

**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 FOR THE
TRANSITION PERIOD FROM TO

Commission File Number 001-40598

ZURA BIO LIMITED

(Exact name of Registrant as specified in its Charter)

Cayman Islands
(State or other jurisdiction of
incorporation or organization)
1489 W. Warm Springs Rd. #110
Henderson, Nevada
(Address of principal executive offices)

98-1725736
(I.R.S. Employer
Identification No.)

89014
(Zip Code)

Registrant's telephone number, including area code: (702) 825-9872

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Ordinary Shares, par value \$0.0001 per share	ZURA	The Nasdaq Stock Market LLC (The Nasdaq Capital 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, 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 Exchange Act). YES NO

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the Registrant's units on The Nasdaq Capital Market on June 30, 2025 (the last business day of the Registrant's most recently completed second fiscal quarter) was \$58,992,819.

As of March 16, 2026, the Registrant had 94,880,710 Class A Ordinary Shares, par value US\$0.0001 each, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report incorporates by reference information from the definitive proxy statement for the registrant's 2026 Annual General Meeting of Shareholders, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2025.

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SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Annual Report”) contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our forward-looking statements include, but are not limited to, statements regarding our and our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward- looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

These forward-looking statements are based on the current expectations of Zura Bio Limited (the “Company” or “Zura”) and its management thereof and are inherently subject to uncertainties and changes in circumstances and their potential effects and speak only as of the date of such statement. Forward-looking statements are not guarantees of performance. You should not put undue reliance on our forward-looking statements. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to:

- our expectations regarding our product candidates and their related benefits, and our beliefs regarding competing product candidates and products both in development and approved, may not be achieved;
- our vision and strategy may not be successful;
- the timing of key events and initiation of our studies and release of clinical data may take longer than anticipated or may not be achieved at all;
- expectations regarding the potential general acceptability and maintenance of our product candidates by regulatory authorities, payors, physicians, and patients may not be achieved;
- we may be unable to attract and retain key personnel;
- expectations with respect to our future operating expenses, capital requirements and needs for additional financing may not be achieved;
- we have not completed any clinical trials, not engaged in topline readout activities, and have no products approved for commercial sale;
- we have incurred significant losses since inception, and expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future;
- we require substantial additional capital to finance our operations, and if we are unable to raise such capital when needed or on acceptable terms, we may be forced to delay, reduce, and/or eliminate one or more of our development programs or future commercialization efforts;
- we may be unable to renew existing contracts, enter into new contracts or may experience disputes or other challenges with respect to our vendors or other third parties;
- we rely on third-party contract development manufacturing organizations for the manufacture of clinical materials;
- we rely on contract research organizations, clinical trial sites, and other third parties to conduct our preclinical studies and clinical trials;
- we may be unable to obtain regulatory approval for our product candidates, and there may be related restrictions or limitations of any approved products;
- we may be unable to successfully respond to general economic and geopolitical conditions;

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- we may be unable to effectively manage growth;
- we face competitive pressures from other companies worldwide;
- we may be unable to adequately protect our intellectual property rights; and
- other factors set forth in documents filed, or to be filed, with the U.S. Securities and Exchange Commission (the “SEC”).

Additional discussion of the risks, uncertainties and other factors described above, as well as other risks material to our business, can be found under “Risk Factors” in Part I, Item 1A of this Annual Report. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. New risk factors emerge from time to time and it is not possible to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, investments or other transactions we may execute.

For the reasons described above, we caution you against relying on any forward-looking statements, which should also be read in conjunction with this Annual Report and the documents referenced within this Annual Report and the other cautionary statements that are included elsewhere in this Annual Report and in our public filings, including under “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Forward-looking statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the foregoing cautionary statements. We undertake no obligations to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

SUMMARY OF RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Item 1A “*Risk Factors*”. These risks include, but are not limited to the following:

- We have a limited operating history, have not completed any clinical trials, and have not taken a product through to commercialization.
- We have incurred losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from our product candidates, tibulizumab (ZB-106), torudokimab (ZB-880) and crebankitug (ZB-168) (collectively, the “ZB Assets”), and may never generate revenue or become profitable.
- Our recurring losses from operations and financial condition could raise substantial doubt about our ability to continue as a going concern.
- If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts. We have never successfully completed the regulatory approval process for any product candidates, and we may be unable to do so for any product candidates we develop.
- We are substantially dependent on the success of the ZB Assets, and our ongoing and anticipated clinical trials of the ZB Assets may not be successful.
- We may find it difficult to enroll and retain patients in our clinical trials. If we experience delays or difficulties in the enrollment of patients in clinical trials and our successful completion of clinical trials, our receipt of marketing approvals could be delayed or prevented.
- The results of preclinical studies and early clinical trials may not be predictive of the success of our later clinical trials, and the results of our clinical trials may not satisfy the requirements of the United States Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”), or other foreign regulatory authorities.
- Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results.
- Preliminary, interim data from our clinical trials that we announce or publish may change as more patient data become available and are subject to audit and verification procedures.
- We may develop the ZB Assets in combination with other therapies, which exposes us to additional risks related to other agents or active pharmaceutical or biological ingredients used in combination with our product candidates.
- If the FDA or other regulatory authorities revoke their approval of these other therapies or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the therapies we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.
- We depend on license agreements with Pfizer Inc. and their wholly owned subsidiaries (“Pfizer”) and Eli Lilly and Company and their wholly owned subsidiaries (“Lilly”) to permit us to use certain patents, know-how and technology. Termination of these rights or the failure to comply with obligations under these agreements could materially harm our business and prevent us from developing or commercializing the ZB Assets.
- Our ability to protect our patents and other proprietary rights is uncertain. We have limited geographical protection with respect to our licensed patents and may not be able to protect our intellectual property rights throughout the world. Patent terms may not protect our competitive position with respect to the ZB Assets for an adequate amount of time. If we do not obtain patent term extension in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) and in foreign countries under similar legislation, our business may be materially harmed.

