claims in our favor, he would have been entitled to receive (i) a lump sum cash payment equal to one times the sum of his then-current base salary (or his base salary in effect immediately prior to the change in control, if higher) plus his annual target bonus for the then-current year (or the annual target bonus in effect immediately prior to the change in control, if higher), and (ii) subject to Dr. Lynn's copayment of premium amounts at the applicable active employees' rate and proper election to receive COBRA health continuation, continuation of such group health coverage at the same rate as if he were an active employee, until the earliest of (A) the 6 month anniversary of his termination; (B) his eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of his continuation rights under COBRA; provided, however, that if we determined that we could not pay such amounts to the group health plan provider or the COBRA provider without potentially violating applicable law, then we would convert such payments to payroll payments directly to Dr. Lynn for the time period specified above.

On September 5, 2025, Dr. Lynn entered into a separation agreement and consulting agreement. Pursuant to Dr. Lynn's separation agreement, his employment terminated effective as of September 5, 2025. Dr. Lynn was provided severance benefits equal to 6 months base salary and COBRA continuation and, subject to the closing of the Combination or another meaningful M&A transaction, a $200,000 transaction bonus. Simultaneously, Dr. Lynn entered into a consulting agreement with us whereby he would provide advisory and transaction services to us until December 31, 2025. Dr. Lynn's compensation for such services equaled $18,333.33 per month. If Dr. Lynn provides services after December 31, 2025, he is to be paid $213 per hour for such services.

Gemma Jones. We entered into an employment agreement with Mrs. Jones on September 15, 2022. Pursuant to this employment agreement, Mrs. Jones agreed to serve as our chief financial officer. Mrs. Jones was entitled to an annual base salary, subject to periodic review, target annual bonus opportunity and employee benefits. On February 7, 2025, Mrs. Jones entered into a separation agreement. Pursuant to this settlement agreement, her employment terminated on April 30, 2025, and Mrs. Jones received payment equal to £30,000 as settlement payment, £155,000 as notice payment and £13,509 accrued holiday payment (a total of $261,678 using the average exchange rate for 2025 of £0.7586 to $1.00). Subsequently, we entered into an agreement with CFGI (UK) Limited for CFO services pursuant to which Mrs. Jones will serve as our Chief Financial Officer.

Additional Narrative Disclosure

401(k) Plan. We maintain a tax-qualified retirement plan that provides eligible U.S. employees, including our named executive officers, with an opportunity to save for retirement on a tax-advantaged basis. All participants' interests in their contributions are 100% vested when contributed. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The retirement plan is intended to qualify under Section 401(a) of the Code. We match 100 percent of employee contributions, up to 6 percent of each employee's compensation (as defined in the plan).

Health and Welfare Benefits. All of our full-time employees, including our executive officers are eligible to participate in certain medical, disability and life insurance benefit programs offered by us.

Outstanding Equity Awards at Fiscal Year-End — 2025

The following table summarizes, for each of our named executive officers, the number of ordinary shares underlying outstanding share options and share awards held as of December 31, 2025.

		Option Awards[1]					Stock Awards	
Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Shares, Units or Other Rights that have not Vested ($)
William Enright	April 29, 2021	176,130	—	—	17.00	May 1, 2031	—	—
	January 3, 2022	359,605	—	—	11.12	March 14, 2032	—	—
	January 3, 2023	293,333	146,667	—	2.40	January 3, 2033	—	—
	January 2, 2024	147,993	295,988	—	3.70	January 2, 2034	—	—
	February 3, 2025	—	600,000	—	1.00	February 3, 2035	—	—
Leon Hooftman	June 3, 2024	65,055	130,111	—	2.00	June 3, 2034	—	—
	February 3, 2025	—	140,000	—	1.00	February 3, 2034		
	October 1, 2025	—	—	—	—	—	361,530	540,487
Geoffrey Lynn	January 3, 2022	174,500	—	—	11.12	September 5, 2026	—	—
	January 3, 2023	15,590	—	—	2.40	September 5, 2026	—	—
	January 2, 2024	8,069	—	—	3.70	September 5, 2026	—	—
Gemma Jones	September 6, 2021	30,900	—	—	14.96	April 30, 2026	—	—
	January 3, 2022	7,499	—	—	11.12	April 30, 2026	—	—
	September 15, 2022	222,666	—	—	3.07	April 30, 2026	—	—
	January 3, 2023	22,066	—	—	2.40	April 30, 2026	—	—
	January 2, 2024	64,333	—	—	3.70	April 30, 2026	—	—

[1]Unless otherwise specified, each option vests in three equal annual installments, with the first such annual installment vesting upon the first anniversary of the vesting commencement date, subject to such named executive officer's continued employment as of each such date.

Policy Regarding Timing of Awards of Options and Other Like Instruments

It is the policy of our board of directors and our compensation committee to not take material non-public information into account when determining the timing of equity awards in order to take advantage of a depressed stock price or an anticipated increase in stock price. Similarly, it is our practice not to time the release of material nonpublic information based on equity award grant dates or for the purpose of affecting the value of executive compensation.

Our compensation committee generally grants annual equity awards, including stock option grants to our named executive officers, in the first quarter of each fiscal year. In addition, new hires receive stock option grants at the time of their hiring.

Equity Compensation Plan Information

The following table provides information as of December 31, 2025 with respect to our ordinary shares that may be issued under our existing equity compensation plans.

Plan Category	Equity Compensation Plan Information: Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities in first column)
Equity compensation plans approved by security holders[1][2]	5,976,157	$ 6.28	3,248,605
Equity compensation plans not approved by security holders	—	—	—
Total	5,976,157	$ 6.28	3,248,605

(1) Includes the following plans: our Share Award Plan 2021 (the "2021 Plan") and the Enterprise Management Incentive Share Option Scheme (the "EMI Plan").

(2) As of December 31, 2025, a total of 9,224,762 ordinary shares of our common stock have been reserved for issuance pursuant to the 2021 Plan. The 2021 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2025, by 4% of the outstanding number of ordinary shares on the immediately preceding December 31 or such lesser number of shares as determined by the compensation committee. This number will be subject to adjustment in the event of a share split, share dividend or other change in our capitalization. The Company no longer makes grants under the EMI Plan.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table and related footnotes set forth information with respect to the beneficial ownership of our ordinary shares, as of March 6, 2026, by:

- each beneficial owner of 5% or more of our outstanding ordinary shares;
- each of our named executive officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, ordinary shares subject to options, or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 6, 2026 are considered outstanding. These ordinary shares, however, are not included in the computation of the percentage ownership of any other person. Applicable percentage ownership is based on 40,848,893 ordinary shares outstanding as of March 6, 2026.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.
Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are in care of Barinthus Biotherapeutics plc, 20400 Century Boulevard, Suite 210, Germantown, MD 20874.

	Ordinary Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percent**
5% or Greater Shareholders:		
Oxford Science Enterprises plc[(1)]	8,797,770	21.5 %
M&G Investment Management Limited[(2)]	5,197,349	12.7 %
Frank Cawood[(3)]	3,384,513	8.3 %
Named Executive Officers and Directors:		
William Enright[(4)]	2,715,100	6.3 %
Leon Hooftman[(5)]	111,721	*
Geoffrey Lynn [(6)]	838,798	2.0 %
Gemma Jones[(7)]	347,464	*
Robin Wright[(8)]	160,295	*
Alex Hammacher[(9)]	94,645	*
Pierre A. Morgon[(10)]	122,545	*
Anne M. Philips[(11)]	94,645	*
Karen T. Dawes[(12)]	93,345	*
Joseph C. Scheeren[(13)]	114,645	*
All Executive Officers and Directors as a Group (8 persons)[14]	3,506,941	8.2 %

* Represents beneficial ownership of less than one percent.