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- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.
- We may not be able to maintain or enforce trade secret protection for our product candidates.
- Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect the ZB Assets.
- The regulatory approval processes of the FDA, EMA, and other foreign regulatory authorities are complex, time-consuming, and inherently unpredictable.
- We will be subject to extensive 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.
- Our employees, independent contractors, consultants, commercial collaborators, principal investigators, contract research organizations (“CROs”), suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.
- Healthcare legislative and regulatory reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.
- We are dependent on our key personnel and anticipate hiring additional key personnel. If we are not successful in attracting and retaining qualified personnel, we may not be able to successfully implement our business strategy.
- We rely on third parties, including consultants, independent clinical investigators and CROs to conduct and sponsor some of the clinical trials of our product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.
- In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.
- Our internal computer systems, or those of any third parties with whom we work, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data.
- We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.
- The market price of our securities may be volatile and may decline in the future.
- Our operating results have and may continue to fluctuate significantly.
- We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the capital appreciation, if any, of our Class A ordinary shares, par value \$0.0001 per share (the “Class A Ordinary Shares”).
- Future sales and/or issuances of our securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.
- If certain holders of our Class A Ordinary Shares sell a significant portion of their securities, it may negatively impact the market price of our Class A Ordinary Shares and such holders still may receive significant proceeds.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company developing novel and differentiated medicines for patients with autoimmune and inflammatory diseases, including serious and debilitating conditions with significant unmet medical need. These diseases are often chronic, biologically complex and difficult to treat, and many patients do not achieve durable disease control with currently available therapies.

Our strategy is to identify immune-mediated diseases in which translational and clinical evidence supports the role of specific biological pathways in disease pathogenesis. We focus on targets for which human data, including biomarker findings, genetic associations and prior clinical studies, inform therapeutic rationale and development decisions. We seek to advance product candidates in therapeutic areas where there remains meaningful unmet medical need and where, if clinical benefit is demonstrated, there may be potential for commercial relevance.

We have in-licensed three clinical-stage product candidates:

1. **Tibulizumab (ZB-106)**, a humanized bispecific antibody engineered to bind and neutralize interleukin-17A (“IL-17A”) and B cell activating factor (“BAFF”) within a single therapeutic molecule.
2. **Crebankitug (ZB-168)**, a fully human immunoglobulin G1 (“IgG1”) monoclonal antibody targeting interleukin-7 receptor alpha (“IL-7R α ”).
3. **Torudokimab (ZB-880)**, a fully human immunoglobulin G4 (“IgG4”) monoclonal antibody targeting interleukin-33 (“IL-33”).

We are currently conducting two global Phase 2 clinical trials evaluating tibulizumab in adult participants, each of which includes an optional open-label extension:

1. TibuSHIELD in hidradenitis suppurativa (“HS”)
2. TibuSURE in diffuse cutaneous systemic sclerosis (“dcSSc”)

Crebankitug and torudokimab were previously evaluated in early-stage clinical trials conducted by third parties prior to our licensing of development rights, and we are assessing potential future development strategies for these product candidates based on available clinical and translational data.

We have not completed any Phase 2 or Phase 3 clinical trials and have no products approved for commercial sale.

Overall Opportunity in Autoimmune and Inflammatory Diseases

Autoimmune and inflammatory diseases arise from dysregulated immune signaling involving multiple immune cell types, cytokines and interconnected molecular pathways. Collectively, these diseases affect millions of individuals worldwide and represent a significant and growing global healthcare burden. Many of these conditions are chronic, heterogeneous and biologically complex, often involving persistent immune activation, tissue remodeling and, in certain cases, progressive fibrosis or organ dysfunction.

Over the past two decades, advances in immunology have led to the development of targeted biologic therapies that have transformed treatment in several autoimmune indications. These therapies have demonstrated that selective modulation of specific cytokines and immune pathways can meaningfully alter disease activity. However, a substantial proportion of patients across multiple autoimmune diseases do not achieve adequate or durable disease control, and treatment resistance, partial response or disease progression may occur in certain populations.

Emerging research has highlighted the interconnected nature of immune signaling networks, including interactions between T cell-associated cytokines, B cell survival pathways, innate immune activation and tissue-resident stromal responses. In diseases

characterized by overlapping biological drivers, inhibition of a single pathway may not fully address immune redundancy or compensatory mechanisms that can sustain inflammation or fibrotic progression.

Advances in antibody engineering have enabled the development of highly selective monoclonal antibodies as well as multi-target constructs designed to engage more than one immune mediator within a single therapeutic molecule. Multi-pathway strategies, including bispecific antibodies, are being explored in autoimmune and inflammatory research to evaluate whether coordinated modulation of complementary immune drivers may be appropriate in select disease settings supported by translational and clinical evidence. At the same time, single-target monoclonal antibodies remain a clinically validated approach where a specific signaling axis is strongly implicated in disease pathogenesis.

We believe that continued advances in immune biology, biomarker development and clinical translational research provide opportunities to evaluate differentiated antibody-based approaches in diseases where significant unmet medical need persists. Our strategy is to align the biological rationale of each product candidate with human data supporting the relevance of the targeted immune pathways in the disease under study.

Our Product Candidates

Tibulizumab (ZB-106)

Overview of Tibulizumab

Tibulizumab is a humanized IgG4 single-chain variable fragment bispecific antibody engineered to bind and neutralize both IL-17A and BAFF within a single therapeutic molecule.

IL-17A is a pro-inflammatory cytokine produced primarily by T-helper 17 (“Th17”) cells and other immune cell subsets and has been implicated in chronic inflammatory and fibrotic diseases. BAFF is a cytokine that plays a central role in B cell development, activation, differentiation and survival. Dysregulation of IL-17A and BAFF signaling has been reported in multiple autoimmune and inflammatory diseases.

By targeting both IL-17A and BAFF, tibulizumab is designed to modulate complementary T cell-associated and B cell-associated immune pathways that may contribute to disease pathogenesis in certain immune-mediated conditions.

Tibulizumab incorporates antigen-binding domains derived from antibodies previously evaluated in clinical development, including ixekizumab (marketed as TALTZ®), an anti-IL-17A antibody, and tabalumab, an anti-BAFF antibody.

Prior to our initiation of Phase 2 clinical trials, tibulizumab was evaluated in Phase 1 and Phase 1b clinical trials conducted by Lilly. These studies assessed safety, tolerability, pharmacokinetics (“PK”) and pharmacodynamics (“PD”) activity and supported advancement of tibulizumab into Phase 2 clinical development. See “—Completed Clinical Trials and Clinical Observations for Tibulizumab” below for a summary of these studies.

Biological Rationale

IL-17A Pathway

The IL-17 family of cytokines consists of six structurally related isoforms, including IL-17A and IL-17F. IL-17 promotes the release of pro-inflammatory cytokines and chemokines and contributes to the recruitment and activation of immune cells at sites of inflammation. Dysregulated IL-17 signaling has been associated with chronic inflammatory conditions and, in some contexts, tissue remodeling and fibrotic processes.

IL-17 family members can form both homodimers and heterodimers that signal through a shared receptor complex. IL-17A is the prototypical and most extensively studied member of this family and is the most potent activator of IL-17 signaling. IL-17A can signal as an IL-17A homodimer or it can dimerize with the closely related IL-17F to form an IL-17A/F heterodimer, which has shared signaling properties of IL-17A and IL-17F.

Tibulizumab binds to IL-17A and, through IL-17A engagement, inhibits signaling mediated by IL-17A homodimers as well as signaling mediated by IL-17A/F heterodimers. By targeting IL-17A-dependent signaling while also neutralizing BAFF, tibulizumab is

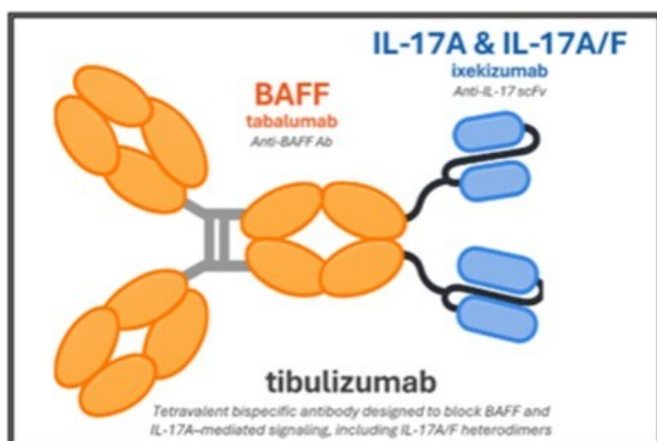
designed to modulate complementary immune pathways that may contribute to disease pathogenesis in certain autoimmune and inflammatory conditions.

BAFF Pathway

BAFF is a cytokine involved in multiple aspects of immune system regulation and is best characterized for its role in B-lymphocyte maturation, activation and survival. BAFF is expressed as a membrane-bound protein and can be cleaved to generate a soluble form.

Elevated BAFF levels have been reported in several autoimmune diseases. Overexpression of BAFF in preclinical models has been associated with autoantibody production and autoimmune-like phenotypes. In humans, increased BAFF concentrations have been observed in diseases including systemic sclerosis (“SSc”), systemic lupus erythematosus, rheumatoid arthritis (“RA”) and primary Sjögren’s syndrome.

By simultaneously neutralizing IL-17A and BAFF, tibulizumab is designed to modulate both T cell- and B cell-associated immune mechanisms that may contribute to disease pathogenesis.



Completed Clinical Trials and Clinical Observations for Tibulizumab

Tibulizumab was previously evaluated in three clinical trials conducted by Lilly:

1. **Phase 1 single ascending dose (“SAD”) clinical trial.** This first-in-human clinical trial evaluated safety, tolerability, PK, immunogenicity and target engagement of tibulizumab in healthy participants and in participants with RA.
2. **Phase 1 SAD clinical trial in healthy Japanese and Caucasian participants.** This single-site, randomized, investigator- and participant-blinded, placebo-controlled clinical trial evaluated safety, tolerability and PK following a single subcutaneous dose.
3. **Phase 1b multiple ascending dose (“MAD”) clinical trial in participants with Sjögren’s syndrome.** This multicenter, parallel-group, randomized, investigator- and participant-blinded, placebo-controlled clinical trial evaluated safety, tolerability, PK, and PD of tibulizumab administered once every 2 weeks (“Q2W”) or once every 4 weeks (“Q4W”) for 16 weeks.

In the Phase 1 clinical trials, tibulizumab demonstrated a PK profile supportive of subcutaneous Phase 2 dosing at four-week intervals. PD observations confirmed impact on human biology and included changes consistent with the product candidate’s mechanism of action, including changes in inflammatory biomarkers, such as CD20+ B cells and high-sensitivity C-reactive protein in participants with RA, and reductions in total and naïve B cell counts in participants with Sjögren’s syndrome.

These PD findings were exploratory and were not designed to evaluate clinical efficacy. The Phase 1 and Phase 1b clinical trials were not powered to assess clinical outcomes.

The safety profile observed in Phase 1 and Phase 1b clinical trials supported advancement into Phase 2 clinical trials.

Hidradenitis Suppurativa

Disease Background and Unmet Medical Need

HS, also known as acne inversa, is a chronic, recurrent and debilitating inflammatory skin disease of the hair follicle. Reported worldwide prevalence estimates range from approximately 0.05% to 4.1%. HS typically presents in early adulthood, although delayed diagnosis is common.

Patients characteristically experience painful nodules, purulent abscesses and draining sinus tracts in intertriginous areas such as the axillary, inguinal, perineal and inframammary regions. HS is associated with substantial physical morbidity, impaired mobility, scarring and psychosocial burden. Comorbidities may include inflammatory arthropathies, metabolic syndrome, cardiovascular risk factors and depression.

Despite approved biologic therapies targeting inflammatory pathways, many patients experience incomplete responses or recurrent disease flares. No therapies specifically targeting B cell survival pathways are currently approved for HS.

Pathogenesis and Translational Evidence

Follicular occlusion is thought to be an initiating event in HS, followed by rupture and a local immune response characterized by neutrophil recruitment and sustained inflammation.

In translational studies, IL-17A-producing cells have been identified in HS lesional tissue, and IL-17-associated signaling has been implicated in amplification of inflammatory responses. B cell and plasma cell infiltration has also been reported in chronic HS lesions, and BAFF expression has been observed in lesional tissue.

These findings support investigation of immune pathways involving both IL-17A and BAFF in HS.