(1) Based solely on a Schedule 13G filed with the SEC on February 11, 2022 by Oxford Science Enterprises plc. The business address for Oxford Science Enterprises plc is 46 Woodstock Road, Oxford, OX2 6HT, United Kingdom.
(2) Based solely on a Schedule 13G filed with the SEC on September 30, 2024 by M&G Investment Management Limited ("MAGIM"). The ordinary shares in the forms of ADSs are legally owned by Luxembourg Specialist Investment Fund FCP-RAIF. Luxembourg Specialist Investment Fund FCP- RAIF is advised by MAGIM. The business address for MAGIM is 10 Fenchurch Avenue, London, EC3M 5AG, UK.
(3) Based solely on a Schedule 13G filed with the SEC on February 11, 2025 by Frank W. Cawood. The business address for Frank W. Cawood is 600 Edgewater Drive, Unit 402, Dunedin, FL 34698.
(4) Consists of (a) 728,454 ordinary shares held by William J Enright TR UA Dated 03/04/2021 Enright Family 2021 Irrevocable Trust, (b) 514,923 ordinary shares held by William Enright Revocable Trust, and (c) 1,471,723 ordinary shares underlying options exercisable within 60 days of March 6, 2026. Mr. Enright is the trustee of the above referenced trusts and may be deemed to beneficially own these securities.
(5) Consists of 111,721 ordinary shares underlying options exercisable within 60 days of March 6, 2026.

(6) Consists of (a) 638,442 ordinary shares held by Dr. Lynn, (b) 2,197 ordinary shares held in an account owned by Dr. Lynn's spouse, and (c) 198,159 ordinary shares underlying options exercisable within 60 days of March 6, 2026.
(7) Consists of 347,464 ordinary shares underlying options exercisable within 60 days of March 6, 2026.
(8) Consists of (a) 48,256 ordinary shares held by Mr. Wright and (b) 112,039 ordinary shares underlying options exercisable within 60 days of March 6, 2026.
(9) Consists of (a) 3,000 ordinary shares held by Dr. Hammacher and (b) 91,645 ordinary shares underlying options exercisable within 60 days March 6, 2026.
(10) Consists of (a) 10,506 ordinary shares held by Dr. Morgon and (b) 112,039 ordinary shares underlying options exercisable within 60 days of March 6, 2026.
(11) Consists of (a) 3,000 ordinary shares held Dr. Philips and (b) 91,645 ordinary shares underlying options exercisable within 60 days of March 6, 2026.
(12) Consists of (a) 1,700 ordinary shares held by Ms. Dawes and (b) 91,645 ordinary shares underlying options exercisable within 60 days of March 6, 2026.
(13) Consists of (a) 23,000 ordinary shares held by Dr. Scheeren and (b) 91,645 ordinary shares underlying options exercisable within 60 days of March 6, 2026.
(14) Consists of (a) 1,332,839 ordinary shares and (b) 2,174,102 ordinary shares underlying options exercisable within 60 days of March 6, 2026.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Other than compensation arrangements which are described under the section titled “Executive Compensation” and the transactions described below, since January 1, 2024, there was not, and there is not currently proposed, any transaction or series of similar transactions to which we have been or are to be a party in which the amount involved exceeded, or exceeds, $120,000 and in which any director, executive officer, holder of five percent or more of any class of our capital stock, or any member of their immediate family had, or will have, a direct or indirect material interest.

License Revenue

In April 2020, we entered into the OUI License Agreement Amendment with OUI, in respect of our rights to 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 sales of Vaxzevria. We recognized $15.0 million and nil in revenue for the years ended December 31, 2024 and 2025, respectively, and were owed nil from OUI as of December 31, 2024 and 2025. In December 2025, we delivered written notice to OUI to terminate the OUI License Agreement, as amended. The agreement remained in effect during the three-month notice period and terminated in February 2026 in accordance with its terms.

Agreements with our Executive Officers

We have entered into employment agreements with certain of our executive officers. These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers and non-executive directors. The enforceability of the non-competition provisions may be limited under applicable law.

Indemnification Agreements

We have entered into a deed of indemnity with each of our directors and executive officers. These agreements and our Articles of Association require us to indemnify our directors and executive officers to the fullest extent permitted by law.

Related Party Transactions Policy

We have adopted a written related party transactions policy that provides that such transactions must be approved by our audit committee. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving “related party transactions,” which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person is defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common shares, in each case since the beginning of the most recently completed year, and their immediate family members.

Item 14. Principal Accounting Fees and Services

The table below sets forth a summary of the fees billed to us by PricewaterhouseCoopers LLP, our independent registered public accounting firm, for professional services rendered during the fiscal years ended December 31, 2025 and December 31, 2024. All such services and fees were pre-approved by the audit committee, which concluded that the provision of such services was compatible with the maintenance of each firm's independence in the conduct of its auditing functions. The amounts reported have been converted from pounds sterling to U.S. dollars using the average exchange rate for 2025 of 0.7586 to $1.00, and 2024 of £0.7826 to $1.00, respectively.

Fees	December 31, 2025 ($000)	December 31, 2024 ($000)
Audit fees (1)	810	795
Audit-related fees (2)	405	324
Tax fees (3)	—	—
All other fees (4)	2	2
Total	**1,217**	**1,121**

(1) "Audit fees" consist of fees billed for the audit of our annual consolidated financial statements, statutory audits, review of interim condensed consolidated financial statements included in quarterly reports, assistance with review of documents filed with the SEC paid to PricewaterhouseCoopers LLP in connection with statutory and regulatory filings or engagements, attest services.
(2) "Audit-related fees" consist of fees paid to PricewaterhouseCoopers LLP in connection with registration statements filed with the SEC.
(3) "Tax fees" consist of fees paid to PricewaterhouseCoopers LLP in connection with tax compliance, tax advice and tax planning. We did not pay any "tax fees" to PricewaterhouseCoopers LLP in 2025 or 2024.
(4) "All other fees" consist of non-audit fees paid to PricewaterhouseCoopers LLP for access to its financial statement disclosure checklist.

Audit Committee Pre-Approval Policy and Procedures

The audit committee has adopted a policy (the "Pre-Approval Policy") that sets forth the procedures and conditions pursuant to which audit and non-audit services proposed to be performed by the independent auditor may be pre-approved. The Pre-Approval Policy generally provides that we will not engage PricewaterhouseCoopers LLP to render any audit, audit-related, tax or permissible non-audit service unless the service is either (i) explicitly approved by the audit committee ("specific pre-approval") or (ii) entered into pursuant to the pre-approval policies and procedures described in the Pre-Approval Policy ("general pre-approval"). Unless a type of service to be provided by PricewaterhouseCoopers LLP has received general pre-approval under the Pre-Approval Policy, it requires specific pre-approval by the audit committee. Any proposed services exceeding pre-approved cost levels or budgeted amounts will also require specific pre-approval. For both types of pre-approval, the audit committee will consider whether such services are consistent with the SEC's rules on auditor independence. On an annual basis, the audit committee reviews and generally pre-approves the services (and related fee levels or budgeted amounts) that may be provided by PricewaterhouseCoopers LLP without first obtaining specific pre-approval from the audit committee. The audit committee may revise the list of general pre-approved services from time to time, based on subsequent determinations.

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 Current 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 our Quarterly Report on Form 10-Q (File No. 001-40367), filed on August 9, 2022).
2.4**	Merger Agreement, dated as of September 29, 2025, by and among the Registrant, Topco Merger Sub, and Clywedog (Incorporated herein by reference to Exhibit 2.1 to our Current Report on Form 8-K (File No. 001-40367) filed on September 30, 2025).
2.5	Merger Agreement Amendment, dated as February 22, 2026, by and among the Registrant, Topco, Merger Sub and Clywedog, (Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K (File No. filed No. 001-40367) filed on February 23, 2026).
3.1	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 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).
10.5#	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).
10.6#**	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).
10.7	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).
10.8	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).
10.9**	Lease Agreement by and between Barinthus Biotherapeutics North America, Inc. and ARE-Maryland No. 52, LLC, dated as of June 14, 2022.
10.10#	Service Agreement with Leon Hooftman, effective February 21, 2024 (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q (File No. 001-40367) filed on November 6, 2024).
10.11#	Service Agreement with Geoffrey Lynn, effective December 1, 2024 (Incorporated by reference to Exhibit 10.17 to our Annual Report on Form 10-K (File No. 001-40367) filed on March 20 2025).
10.12#	Termination Agreement with Nadege Pelletier, effective January 27, 2025 (Incorporated by reference to Exhibit 10.18 to our Annual Report on Form 10-K (File No. 001-40367) filed on March 20, 2025).
19.1	Amended and Restated Insider Trading Policy, effective June 21, 2023 (Incorporated by reference to Exhibit 19.1 to our Annual Report on Form 10-K (File No. 001-40367) filed on March 30, 2025).
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.
97.1	Amended and Restated Compensation Recovery Policy (Incorporated by reference to Exhibit 97.1 to our Annual Report on Form 10-K (File No. 001-40367) filed on March 30, 2025).
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(a)(5) 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 certification furnished in Exhibit 32.1 hereto is 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 13, 2026

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 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 attorney-in-fact and agent 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 attorney-in-fact and agent, or his 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 and Principal Financial Officer)	March 13, 2026
/s/ Gemma Jones Gemma Jones	Chief Financial Officer (Principal Accounting Officer)	March 13, 2026
/s/ Robin Wright Robin Wright	Chairman and Director	March 13, 2026
/s/ Alex Hammacher Alex Hammacher	Director	March 13, 2026
/s/ Pierre A. Morgon Pierre A. Morgon	Director	March 13, 2026
/s/ Anne M. Phillips Anne M. Phillips	Director	March 13, 2026
/s/ Karen T. Dawes Karen T. Dawes	Director	March 13, 2026
/s/ Joseph C. Scheeren Joseph C. Scheeren	Director	March 13, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders 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, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and 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, 2025 and 2024, 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 audits 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 13, 2026

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, 2025	As of December 31, 2024
ASSETS		
Cash and cash equivalents	$ 70,456	$ 110,662
Restricted cash	1,396	1,738
Research and development incentives receivable	1,108	7,139
Prepaid expenses and other current assets	4,830	6,203
Total current assets	77,790	125,742
Property and equipment, net	3,523	7,373
Intangible assets, net	14,288	21,947
Right of use assets, net	1,638	4,384
Other assets	930	881
Total assets	$ 98,169	$ 160,327
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 350	$ 2,474
Accrued expenses and other current liabilities	6,249	9,525
Deferred income	1,396	1,738
Operating lease liability - current	2,023	1,920
Total current liabilities	10,018	15,657
Non-current liabilities:		
Operating lease liability - non-current	9,258	10,087
Contingent consideration	2,871	2,650
Other non-current liabilities	1,476	1,360
Deferred tax liability, net	254	438
Total liabilities	$ 23,877	$ 30,192
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Ordinary shares, £0.000025 nominal value; 40,848,893 shares authorized, issued and outstanding (December 31, 2024: authorized, issued and outstanding: 40,234,663)	1	1
Deferred A shares, £1 nominal value; 63,443 shares authorized, issued and outstanding (December 31, 2024: authorized, issued and outstanding: 63,443)	86	86
Additional paid-in capital	393,944	393,474
Accumulated deficit	(304,092)	(237,664)
Accumulated other comprehensive loss – foreign currency translation adjustments	(15,731)	(25,868)
Total stockholders' equity attributable to Barinthus Biotherapeutics plc shareholders	74,208	130,029
Noncontrolling interest	84	106
Total stockholders' equity	$ 74,292	$ 130,135
Total liabilities and stockholders' equity	$ 98,169	$ 160,327

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, 2025	December 31, 2024
License revenue [1]	$ —	$ 14,969
Total revenue	—	14,969
Operating expenses		
Research and development	25,564	42,236
General and administrative	40,830	29,670
Impairment of intangible assets	4,667	—
Goodwill impairment	—	12,209
Total operating expenses	71,061	84,115
Other operating income	506	1,176
Loss from operations	(70,555)	(67,970)
Other income/(expense):		
Interest income	1,957	2,678
Interest expense	(51)	(53)
Research and development incentives	2,000	3,983
Other income	16	135
Total other income, net	3,922	6,743
Loss before income tax	(66,633)	(61,227)
Tax benefit	175	44
Net loss	(66,458)	(61,183)
Net loss attributable to noncontrolling interest	30	109
Net loss attributable to Barinthus Biotherapeutics plc shareholders	(66,428)	(61,074)
Weighted-average ordinary shares outstanding, basic	40,527,218	39,348,240
Weighted-average ordinary shares outstanding, diluted	40,527,218	39,348,240
Net loss per share attributable to ordinary shareholders, basic	$ (1.64)	$ (1.55)
Net loss per share attributable to ordinary shareholders, diluted	$ (1.64)	$ (1.55)
Net loss	$ (66,458)	$ (61,183)
Other comprehensive gain/(loss) – foreign currency translation adjustments	10,145	(2,549)
Comprehensive loss	(56,313)	(63,732)
Comprehensive loss/(gain) attributable to noncontrolling interest	22	105
Comprehensive loss attributable to Barinthus Biotherapeutics plc shareholders	$ (56,291)	$ (63,627)

[1] All license revenue is from related parties and is generated in the U.K. for the year ended December 31, 2024.

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, 2025									
	Ordinary Shares		Deferred A Shares							
	Shares	Amount	Shares	Amount	Additional Paid-in-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total stockholders' equity attributable to Barinthus Biotherapeutics plc stockholders	Noncontrolling Interest	Total Stockholders' Equity
Balance, January 1, 2025	**40,234,663**	**$ 1**	**63,443**	**$ 86**	**$ 393,474**	**$ (237,664)**	**$ (25,868)**	**$ 130,029**	**$ 106**	**$ 130,135**
Share based compensation	—	—	—	—	468	—	—	468	—	468
Issue of ordinary shares, net of issuance costs	614,230	0 [1]	—	—	2	—	—	2	—	2
Foreign currency translation adjustments	—	—	—	—	—	—	10,137	10,137	8	10,145
Net loss	—	—	—	—	—	(66,428)	—	(66,428)	(30)	(66,458)
Balance, December 31, 2025	**40,848,893**	**$ 1**	**63,443**	**$ 86**	**$ 393,944**	**$ (304,092)**	**$ (15,731)**	**$ 74,208**	**$ 84**	**$ 74,292**