Diffuse Cutaneous Systemic Sclerosis

Disease Background and Unmet Medical Need

SSc is an orphan autoimmune disease characterized by immune dysregulation, vasculopathy and progressive fibrosis of the skin and internal organs. dcSSc is associated with rapid disease progression, extensive skin involvement and early visceral organ complications.

There are currently no therapies approved to treat the totality of dcSSc manifestations. Approved agents for systemic sclerosis-associated interstitial lung disease slow lung function decline but do not broadly reverse fibrosis or address multi-organ disease.

Pathogenesis and Translational Evidence

Elevated BAFF levels have been reported in patients with SSc and have been associated with disease activity in observational studies. In translational investigations, BAFF signaling has been associated with B cell activation and profibrotic gene expression.

Increased Th17 cell activity and IL-17 expression have also been reported in SSc. IL-17 signaling has been implicated in fibroblast activation and collagen production in certain experimental systems.

Dual inhibition of IL-17A and BAFF is intended to address inflammatory and B cell-associated components implicated in SSc pathogenesis. The clinical effect of this approach is being evaluated in the ongoing Phase 2 clinical trial of TibuSURE in dcSSc.

Ongoing Clinical Trials of Tibulizumab

Tibulizumab is currently being evaluated in two ongoing global Phase 2 clinical trials:

TibuSHIELD – Hidradenitis Suppurativa

In May 2025, we initiated TibuSHIELD, a randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating tibilizumab in adults with moderate-to-severe HS.

The trial is designed to assess safety, tolerability and efficacy in approximately 225 participants across the United States, Canada and Europe. In January 2026, we expanded the planned enrollment from approximately 180 participants to approximately 225 participants pursuant to a protocol amendment.

The primary endpoint is the percent change from baseline in total abscess and inflammatory nodule count at Week 16. Key secondary endpoints include the proportion of participants achieving HiSCR50 or HiSCR75 at Week 16, as well as additional safety and clinical activity measures.

The trial includes:

- A 16-week double-blind efficacy assessment period
- An optional open-label extension period following completion of the double-blind portion
- A 12-week safety follow-up period after the last dose

Topline results from the 16-week double-blind portion of the trial are expected in the fourth quarter of 2026.

TibuSURE – Diffuse Cutaneous Systemic Sclerosis

In December 2024, we initiated TibuSURE, a randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating tibilizumab in adults with early dcSSc.

The trial is designed to assess safety, tolerability and efficacy in approximately 80 participants across the United States, Latin America, and Europe.

The primary endpoint is the modified Rodnan Skin Score at Week 24. Secondary endpoints include measures of lung involvement, including forced vital capacity and quantitative high-resolution computed tomography, as well as functional and composite clinical measures such as the Health Assessment Questionnaire-Disability Index and the revised Combined Response Index in Systemic Sclerosis.

The trial includes:

- A 24-week double-blind efficacy assessment period
- An optional open-label extension period following completion of the double-blind portion

Topline results from the 24-week double-blind portion of the trial are expected in the first half of 2027.

Crebankitug (ZB-168)

Overview of Crebankitug

Crebankitug is a fully human immunoglobulin G1 monoclonal antibody that binds and neutralizes the interleukin-7 receptor alpha chain (“IL-7R α ”). IL-7R α is a shared receptor component involved in signaling mediated by interleukin-7 (“IL-7”) and thymic stromal lymphopoietin (“TSLP”). Through binding to IL-7R α , crebankitug is designed to inhibit signaling mediated by both IL-7 and TSLP.

Biological Background

IL-7 was initially characterized for its role in lymphocyte growth and survival and is now recognized as an important regulator of T cell development and peripheral T cell homeostasis. IL-7 signaling occurs through IL-7R α in combination with the common gamma chain receptor and contributes to T cell survival, proliferation and differentiation.

IL-7R α also serves as a receptor component for TSLP, a cytokine involved in modulation of immune responses, particularly at epithelial barrier tissues. TSLP signaling has been implicated in inflammatory and autoimmune conditions through activation of dendritic cells and promotion of T-helper cell responses.

Dysregulation of the IL-7/IL-7R α axis and related signaling pathways has been associated with autoimmune and inflammatory diseases. Genetic polymorphisms involving IL-7R have been reported in multiple autoimmune conditions, including multiple sclerosis (“MS”), type 1 diabetes (“T1D”), RA and primary Sjögren’s syndrome.

By targeting IL-7R α , crebankitug is designed to modulate signaling associated with both IL-7 and TSLP pathways, which are involved in T cell survival, activation and immune homeostasis.

Completed Clinical Trials and Clinical Observations for Crebankitug

Crebankitug was previously evaluated in three Phase 1/1b clinical trials conducted by Pfizer prior to our in-licensing of development rights:

- 1. Phase 1 SAD clinical trial** in adult healthy participants to assess safety, tolerability and PK.
- 2. Phase 1b clinical trial in participants with established T1D.** This was a multicenter, randomized, double-blind, sponsor-open, placebo-controlled clinical trial evaluating multiple ascending doses of crebankitug in adult participants diagnosed with T1D within the preceding two years.
- 3. Phase 1b clinical trial in participants with MS.** This was a randomized, multicenter, double-blind, sponsor-open, placebo-controlled clinical trial designed to evaluate multiple ascending doses of crebankitug in adult participants with MS. The clinical trial enrolled four participants and was terminated by the sponsor for reasons other than participant safety.

Across clinical development, crebankitug was administered to 93 participants. In Phase 1 and Phase 1b clinical trials, safety, tolerability and PK were evaluated. In the Phase 1b clinical trial in participants with T1D, crebankitug demonstrated biologic activity consistent with IL-7R α blockade, including reductions in effector and memory T cell populations while sparing regulatory T cell populations. Changes in gene expression associated with T cell activation, trafficking and differentiation were also observed. The majority of adverse events were Grade 1 or Grade 2. There were no deaths or permanent discontinuations due to adverse events.

Crebankitug has been administered via intravenous (“IV”) infusion and subcutaneous (“SC”) injection in clinical trials.

Potential Future Development Considerations for Crebankitug

We are assessing the competitive landscape, including developments in IL-7 and TSLP-targeted programs, and evaluating potential therapeutic indications and development strategies for crebankitug. These evaluations may include consideration of disease selection, clinical trial design and the timing and scope of potential future development and clinical studies.