	Year ended December 31, 2024									
	Ordinary Shares		Deferred A Shares							
	Shares	Amount	Shares	Amount	Additional Paid-in-Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total stockholders' equity attributable to Barinthus Biotherapeutics plc stockholders	Noncontrolling Interest	Total Stockholders' Equity
Balance, January 1, 2024	**38,643,540**	**$ 1**	**63,443**	**$ 86**	**$ 386,602**	**$ (176,590)**	**$ (23,315)**	**$ 186,784**	**$ 211**	**$ 186,995**
Share based compensation	—	—	—	—	4,709	—	—	4,709	—	4,709
Issue of ordinary shares, net of issuance costs	1,591,123	0 [1]	—	—	2,163	—	—	2,163	—	2,163
Foreign currency translation adjustments	—	—	—	—	—	—	(2,553)	(2,553)	4	(2,549)
Net loss	—	—	—	—	—	(61,074)	—	(61,074)	(109)	(61,183)
Balance, December 31, 2024	**40,234,663**	**$ 1**	**63,443**	**$ 86**	**$ 393,474**	**$ (237,664)**	**$ (25,868)**	**$ 130,029**	**$ 106**	**$ 130,135**

[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, 2025	December 31, 2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (66,458)	$ (61,183)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	468	4,709
Impairment of long-lived assets	5,794	5,260
Impairment of goodwill	—	12,209
Depreciation and amortization	5,845	5,800
Non-cash lease expenses	3,332	1,443
Unrealized foreign exchange loss	3,742	(649)
Change in contingent consideration	26	866
Non-cash interest expense	51	48
Deferred tax benefit	(175)	(44)
Profit on sale of property and equipment	(245)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,704	3,643
Research and development incentives receivable	6,417	(2,345)
Accounts payable	(2,202)	898
Accrued expenses and other current liabilities	(3,793)	456
Deferred income	(506)	1,738
Operating lease liabilities	(1,979)	(1,789)
Net cash used in operating activities	$ (47,979)	$ (28,940)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of property and equipment	453	—
Purchases of property and equipment	(37)	(892)
Net cash provided by/(used) in investing activities	$ 416	$ (892)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issue of shares from the exercise of stock options	2	0 [1]
Proceeds from issue of ordinary shares, net of issuance costs	—	2,163
Net cash provided by financing activities	$ 2	$ 2,163
Effect of exchange rates on cash, cash equivalents and restricted cash	7,013	(2,021)
Net decrease in cash, cash equivalents and restricted cash	(40,548)	(29,690)
Cash, cash equivalents and restricted cash, beginning of the period	112,400	142,090
Cash, cash equivalents and restricted cash, end of the period	$ 71,852	$ 112,400

[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 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, Barinthus Biotherapeutics North America, Vaccitech Oncology Limited ("VOLT"), Barinthus Biotherapeutics Pty Limited, Barinthus Biotherapeutics Switzerland GmbH are collectively referred to as the "Company" or "Barinthus Bio". During the quarterly period ended September 30 2025, the Company incorporated two new subsidiaries, Beacon Topco, Inc. ("Topco") and Cdog Merger Sub, Inc. ("Merger Sub"), for the purpose of the transactions contemplated by the recently announced merger agreement with Clywedog Therapeutics, Inc. ("Clywedog"). These entities are not material to the Company's consolidated financial position or results of operations.

The Company is a clinical-stage biopharmaceutical company focused on developing novel immunotherapeutic drug candidates for treating autoimmune and inflammatory diseases within the immunology and inflammation ("I&I") space enabled by the proprietary and highly differentiated platform for promoting immune tolerance, referred to as SNAP-TI. The Company's lead candidate, VTP-1000, is designed to restore immune non-responsiveness to gluten in patients with celiac disease, and is currently being assessed in a Phase 1 clinical trial. The Company occupies laboratory and office space in Germantown, Maryland, United States.

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 that are also 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 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.

Merger Agreement with Clywedog

On September 29, 2025, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among the Company, Topco, Merger Sub and Clywedog. The Merger Agreement provides that, among other things, upon the terms and subject to the conditions set forth therein: (i) Topco will acquire the entire issued and to be issued share capital of the Company pursuant to a scheme of arrangement (subject to any modification, addition or condition which (a) the Company, Topco and Clywedog mutually agree and which (if required) is approved by the High Court of Justice of England and Wales (the "Court") or (b) is otherwise imposed by the Court and mutually acceptable to the Company, Topco and Clywedog, each acting reasonably and in good faith, in each case in accordance with the Part 26 of the United Kingdom Companies Act 2006 and the Merger Agreement (the "Scheme of Arrangement" and such transaction, the "Scheme Transaction")), resulting in the Company becoming a direct wholly owned subsidiary of Topco, and (ii) Merger Sub will merge with and into Clywedog, with Clywedog continuing as the surviving corporation and a direct wholly owned subsidiary of Topco in accordance with the Delaware General Corporations Law (the "Merger" and, together with the Scheme Transaction, the "Combinations", and, together with such other transactions contemplated by the Merger Agreement, the "Contemplated Transactions"). The Scheme Transaction will be consummated prior to the Merger.

At the effective time of the Scheme Transaction (the "Scheme Effective Time"), upon the terms and subject to the conditions set forth in the Merger Agreement, Topco will acquire each outstanding ordinary share of the Company, with a par value £0.000025 per ordinary share (each such acquired ordinary share, a "Scheme Share"), which, for the avoidance of doubt, will include ordinary shares held by The Bank of New York Mellon (the "Depositary") (or to the extent that the Depositary is not itself the registered holder of such shares that underly the Company's American Depositary Shares (the "ADSs"), each representing one (1) ordinary share, whichever nominee, custodian or other entity is the registered holder under the terms of the Deposit Agreement, dated as of April 29, 2021, among the Company, the Depositary, and all holders from time to time of the ADSs, as may be amended from time to time), from the holders of Scheme Shares whose names appear in the register of members of the Company at the Scheme Effective Time) in accordance with the provisions of the

BARINTHUS BIOTHERAPEUTICS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Scheme of Arrangement, and each Scheme Share will be converted into the right to receive (i) one (1) share of common stock, 0.0001 par value per share, of Topco (the "Topco Common Stock") subject to and strictly in accordance with the terms of the Scheme of Arrangement plus (ii) cash in lieu of any fractional shares, rounded down to the nearest whole share. Following the Scheme Effective Time, Topco may in its discretion elect to commence a self-tender offer ("Self-Tender Offer") to purchase up to $27.0 million in shares of Topco Common Stock then issued and outstanding, which Self-Tender Offer, if elected, will be consummated prior to the Merger.

At the effective time of the Merger (the "Merger Effective Time"), subject to adjustment in accordance with the terms of the Merger Agreement, each share of common stock, $0.0001 par value per share, of Clywedog (the "Clywedog Common Stock") and each share of Series Seed Preferred Stock, $0.0001 par value per share, of Clywedog (the "Clywedog Preferred Stock", and together with the Clywedog Common Stock, the "Clywedog Capital Stock"), other than Clywedog Capital Stock held as treasury stock or owned by Topco or Merger Sub immediately prior to the Merger Effective Time, will be converted solely into the right to receive (i) 4.358932 of shares of Topco Common Stock rounded down to the nearest whole share plus (ii) cash in lieu of any fractional shares.

The closing of the Contemplated Transactions is subject to the satisfaction or waiver of certain customary conditions, including, among other things: (i) the effectiveness of a registration statement (the "Registration Statement") to register the shares of Topco Common Stock to be issued in connection with the Combinations; (ii) approvals by the Company's shareholders of the Scheme Transaction and certain related matters, and sanction by the Court of the Scheme Transaction; (iii) approval by Clywedog's stockholders of the Merger Agreement, the Merger and Contemplated Transactions; (iv) the approval for listing by the Nasdaq Stock Market of the shares of Topco Common Stock issuable in the Combinations, subject to official notice of issuance; (v) the completion of the Self-Tender Offer to the extent that Topco elects to commence the Self-Tender Offer; (ivi) minimum cash requirements for each party.

The Merger Agreement may be terminated and the transactions contemplated thereby abandoned at any time prior to the closing under certain specified circumstances. Either the Company or Clywedog may terminate the Merger Agreement if, among other things: (i) the closing date will not have occurred by September 30, 2026, subject to up to a 60 day extension if the U.S. Securities and Exchange Commission (the "SEC") has not declared effective the Registration Statement by July 31, 2026, (ii) a governmental authority of competent jurisdiction has issued a final, non-appealable order prohibiting the Contemplated Transactions, (iii) the required Company shareholder approval or Clywedog shareholder approval is not obtained in accordance with the Merger Agreement, (iv) the Scheme of Arrangement is not sanctioned by the Court, or (v) another party breaches or fails to perform in any material respect any of its covenants or any of the other party's representations or warranties are inaccurate and such breach, failure to perform or inaccuracy would result in certain of the closing conditions not being satisfied, subject to a cure period.

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, 2025, the Company had cash, cash equivalents and restricted cash of $71.9 million and an accumulated deficit of $304.1 million and the Company expects to incur losses for the foreseeable future as it continues to pursue its activities, including the commercialization of its research and development. The Company expects to continue to incur costs and expenditures in connection with the Contemplated Transactions, further in connection with the Contemplated Transactions Barinthus may pay up to $27.0 million to existing shareholders under a Self Tender offer. If the Contemplated Transactions are consummated, any additional funding will be sought by the combined company. However as the transaction is not yet consummated, when performing the going concern assessment, management have assessed the Company on a standalone basis and expects that its cash, cash equivalents and restricted cash will be sufficient to fund current operations for at least the next 12 months from the issuance of the consolidated financial statements. In the future the Company will need additional cash inflows to pursue its activities, including the commercialization of its research and

development. There is no assurance that the Company will be successful in obtaining sufficient cash inflows 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, 2025 and 2024, 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.

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.

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 income and expenses during the reporting period. The Company bases its 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. The Company's actual results may differ from these estimates under different assumptions or conditions.

During the current year, the Company updated certain estimates related to the carrying value of long-lived assets as a result of the announced Contemplated Transactions with Clywedog. The adjustment reflects updated assumptions regarding expected future cash flows and market participant perspectives. Additional information regarding this change in estimate and its impact on the financial statements is included in Note 7.

As of the date of issuance of these consolidated financial statements, the Company is not aware of any other 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.

Comprehensive loss

Comprehensive loss for all periods presented is comprised primarily of net loss 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

general and administrative expenses. The aggregate net foreign exchange gain or loss included in determining net loss was a loss of $9.6 million and gain of $2.4 million for the years ended December 31, 2025 and 2024, respectively.

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 subsequent financial years. 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.

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, 2025, and 2024 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.

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 are generally recognized as accounts receivable or contract assets.

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 at their standalone selling prices, 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 free 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.

Other Operating Income

Other operating income includes grant income from the CEPI Funding Agreement pursuant to which CEPI will provide funding to us to advance the development of VTP-500, a vaccine candidate against MERS. When there is reasonable assurance that we 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 we recognize expenses for the related costs for which the grants are intended to compensate. Payments received in advance of incurring reimbursable expenses are recorded as deferred income. Any remaining unused amounts of the cash payments received will be disclosed as restricted cash in the consolidated balance sheets.

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 typically 30 days.

The Company recognizes revenue earned in connection with the license and services provided to customers. The Company provides credit to licensees 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 licensees. Historically, the Company has not experienced any credit losses related to accounts receivable and does not maintain allowances for uncollectible amounts.

Licensees that represented 10% or more of the Company's revenue are presented below:

Revenue	Country	Year ended December 31, 2025	Year ended December 31, 2024
Oxford University Innovation	U.K.	— %	100 %

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 and accumulated impairment losses. Expenditures for maintenance and repairs are charged to operating expenses as incurred, whereas major betterments are capitalized as additions to property and equipment. Impairment losses are recorded within general and administrative expenses. 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

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. There were impairments recorded during the year ended December 31, 2025 and 2024.

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 and measures the amount of goodwill impairment loss, if any, 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, if the fair value is less than the carrying amount, the difference is recognized as a goodwill impairment loss not to exceed the carrying amount of the goodwill. The carrying amount of goodwill was nil at December 31, 2024 . The Company has performed the annual impairment assessment and identified qualitative indicators of impairment, most notably the share price drop in November 2024, including the lack of recovery thereof, and the strategic considerations to partner VTP-300 for future clinical development. Therefore, the Company performed a qualitative impairment assessment and determined that it was more likely than not that the fair value of the reporting unit is less than its carrying amount. The reporting unit comprises the net assets of the Company. The Company then performed a quantitative impairment assessment using the income approach to determine the fair value of the reporting unit, including the net present value of clinical stage assets and overhead costs. Based on the quantitative assessment, the Company determined that the fair value of the reporting unit is less than its carrying amount as of December 31, 2024, and, as a result, recognized a goodwill impairment charge of $12.2 million. For the year ended December 31, 2025 there was no impairment charge to Goodwill (December 31, 2024: $12.2 million).

Financial instruments

The Company's financial instruments consist of cash, cash equivalents, restricted cash, accounts receivable, accounts payable, certain accrued expenses and contingent consideration. The carrying amounts of cash, cash equivalents, accounts receivable, security deposits, accounts payable and accrued expenses 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, 2025 and 2024.

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 accrual 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 there is uncertainty as to any future economic benefits arising from these costs.

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 and comprehensive loss 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 the Company's ordinary shares was estimated using the average historical volatility of industry peers' shares as of the grant date of the Company's 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. For options granted since 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 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 U.K. 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 U.K., 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 (“SME”),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. For the year ended December 31, 2025, we benefit from the applicable United Kingdom research and development tax credit regime which is the merged scheme Research & Development expenditure credit ("RDEC") and enhanced R&D intensive support ("ERIS") that replaces the prior schemes. 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. For expenditure under the merged RDEC scheme, the rate of Research and Development expenditure credit will is 20%, which is the same as the rate under the old RDEC scheme for expenditure incurred on or after April 1, 2023. For loss-makers and small profit-makers, a lower rate of notional tax restriction (currently 19%) applies at payment. Under both the merged RDEC scheme and the prior SME program, a company qualifies as an R&D intensive business if R&D expenditure constitutes at least 30% of total expenditure. From the analysis performed, the Company has not and do not currently expect to claim under the loss-making R&D intensive scheme primarily due to the proportion of total relevant expenditure occurring outside the U.K. 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, 2025 and 2024, the Company recognized research and development incentives of $2.0 million and $4.0 million respectively.

Net loss per share

Basic net loss per share is computed by dividing the net loss 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 attributable to ordinary shareholders is computed as if all net loss 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 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 per share is computed by dividing the net loss 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, 2025, 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

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("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 application 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.

The Company has reviewed all recently issued standards and have determined that such standards do not or are not expected to have a material impact on its condensed consolidated financial statements or do not otherwise apply to its current operations.

In December 2025, the FASB issued ASU 2025-12, Accounting Standards Update Codification Improvements. The amendments in this update facilitates codification updates for a broad range of Topics arising from technical corrections, unintended application of the codification, clarifications, and other minor improvements. This standard is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. The Company is currently evaluating the impact of adopting this standard to determine its impact on its disclosures.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements. The amendments in this update clarify interim disclosure requirements and the applicability of Topic 270. This standard is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact of adopting this standard to determine its impact on its disclosures.