Torudokimab (ZB-880)

Overview of Torudokimab

Torudokimab is a fully human IgG4 monoclonal antibody that binds and neutralizes soluble human IL-33. IL-33 signaling occurs primarily through suppression of tumorigenicity 2 (“ST2”), a receptor expressed on multiple immune cell types.

Torudokimab was previously evaluated in three clinical trials conducted by Lilly prior to our in-licensing of development rights.

Biological Background

IL-33 is a member of the interleukin-1 (“IL-1”) cytokine superfamily and is characterized as an epithelial-derived cytokine released in response to cellular stress or tissue injury. Upon binding to the ST2 receptor, IL-33 can activate innate and adaptive immune cells and promote type 2 immune responses.

The IL-33/ST2 signaling axis has been investigated as a therapeutic target in inflammatory and respiratory diseases, including asthma and chronic obstructive pulmonary disease (“COPD”). IL-33 signaling has also been studied in dermatologic and other immune-mediated conditions.

By neutralizing IL-33, torudokimab is designed to inhibit signaling mediated through the IL-33/ST2 pathway.

Completed Clinical Trials and Clinical Observations for Torudokimab

Torudokimab was previously evaluated in three clinical trials conducted by Lilly:

- 1. Phase 1 SAD and MAD clinical trial.** This was a first-in-human clinical trial in healthy participants evaluating safety, tolerability, PK, immunogenicity, and target engagement.
- 2. Phase 1 clinical trial.** This was a safety, tolerability, and PK trial evaluating different solution formulations and injection methods in healthy participants.
- 3. Phase 2 clinical trial in participants with atopic dermatitis (“AD”).** This was a multicenter, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating efficacy and safety in adult participants with moderate-to-severe AD.

Across clinical development, 244 participants were dosed with torudokimab. In Phase 1 clinical trials, torudokimab demonstrated a PK profile consistent with monoclonal antibodies, with an average half-life of approximately 20 days. The majority of adverse events were Grade 1 or Grade 2. There were no deaths and no serious adverse events assessed as causally related to torudokimab. No apparent clinical impact of anti-drug antibodies was observed.

The Phase 2 clinical trial in moderate-to-severe AD was terminated early following a planned interim analysis due to lack of efficacy. Safety findings did not contribute to the study termination.

Torudokimab was administered via IV infusion and SC injection in clinical trials. In healthy participants, both SC and IV formulations were evaluated. In patient populations, torudokimab was administered via SC injection.

Potential Future Development Considerations for Torudokimab

We are assessing the competitive landscape, including developments in IL-33 and ST2-targeted programs, and evaluating potential therapeutic indications and clinical development strategies for torudokimab. These evaluations may include consideration of disease selection, clinical trial design, and the timing and scope of potential future clinical studies.

Manufacturing

We do not own or operate, and currently have no plans to establish, any dedicated Zura manufacturing facilities. Our current and future requirements for producing bulk drug substance and finished drug product are met through contract manufacturers.

We have manufactured three batches of tibilizumab finished drug product in Italy and three batches of tibilizumab drug substance in the Netherlands through contract manufacturers in accordance with current good manufacturing practices (“cGMP”). Additional batches of both tibilizumab drug substance and drug product are anticipated to be manufactured in 2026. Prior to our licensing of tibilizumab, Lilly manufactured tibilizumab. Pursuant to the Lilly license, we have a license to the drug substance manufacturing process and the associated analytical testing.

In 2024, torudokimab drug substance and drug product were moved from WuXi, People’s Republic of China (“PRC”) to the United Kingdom (“U.K.”). We have an ongoing stability study in WuXi. The PRC, and WuXi specifically, have faced increased scrutiny by the U.S. government, which could necessitate the selection of a new manufacturer and require additional stability studies thus

impacting our ability to supply torudokimab to meet future demand. See the risk factor titled “*Our business, operations, financial position, and clinical development plans and timelines could be materially adversely affected by international conflicts and economic sanctions*” under Part I, Item 1A Risk Factors in this Annual Report.

For crebankitug, we transferred the cGMP drug substance manufacturing process and associated analytical testing to the Netherlands. The facility manufactured a batch of cGMP drug substance and this material is available for release for use in crebankitug clinical studies. Similarly, the cGMP drug product manufacturing process was transferred to Italy and a batch of cGMP drug product was manufactured and is available for release for use in crebankitug clinical studies.

We believe our outsourced manufacturing facilities are equipped to produce tibulizumab and crebankitug for both clinical and commercial use. We continue to monitor and assess contract manufacturers for our future needs. We currently have no plans to establish in-house manufacturing capabilities.

Intellectual Property

With respect to our intellectual property, our continued development, clinical and commercial success depends in large part on our ability to: obtain and maintain patent protection for the ZB Assets (including but not limited to their components, formulations, methods of manufacturing, and methods of treatment in the United States and other countries); operate without infringing valid and enforceable patents and proprietary rights of others; and prevent others from infringing on our proprietary or intellectual property rights.

We intend to take advantage of regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions, where available. We may also seek to rely on regulatory protection afforded through Orphan Drug Designation, if appropriate. We may also rely on trade secrets and know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate or timely for, patent protection.

Tibulizumab Intellectual Property

We hold a license to issued patents that cover the composition of matter for tibulizumab in several major pharmaceutical markets, including the United States, China, Japan, Germany, France, Italy, the United Kingdom, and Spain. The earliest priority date for these patents is 2012. The terms of these patents are capable of continuing into 2033 in most jurisdictions without taking into account any patent term adjustment or extension regime of any country.

Crebankitug Intellectual Property

We hold a license to issued patents that cover the composition of matter for crebankitug in several major pharmaceutical markets, including the United States, Japan, Germany, France, Italy, the United Kingdom, and Spain. The earliest priority date for these patents is 2010. The terms of these patents are capable of continuing into 2031 in most jurisdictions without taking into account any patent term adjustment or extension regime of any country.

Torudokimab Intellectual Property

We hold a license to issued patents that cover the composition of matter for torudokimab in several major pharmaceutical markets, including the United States, China, Japan, Germany, France, Italy, the United Kingdom, and Spain. The earliest priority date for these patents is 2016. The terms of these patents are capable of continuing into 2037 in most jurisdictions without taking into account any patent term adjustment or extension regime of any country.