In May 2025, the FASB issued ASU 2025-03, Business Combinations (Topic 805): Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity. This ASU amends the guidance for identifying the accounting acquirer in transactions involving variable interest entities ("VIEs") where the transaction is achieved primarily through the exchange of equity interests, aligning it more closely with the guidance for voting interest entities. The amendments are effective for

fiscal years beginning after December 15, 2026, including interim periods within those fiscal years, with early adoption permitted. The Company elected to early adopt ASU 2025-03 as of July 1, 2025. The adoption did not have a material impact on the consolidated financial statements. The Company will apply the amended guidance prospectively to applicable transactions.

In January 2025, the FASB issued ASU 2025-01, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date, in which the Board's intent in the basis of conclusion of Update 2024-03 is clear that all public business entities should initially adopt the disclosure requirements in the first annual reporting period beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact of adopting this standard to determine its impact on its disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40), which requires disaggregation of specific expense categories in the notes to the financial statements and a qualitative description of the remaining expense amounts not separately disaggregated. This standard is effective for annual reporting periods beginning after December 15, 2026, and requires prospective application with the option to apply it retrospectively. The Company is currently evaluating the impact of adopting this standard to determine its impact on its disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires that public business entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). This standard is effective for fiscal years beginning after December 15, 2024. The Company has retrospectively adopted the ASU and the adoption did not have a material impact on the consolidated financial statements.

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3. 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 ("CODM"), the Company's Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The CODM approves key operating and strategic decisions, including key decisions in clinical development and clinical operating activities, entering into significant contracts and approves the Company's consolidated operating budget. The Company views its operations and manages its business as one operating segment, the research and development of immunotherapies and vaccines. The CODM uses loss before income tax to monitor budget versus actual results and decide how to use the Company's resources. As the Company operates in one operating segment, all required financial segment information can be found in these consolidated financial statements. The following table is a summary of the Company's significant segment expenses:

	Year ended December 31, 2025	Year ended December 31, 2024
Direct research and development expenses:		
VTP-1000 Celiac	$ 6,063	$ 5,486
Barinthus legacy assets[1]	8,531	18,223
Total direct research and development expenses	$ 14,594	$ 23,709
Indirect research and development expenses:		
Personnel-related (including share-based compensation)	8,413	15,867
Facility related	1,370	1,249
Other indirect costs	1,187	1,411
Total indirect research and development expenses	10,970	18,527
Total research and development expenses	$ 25,564	$ 42,236

[1] *In January 2025, we announced a strategic focus on developing a pipeline in I&I, and the deprioritization of our programs in infectious disease and oncology. The following programs were previously presented separately and have been grouped collectively as "Barinthus Legacy Assets" for both years presented: VTP-300 HBV, VTP-850 Prostate Cancer, VTP-200 HPV, VTP-600 NSCLC, VTP-500 MERS and other and earlier stage programs.*

The Company operates in two geographic regions: the U.S. and the U.K. The following table summarizes the Company's long-lived assets, which include the Company's intangible assets, property and equipment, net and right-of-use assets by geography:

	Year ended December 31, 2025	Year ended December 31, 2024
United States	$ 19,449	$ 28,907
United Kingdom	—	4,797
	$ 19,449	$ 33,704

4. Foreign Currency Translation in General and Administrative Expenses

The aggregate, net foreign exchange gain or loss recognized in general and administrative expenses for the year ended December 31, 2025, and 2024, was a loss of $9.6 million and a gain of $2.4 million, respectively.

5. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share for the years ended December 31, 2025 and 2024 (in thousands, except number of shares and per share amounts):

	Year Ended December 31,	
Numerator:	2025	2024
Net loss	$ (66,458)	$ (61,183)
Net loss attributable to noncontrolling interest	30	109
Net loss attributable to Barinthus Biotherapeutics plc shareholders	$ (66,428)	$ (61,074)
Denominator:		
Weighted-average ordinary shares outstanding, basic	40,527,218	39,348,240
Weighted-average ordinary shares outstanding, diluted	40,527,218	39,348,240
Net loss per share attributable to ordinary shareholders, basic	$ (1.64)	$ (1.55)
Net loss per share attributable to ordinary shareholders, diluted	$ (1.64)	$ (1.55)

Since the Company was in a loss position for all periods presented, 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, 2025, 5,976,157 (December 31, 2024: 7,285,275) 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.

6. Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	December 31, 2025	December 31, 2024
Office furniture and equipment	$ 452	$ 1,333
Laboratory equipment	1,752	6,178
Leasehold improvements	8,910	9,282
Property and equipment, at cost	11,114	16,793
Less: accumulated depreciation and impairment charges	(7,591)	(9,420)
Property and equipment, net	$ 3,523	$ 7,373

Depreciation expense for the year ended December 31, 2025 was $2.9 million (December 31, 2024: $2.6 million).

For the year ended December 31, 2025 and 2024, the Company recorded a gain of $0.2 million and nil, respectively, from the sale of U.K. laboratory equipment. The recorded associated proceeds from the equipment sale for the year ended December 31, 2025 and 2024 was $0.5 million and nil, respectively).

The Company identified circumstances that could indicate that the carrying amount of leasehold improvements located in the U.S. and the U.S. operating lease right-of-use asset may not be recoverable as of December 31, 2025, as it was more likely than not that the Company would cease to utilize some of the laboratory and office space in Germantown, Maryland in 2026, before the end of the previously estimated useful lives. The Company performed an impairment assessment of the leasehold improvements within the U.S. asset group using the income approach as of December 31, 2025 and recorded an impairment charge within general and administrative expenses of $0.7 million (December 31, 2024: U.K. property and equipment impairment $2.7 million) to write down assets to their estimated recoverable amount. The impairment charge is subject to a number of assumptions and actual results may differ. The Company will continue to refine these assumptions as additional information becomes available. The significant assumptions used in determining the estimated fair value of the leasehold improvements located in the U.S. included how much floor space would be relinquished during sub-leasing. Significant changes in these inputs could have a material effect on the fair value measurement. See Note 16 Commitments and Contingencies for details of the impairment assessment performed over the U.S. operating lease right-of-use asset, which is part of the U.S. asset group.

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7. Intangible Assets, Net

The gross amount of amortizable intangible assets, consisting of acquired developed technology, was $31.6 million at both December 31, 2025 and 2024 and accumulated amortization was $17.3 million and $9.7 million as of December 31, 2025 and 2024, respectively. The amortization expense for the year ended December 31, 2025 was $3.0 million (December 31, 2024: $3.2 million). The estimated annual amortization expense is $2.5 million for the years 2026 through to 2031.

During the quarter ended September 30, 2025, the Company announced it had entered into a definitive merger agreement to combine in an all-stock transaction with Clywedog. The indicative offer price was below fair value of the Company's net assets expected at completion and below prior valuations utilized in our most recent impairment assessments, thereby constituting an impairment triggering event. As a result, the Company recorded a total impairment charge for acquired development technology intangible assets of $4.7 million during the third quarter of 2025. The determination of the fair value of the Company's net assets expected at completion is a non-recurring fair value measurement. Subsequently, we reviewed through to December 31, 2025, for additional indicators of impairment and did not identify any additional impairment triggers nor was any additional impairment expense recorded.