License Agreements

We are a party to certain licenses that provide rights that are necessary or useful for developing and commercializing our assets.

2023 Lilly License

On April 26, 2023, our consolidated subsidiary ZB17 LLC (“ZB17”) entered into a license agreement with Lilly (the “2023 Lilly License” and, together with the 2022 Lilly License defined below, the “Lilly Licenses”) pursuant to which Lilly granted ZB17 an exclusive license to develop, manufacture and commercialize tibulizumab. As consideration, we paid Lilly an upfront payment consisting of \$5.8 million during 2023 and issued 1,000,000 Class A Ordinary Shares at an aggregate fair value of \$7.8 million during the year ended 2023. During certain specified periods, Lilly shall have the exclusive right to evaluate certain clinical trial results and determine whether it wishes to negotiate an agreement for the further development and commercialization of ZB-106 by Lilly. If Lilly provides notice to the Company before the expiry of the applicable period that it wishes to seek to negotiate an agreement, the parties will have good faith negotiations regarding an agreement for further development and commercialization.

During 2024, ZB17 made an additional payment of \$5.0 million to Lilly in connection with the receipt of certain know-how, data, information and materials that Lilly is required to provide under the license agreement.

We are also obligated to make payments to Lilly (a) for four development milestone payments up to an aggregate of \$155.0 million, and sales milestone payments up to an aggregate of \$440.0 million based on respective thresholds of net sales of products developed from tibulizumab; and (b) over a multi-year period (twelve years, or upon the later expiration of regulatory exclusivity of tibulizumab in a country) for an annual earned royalty at a marginal royalty rate in the mid-single digits to low-double digits, with increasing rates based on net sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of years (collectively, the “2023 Lilly Contingent Payments”). As of December 31, 2025, none of the 2023 Lilly Contingent Payments are due and accordingly will not be recorded in our financial statements until they are due.

2022 Lilly License

On December 8, 2022, our consolidated subsidiary Z33 Bio Inc. (“Z33”) entered into a license agreement with Lilly (the “2022 Lilly License”) pursuant to which Lilly granted Z33 an exclusive (even as to Lilly) license to develop, manufacture, and commercialize torudokimab. As consideration, we paid Lilly an upfront fee of \$7.0 million during 2022 and issued Lilly 550,000 Class A Ordinary Shares at an aggregate fair value of \$4.5 million upon the Closing Date of the Business Combination during the year ended December 31, 2023.

In addition to the consideration paid and transferred in 2022, we paid an additional \$3.0 million to Lilly in December 2025 because a financing by Z33 with gross proceeds exceeding \$100.0 million did not occur by December 7, 2025. We are also obligated to make payments to Lilly for (a) 10 commercial, development and regulatory milestone payments up to an aggregate of \$155.0 million and sales milestone payments up to an aggregate of \$440.0 million based on respective thresholds of net sales of products developed from the licensed compound; and (b) an annual earned royalty at a marginal royalty rate in the mid-single to low-double digits, with increasing rates based on net sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of the year (collectively, the “2022 Lilly Contingent Payments”). As of December 31, 2025, none of the 2022 Lilly Contingent Payments are due and accordingly will not be recorded in our financial statements until they are due.

Pfizer Agreement

On March 22, 2022, we entered into a license agreement and a Series A-1 Subscription and Shareholder's Agreement (collectively, the "Pfizer Agreement") with Pfizer. Under the Pfizer Agreement, we acquired a license for crebankitug in exchange for \$5.0 million in cash and 2,702,083 shares (as adjusted by the exchange ratio established in the Business Combination Agreement (as defined herein)) of our Series A-1 convertible preferred shares, representing a 20% interest in us. The Pfizer Agreement is accounted for as an asset acquisition, as substantially all of the \$7.5 million value transferred to us was allocated to in-process research and development. On the acquisition date, the compound licensed had not yet received regulatory approval and the in-process research and development (the "IPR&D") did not have an alternative use.

In addition to the consideration transferred during 2022, we are obligated to make payments to Pfizer for (a) twelve (12) development and regulatory milestone payments aggregating up to \$70.0 million and sales milestone payments up to an aggregate of \$525.0 million based on respective thresholds of net sales of products (developed from the licensed compound) (the "Products"); and (b) an annual earned royalty at a marginal royalty rate in the mid-single digits to low double digits, based on thresholds of net sales of Products (collectively, the "Pfizer Contingent Payments"). Royalties are payable on a country-by-country basis for a certain period of years or upon the later expiration of regulatory exclusivity of our Products in a country.

We recorded the first \$1.0 million development milestone, included in the Pfizer Contingent Payments, as a component of research and development in the consolidated statement of operations during the year ended December 31, 2023. This amount was fully paid to Pfizer during the year ended December 31, 2024. As of December 31, 2025, no additional Pfizer Contingent Payments are due and accordingly no additional Pfizer Contingent Payments will be recorded in our financial statements until they are due.

The Pfizer Agreement also had an anti-dilution provision to allow Pfizer to maintain an 18% interest in us. Immediately prior to the Closing Date of the Business Combination (each as defined below), additional share options and restricted share units were issued to certain employees, executives, and directors that would result in the dilution of Pfizer's ownership in us. In accordance with the anti-dilution provision of the Pfizer Agreement, Pfizer was issued additional Series A-1 convertible preferred shares upon the closing of the Business Combination that were immediately converted to 267,939 Class A Ordinary Shares. Following the Business Combination, the anti-dilution provision is no longer in effect.

Lonza License

In July 2022, we entered into a license agreement (the "Lonza License") with Lonza Sales AG ("Lonza") for a worldwide nonexclusive license for Lonza's gene expression system in exchange for varying considerations depending on a number of factors such as whether we enter further into manufacturing agreements with Lonza or with a third party, and whether we enter into sublicense agreements with third parties (including up to middle six-figure annual payments per sublicense upon commencement of a sublicense, as well as royalties of up to low-single digit percentages of net sales of certain products over a commercially standard double-digit multi-year term). The Lonza License will remain in effect until terminated. We are free to terminate the Lonza License at any time upon 60 days' notice, with or without cause. Lonza may terminate the Lonza License for cause upon a breach by us or for other commercially standard reasons.

During October 2023, we began manufacturing drug substance with another third party. As a result of manufacturing with a third party other than Lonza, under the terms of the Lonza License, we had a license fee of \$0.4 million due to Lonza in the fourth quarter of 2023 and annually thereafter. During each of the years ended December 31, 2025 and 2024, \$0.4 million was paid for the Lonza License.

For more information, see the factors regarding third parties and manufacturing described under the heading "Risk Factors."

WuXi Biologics License

In July 2023, we entered into a biologics master services agreement (the "WuXi Biologics MSA") with WuXi Biologics and its affiliates ("WuXi Biologics"). Under the WuXi Biologics MSA, we are obligated to pay WuXi Biologics a service fee and all non-cancellable obligations in the amount specified in each work order associated with the agreement for the provision of services.

The WuXi Biologics MSA may be terminated upon 30 days' written notice by either party. Each work order under the WuXi Biologics MSA terminates upon completion of the services under such work order, or earlier under certain circumstances: (i) by us upon 3 months' written notice for reasonable cause, (ii) by WuXi if the services cannot be reasonably performed due to technical difficulties, or (iii) immediately by either party if a material breach is uncured for 30 days. Termination fees may apply under (i) and in the case of

our material breach in (iii). In July 2023, we entered into a cell line license agreement (the “Cell Line License Agreement”) with WuXi Biologics. The Cell Line License Agreement provides us with a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics’s know-how, cell line, and biological materials to manufacture, have manufactured, use, sell and import certain products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the “WuXi Biologics Licensed Products”). In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of \$150,000. Additionally, if we manufacture all of our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer (the “Royalty”). If we manufacture part of our commercial supplies of the WuXi Biologics Licensed Products with WuXi Biologics or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis. The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon three months’ prior written notice and its payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 30 days after written notice, or (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure. As of December 31, 2025, there are no payments currently due under the Cell Line License Agreement.

Athantor Letter Agreement

On December 29, 2025, in connection with the termination of the (i) letter agreement with Stone Peach Properties, LLC (“Stone Peach”) and ZB17, dated April 24, 2023, as amended by letter agreement dated November 21, 2023 (the “ZB17 Letter Agreement”) and (ii) letter agreement dated December 8, 2022, as amended on November 21, 2023 (the “Z33 Letter Agreement”) and, together with the ZB17 Letter Agreement, the “Stone Peach Letter Agreements”) by and between Stone Peach, us and Z33, as described in Note 5 to our consolidated financial statements located in “*Item 15—Exhibits and Financial Statement Schedules—Financial Statements,*” we entered into a letter agreement with Athantor Capital, an exempted company incorporated under the laws of the Cayman Islands with limited liability (“Athantor”) (the “Athantor Agreement”), pursuant to which we issued to Athantor 8,657,402 Class A Ordinary Shares (the “Athantor Shares”). Athantor is also entitled to piggyback registration rights pursuant to which Athantor has the right to include Athantor Shares in certain registered offerings by us or if we propose to file a registration statement under the Securities Act of 1933, as amended (the “Securities Act”), with respect to the registration of equity securities, as set forth in the Athantor Agreement. In addition, pursuant to the terms of the Athantor Agreement, we paid Athantor an upfront fee in an amount equal to \$7.3 million and shall pay a one-time milestone payment in the amount of \$25.0 million after the occurrence of the earliest of the following events: (i) we or ZB17 undergoes a Change of Control (as defined in the Athantor Agreement), (ii) the consummation by us or ZB17 of a sale of assets resulting in net proceeds in excess of \$500.0 million, or (iii) First Indication Regulatory Approval (as defined in the Athantor Agreement). In addition, pursuant to the terms of the Athantor Agreement, we agreed to pay an amount equal to 2% of Net Sales (as defined in the Athantor Agreement) for the Product (as defined in the Athantor Agreement) to the extent such Net Sales (collectively, the “Net Sales Payments”) are the subject of a royalty payment under the 2023 Lilly License. The Athantor Agreement contains representations, warranties and covenants by the parties in addition to the terms described above and shall remain in effect on a country-by-country basis until the expiration of the obligation to pay the Net Sales Payments. See also Part II, Item 7. “*Management’s Discussion and Analysis of Financial Condition and Results of Operations—Athantor Letter Agreement,*” “*—Stone Peach Settlement and Release Agreement,*” and “*—Audit Subcommittee Investigation*” for more information.

Approval and Regulation of Drugs and Biologics in the United States

In the United States, drug products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and other laws, including, in the case of biologics, the Public Health Service Act (“PHSA”). Drug products are also subject to other federal, state and local statutes and regulations. A failure to comply with any applicable requirements during the product development, approval, or post-approval periods may lead to administrative or judicial sanctions, including, among other things, the imposition by the FDA or an institutional review board (“IRB”) of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, or administrative, civil and/or criminal investigation, penalties or prosecution.

In the United States, our drug product candidates are all regulated by the FDA as biologics. Biologics require the submission of a biologics license application (“BLA”) and approval by the FDA prior to being marketed in the United States. Manufacturers of

biologics may also be subject to state and local regulation. The steps required before a biologic may be marketed in the United States generally include:

- completion of preclinical studies, animal studies and formulation studies, performed in accordance with the FDA’s good laboratory practices (“GLP”) requirements, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may commence;
- approval of the protocol and related documentation by an independent IRB or ethics committee at each clinical trial site before each trial may be initiated at the site;
- performance of adequate and well-controlled clinical trials under protocols submitted to the FDA and reviewed and approved by each IRB, conducted in accordance with the FDA’s good clinical practices (“GCPs”) requirements and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity and potency of the biologic for each targeted indication;
- preparation of and submission to FDA of a BLA for marketing approval that includes sufficient evidence of establishing the safety, efficacy, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept and file the application;
- satisfactory completion of an FDA pre-license inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the biological product’s identity, strength, quality and purity;
- satisfactory completion of an FDA Advisory Committee meeting, if applicable;
- potential FDA audit of the preclinical study and clinical trial sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical Studies and the IND Process