8. Prepaid and Other Current Assets

Prepaid and other current assets consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Prepayments	$ 4,518	$ 5,859
Value Added Tax receivable	197	—
Other	115	344
Total	$ 4,830	$ 6,203

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued manufacturing and clinical expenses	$ 1,786	$ 3,326
Value Added Tax payable	—	2,416
Accrued bonus	—	1,774
Accrued payroll and employee benefits	245	656
Accrued professional fees	3,677	737
Accrued other	541	616
Total	$ 6,249	$ 9,525

10. Grant Income

Coalition for Epidemic Preparedness Innovations ("CEPI") Funding Agreement

On December 20, 2023, Barinthus Biotherapeutics (UK) Limited, the Chancellors, Masters and Scholars of the University of Oxford ("Oxford," together with Barinthus Biotherapeutics (UK) Limited, the "Partners") and the Coalition for Epidemic Preparedness Innovations ("CEPI") entered into a Funding Agreement (the "Funding Agreement") pursuant to which CEPI would provide funding of up to $34.8 million to the Company to advance the development of VTP-500, a 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. There have been no changes to the terms or conditions of the grant since the previous reporting period.
In January 2025, the Company announced its strategic focus on developing a pipeline in I&I, and the deprioritization of its programs in infectious disease and oncology. The Company intends to exit the Funding Agreement as part of aligning resources in accordance with the Company's strategy.

For the year ended December 31, 2025, nil (December 31, 2024: $3.0 million) proceeds have been received. For the year ended December 31, 2025 $0.4 million (December 31,2024: $1.2 million) income has been recognized in relation to this contract. This is presented as other operating income in the consolidated statements of operations and comprehensive loss.

The Funding Agreement cash payments are restricted as to the use and management of the funds. The remaining unused amounts of the Funding Agreement cash payments of $1.4 million as of December 31, 2025 (December 31, 2024: $1.7 million), are reflected in restricted cash in the consolidated balance sheets until expenditures contemplated in the Funding Agreement are incurred.

Deferred income

Deferred income relates to payments received from CEPI in advance of the eligible research and development expenses being incurred and is disclosed as deferred income separately in the consolidated balance sheets. Deferred income is released to the consolidated statements of operations and comprehensive loss in the period in which such research and development activities are actually performed in a manner that satisfies the conditions of the Funding Agreement.

Changes in deferred income during the years ended December 31, 2025 and 2024, are as follows (in thousands):

	December 31, 2025	December 31, 2024
Beginning balance	$ 1,738	$ —
Cash payments received	—	2,989
Other operating income recognized related to the Funding Agreement	(435)	(1,176)
Foreign exchange translation	93	(75)
Ending balance	$ 1,396	$ 1,738

11. Ordinary Shares

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, 2025:

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: The Company may, subject to the provisions of the Companies Act 2006 and its Articles, by ordinary resolution from time to time declare dividends to be paid to shareholders not exceeding the amount recommended by the Company's board of directors. Subject to the provisions of the Companies Act 2006, insofar as, in the board of directors' opinions, the Company's profits justify such payments, the board of directors (the "Board") may pay interim dividends on the Company's ordinary shares.

Voting Rights: Each holder of ordinary shares has the right to receive notice of, and to vote at, the Company's general meetings. Each holder of ordinary shares who is present (in person or by proxy) at a general meeting on a show of hands has one vote and, on a poll, every such holder who is present (in person or by proxy) has one vote in respect of for each share of which they are the holder.

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 under the Articles, for shareholders at a general meeting representing at least 75% of the Company's ordinary shares present (in person or by proxy) and eligible to vote at that general meeting, to disapply these preemptive rights by passing a special resolution. Such a disapplication of preemption rights may be for a maximum period of up to five years from the date on which the shareholder resolution was passed. In either case, this disapplication would need to be renewed by the Company's shareholders upon its expiration (*i.e.*, at least every five years) to remain effective.

On April 21, 2021, the Company's 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 shareholders. This included the disapplication of preemption rights in relation to the allotment of the Company's ordinary shares in connection with the initial public offering ("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, the Company held a general meeting where its shareholders approved resolutions granting the Board or any duly authorized committee of the Board 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 pre-emption rights. Pursuant to such approval, the Board was authorized to allot shares up to an aggregate nominal amount of £1,928 free from statutory pre-emption rights. The granting of this authority and the corresponding disapplication of preemptive rights was in addition to all subsisting authorities. 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).

As of December 31, 2025, the Company has reserved the following ordinary shares for future issuance:

Exercise of stock options	5,976,157
Shares available for future stock incentive plan awards	3,248,605
Total	9,224,762

12. Deferred Shares

All deferred shares rank pari passu as a single class. The deferred shares do not have rights to dividends or to any other rights of participation in the profits of the Company. 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 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.

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.

13. Fair Value

The Company's financial instruments consist of cash, cash equivalents and restricted cash, accounts payable, certain accrued expenses, and contingent consideration. The carrying amounts of cash, cash equivalents and restricted cash, accounts payable, and accrued expenses approximated their respective fair value due to the short-term nature and maturity of these instruments.

As of December 31, 2025, the Company had a contingent consideration liability of $2.9 million related to the acquisition of Avidea. 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 American Depositary Shares, upon the achievement of certain milestones. To date, the Company has made settlement payments of $0.5 million. The fair value of the contingent consideration is a Level 3 valuation and determined using the cost approach. The significant unobservable inputs used in the fair value measurement of the contingent consideration are 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. Significant increases (decreases) in the probability of success of achievement of the milestones would have resulted in a significantly higher (lower) fair value measurement. Significant extension (reduction) in the expected date of the milestone achievement would have resulted in a significantly lower (higher) fair value measurement.

The following table summarizes changes to the Company's financial instruments carried at fair value and classified within Level 3 of the fair value hierarchy (in thousands):

	December 31, 2025	December 31, 2024
Beginning balance	$ 2,650	$ 1,823
Change in fair value recognized in net loss	26	866
Foreign exchange translation recognized in other comprehensive loss	195	(39)
Ending balance	$ 2,871	$ 2,650

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 2022, 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 1,609,386 as of January 1, 2025. 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, 2025 and 2024, 3,248,605 and 1,906,080 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.

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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,	
	2025	2024
Expected volatility	114.07 %	108.73 %
Expected term (years)	6	6
Risk-free interest rate	4.4 %	4.0 %
Expected dividend yield	— %	— %

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. For options granted in and after 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, 2025	7,285,275	$ 5.76	7.61	$ 942
Granted	1,470,812	1.00		
Exercised	(614,230)	0.00010		
Forfeited/expired	(2,165,700)	2.74		
Outstanding, December 31, 2025	5,976,157	$ 6.28	2.28	$ 37
Exercisable, December 31, 2025	4,351,787	$ 7.94	1.81	$ 37

The weighted-average grant date per-share fair value of stock options granted during the year ended December 31, 2025 was $0.85 per share (December 31, 2024: $2.66 per share). The aggregate intrinsic value of stock options exercised during the year ended December 31, 2025 was $0.2 million (December 31, 2024: $0.4 million). As of December 31, 2025, there was $0.6 million (2024: $3.1 million) of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 1.42 years (2024: 1.46 years).

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Restricted stock units:

The following table summarizes the Company's restricted stock units ('RSUs") under the Plan since December 31, 2025:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, January 1, 2025	—	$ —
Granted	886,018	1.50
Vested and settled	—	—
Vested and deferred	—	—
Forfeited	(21,294)	1.50
Unvested outstanding, December 31, 2025	864,724	1.50
Vested but subject to deferred settlement at December 31, 2025	—	$ —
Outstanding at December 31, 2025	864,724	$ 1.50

In October 2025, the Company granted an aggregate of 886,018 restricted stock units (“RSUs”) to employees under the Plan. The RSUs will vest in full on the seventh day following the occurrence of either the closing of the Contemplated Transactions or the termination of the Merger Agreement pursuant to its terms, subject to the employee’s continued employment with the Company through such vesting date, and were granted as part of the Company’s equity incentive program to support employee retention and alignment with shareholder interests. The grant date fair value of the RSUs was $1.3 million.

Total share-based compensation expense for RSUs granted for the years ended December 31, 2025 and 2024 was $0.5 million and nil, respectively. As of December 31, 2025, the total unrecognized compensation expense related to RSUs was $0.8 million, which is expected to be recognized over a weighted-average of 0.7 years.

Share based compensation expense is classified in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year ended December 31, 2025	Year ended December 31, 2024
Research and development	$ 133	$ 1,680
General and administrative	335	3,029
Total	$ 468	$ 4,709

15. Income Taxes

Loss before income before income taxes are as follows (in thousands):

	Year ended December 31, 2025	Year ended December 31, 2024
United Kingdom	$ (42,544)	$ (27,510)
United States	(24,053)	(32,833)
Other foreign	(36)	(884)
Loss before income taxes	$ (66,633)	$ (61,227)

The components of income tax benefit are as follows (in thousands):

	Year ended December 31, 2025	Year ended December 31, 2024
Current income tax benefit/(expense):		
United States	$ —	$ (70)
Other Foreign	(9)	(22)
Deferred income tax benefit:		
United States	184	136
Total income tax benefit	$ 175	$ 44

A reconciliation of the U.K. 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, 2025		Year ended December 31, 2024	
Statutory tax rate	$ 16,658	25.00 %	$ 15,307	25.00 %
Increase (decreases) resulting from:				
Foreign tax effects-United States:				
Changes in valuation allowance	(6,122)	(9.17)	(4,002)	(6.54)
Share-based compensation	(118)	(0.18)	—	—
Non-taxable or non-deductible items	(506)	(0.76)	(3,505)	(5.73)
Foreign tax effects-Switzerland:				
Share-based compensation	(2)	—	(30)	(0.05)
Effect of change in tax laws or rates enacted in the current period	598	0.90	721	1.18
Tax credits	(81)	(0.12)	(3,501)	(5.72)
Changes in valuation allowance	(7,513)	(11.27)	(2,116)	(3.46)
Non-taxable or non-deductible items	(2,496)	(3.75)	(46)	(0.06)
Other adjustments	(243)	(0.37)	(2,784)	(4.55)
Effective tax rate	$ 175	0.28 %	$ 44	0.07 %

The Company has adopted ASU 2023-09 and evaluated all required categories and determined that no additional jurisdictional disaggregation or reconciling items were individually material.

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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, 2025	December 31, 2024
Deferred tax assets:		
Net operating loss carryforwards	$ 40,691	$ 26,040
Research and development credit carryforwards	313	47
Share based compensation	4,190	4,753
Lease liability	2,965	3,156
Accruals	28	—
Intangible amortization	459	452
Capitalized Research and Development expenditure	4,765	6,185
Other	62	10
Gross deferred tax asset	53,473	40,643
Valuation allowance	(46,266)	(30,830)
Net deferred tax assets	7,207	9,813
Deferred tax liabilities:		
Depreciation	(1,130)	(1,815)
Right-of-use lease asset	(1,060)	(1,149)
Undistributed earnings of subsidiaries	(1,339)	(1,248)
Intangible assets	(3,932)	(6,039)
Net deferred tax liabilities	(7,461)	(10,251)
Total deferred tax, net	$ (254)	$ (438)

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 $4.8 million deferred tax asset (2024: $6.2 million).

As of December 31, 2025, the Company had a valuation allowance of $46.3 million (2024: $30.8 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, 2025 and 2024 related primarily to the increase in net operating loss and credit carryforwards, and were as follows:

	Year ended December 31, 2025	Year ended December 31, 2024
Valuations allowance at beginning of year	$ 30,830	$ 25,057
Changes in valuation allowance arising from in-year additions	—	—
Increases recorded to income tax provision	13,634	6,123
Foreign exchange translation	1,802	(350)
Valuation allowance at end of year	$ 46,266	$ 30,830

As of December 31, 2025, the Company had net operating loss ("NOL") carryforwards totaling approximately $160.4 million which have an unlimited carryforward period, of which $114.0 million originate in the U.K. As of December 31, 2025, the Company had $0.3 million of research and development tax credit carryforwards which also have an unlimited carryforward period.

As of December 31, 2024, the Company had NOL carryforwards totaling approximately $101.7 million which have an unlimited carryforward period, of which $75.6 million originate in the U.K. As of December 31, 2024, the Company had $0.1 million of research and development tax credit carryforwards which also have an unlimited carryforward period.

As of December 31, 2025 and 2024, the Company does not have any material unrecognized tax benefit liabilities. The Company files corporation/income tax returns in the U.K., the United States, Switzerland, Australia and Italy. 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 U.K., tax years from 2022 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, 2025 and 2024.

16. Commitments and Contingencies

In-License Agreements

The Company is party to a number of licensing agreements, most of which are with related parties. 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 or accrued any material payments under these license agreements during the years ended December 31, 2025, and 2024.

Leases

The Company leases certain laboratory and office space under operating leases, which are described below.

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. 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.

In 2024, an impairment charge to write down the U.K. operating lease right-of-use asset to the estimated recoverable amount was recorded and the estimated useful life of the asset reduced. In August 2025, the Company ceased the research and development activities undertaken in the laboratory and transitioned the remaining clinical and operational workforce to remote roles. The U.K. operating lease right-of-use asset has a value of nil as of December 31, 2025. The Company is actively marketing the building in Harwell, Oxfordshire, for the remainder of the lease.

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 houses 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 had a rent-free period up to February 29, 2024 and was 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 asset and lease liabilities are as follows (in thousands):

	December 31, 2025	December 31, 2024
Right-of-use asset	$ 1,638	$ 4,384
Lease liability, current	$ 2,023	$ 1,920
Lease liability, non-current	$ 9,258	$ 10,087
Other information		
Operating cash flows from operating leases	$ 1,979	$ 1,789
Weighted average remaining lease term (years)	6.98	7.98
Weighted average discount rate	7.5 %	7.5 %
Lease Costs		
Operating leases	$ 3,332	$ 1,443
Total lease cost	$ 3,332	$ 1,443

The Company identified circumstances that could indicate that the carrying amount of the U.S. operating lease right-of-use asset and the leasehold improvements located in the U.S. may not be recoverable as of December 31, 2025, as it was more likely than not that the Company would cease some of the operating activities undertaken in the laboratory and office space in Germantown, Maryland in 2026, before the end of the previously estimated useful lives. The Company performed an impairment assessment of the U.S. operating lease right-of-use asset, which is part of the U.S. asset group, using the income approach and recorded an impairment charge within general and administrative expenses of $0.4 million (December 31, 2024: U.K. impairment $2.6 million) to write down the asset to the estimated recoverable amount. The impairment charge is subject to a number of assumptions and actual results may differ. The Company will continue to refine these assumptions as additional information becomes available. The significant assumptions used in determining the estimated fair value of the U.S. operating lease right-of-use asset are the timing of successful sub-leasing of the Company's U.S. lease obligations and the value of any charges associated with sub-leasing the Company's U.S. lease obligations. Significant changes in these inputs could have a material effect on the fair value measurement. See Note 6 Property and Equipment, Net for details of the impairment assessment performed over the property and equipment within the U.S. asset group.

Maturities of the Company's minimum lease liabilities as of December 31, 2025 were as follows (in thousands):

Maturity of lease liabilities:	
2026	$ 2,025
2027	2,050
2028	2,076
2029	2,102
2030	2,129
Thereafter	3,940
Total minimum lease payments	14,322
Less: imputed interest	(3,041)
Total lease liability	$ 11,281