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of a product's biological characteristics, chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of preclinical studies must comply with federal regulations and requirements, including, as applicable, GLP and the Animal Welfare Act. Prior to commencing an initial clinical trial in humans with a product candidate in the United States, an IND must be submitted to the FDA, and the FDA must allow the IND to proceed. An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, the clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND must become effective before human clinical trials commence. Once submitted, the IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a full or partial clinical hold within that 30-day period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial or part of the study can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. The FDA also may impose clinical holds on a sponsor's IND at any time before or during clinical trials due to, among other considerations, unreasonable or significant safety concerns, inability to assess safety concerns, lack of qualified investigators, a misleading or materially incomplete investigator brochure, study design deficiencies, interference with the conduct or completion of a study designed to be adequate and well-controlled for the same or another investigational product, insufficient quantities of investigational product, lack of effectiveness, or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical Trials

Clinical trials involve the administration of the product candidate to healthy volunteers or participants under the supervision of qualified investigators. Clinical trials are subject to extensive regulation and must be conducted in compliance with (i) federal regulations, (ii) GCP standards, which set safeguards to protect the rights and health of participants and establish standards for conducting, recording data from, and reporting results of clinical trials, and (iii) protocols detailing, among other things, the objectives of the trial, subject selection and exclusion criteria, the parameters and criteria to be used in monitoring safety, and the effectiveness criteria to be evaluated, if any. Foreign studies conducted under an IND generally must meet the same requirements that apply to studies being conducted in the United States. The informed written consent of each study participant must be obtained before participation in the clinical trial may begin. The study protocol, study plan, and informed consent forms for each clinical trial must be reviewed and approved by an IRB for each clinical site, and the study must be conducted under the auspices of an IRB for each trial site. Investigators and IRBs must also comply with FDA regulations and guidelines, including those regarding oversight of study participant informed consent, complying with the study protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. 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 participants.

Clinical development for a product candidate is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases are as follows:

- **Phase 1.** Phase 1 involves the initial introduction of a product candidate into humans. Phase 1 clinical trials are typically conducted in healthy volunteers, but in some situations are conducted in participants with the target disease or condition. These clinical trials are generally designed to evaluate the safety, metabolism, PK properties and pharmacologic actions of the product candidate in humans, the side effects associated with increasing doses and, if possible, to gain early evidence of effectiveness. During Phase 1 clinical trials, sufficient information about the product candidate's PK properties and pharmacological effects may be obtained to inform and support the design of Phase 2 clinical trials;
- **Phase 2.** Phase 2 includes the controlled clinical trials conducted to obtain initial evidence of effectiveness of the product candidate for a particular indication(s) in participants with the target disease or condition, to determine dosage tolerance and optimal dosage, and to gather additional information on possible adverse side effects and safety risks associated with the product candidate. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population; and

- **Phase 3.** Phase 3 clinical trials are clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product candidate has been obtained and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for regulatory approval. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the product candidate, although a single Phase 3 clinical trial with other confirmatory evidence may be sufficient in certain instances. In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may also be made a condition to approval of the BLA. Failure to exhibit due diligence regarding conducting required Phase 4 clinical trials could result in withdrawal of approval for products. Concurrent with clinical trials, companies usually complete additional animal studies and must develop additional information about the chemistry and physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

The decision to suspend or terminate development of a product candidate may be made by either a health authority body, such as the FDA, by an IRB, or by a company for various reasons and during any phase of clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by a data safety monitoring board, which is an independent group of qualified experts organized by the trial sponsor to evaluate at designated points in time whether a trial may move forward and/or should be modified. These decisions are based on unblinded access to data from the ongoing trial and generally involve determinations regarding the benefit-risk ratio for study patients and the scientific integrity and validity of the clinical trial. In addition, there are requirements for the registration of certain clinical trials of product candidates on public registries, such as www.clinicaltrials.gov, and the submission of certain information pertaining to these trials, including clinical trial results, after trial completion.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, a sponsor submits extensive information about the product candidate to the FDA in the form of a BLA to request marketing approval for the product candidate in specified indications.

Biologics License Applications

To obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The BLA includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product candidate, or from alternative sources. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the product candidate to the satisfaction of the FDA.

Under the Prescription Drug User Fee Act, as amended, ("PDUFA") the fees payable to the FDA for reviewing an original BLA, as well as annual program fees for approved products, can be substantial, subject to certain limited deferrals, waivers and reductions that may be available. The FDA has 60 days from receipt of a BLA to determine whether the application will be accepted for

filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to accept for filing any BLA that it deems incomplete or not properly reviewable at the time of submission, in which case the BLA will have to be updated and resubmitted. The FDA's PDUFA review goal (which is not a legal requirement) is to review 90% of priority BLA applications within six months of filing and 90% of standard applications within 10 months of filing, but the FDA can and frequently does extend this review timeline to consider certain later-submitted information or information intended to clarify or supplement information provided in the initial submission. The FDA may not complete its review or approve a BLA within these established goal review times. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure, and potent for its intended use, and whether the product is being manufactured in compliance with cGMP to ensure its continued safety, purity and potency. The FDA may also refer applications for novel product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured or the facilities that are significantly involved in the product development and distribution process. The FDA will not approve the product candidate unless cGMP compliance is satisfactory and the manufacturing processes and facilities are adequate to assure consistent production of the product within required specifications. Additionally, before approving, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements.

Under the Pediatric Research Equity Act, certain BLAs must include an assessment, generally based on clinical trial data, of the safety and effectiveness of the biological product in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at a company's request or by its own initiative, including waivers for certain products not likely to be used in a substantial number of pediatric patients. Unless otherwise required by regulation, products with orphan drug designation are exempt from these requirements for orphan-designated indications with no formal waiver process required. After the FDA evaluates the BLA and the manufacturing facilities, the FDA may issue either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. When those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA may issue an approval letter. The FDA's PDUFA review goal is to review such resubmissions within two or six months of receipt, depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the BLA does not satisfy the regulatory criteria for approval and deny approval of a resubmitted application. FDA approval of any application may include many delays or may never be granted. An approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the product outweigh the potential risks. REMS can include Medication Guides, communication plans for healthcare professionals, and may include elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the safety, purity, or potency, which can be costly.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA and/or a supplemental BLA ("sBLA") before the change can be implemented. An sBLA for a new indication typically requires clinical data similar to that in the original application, and the FDA generally uses the same procedures and actions in reviewing an sBLA as it does in reviewing a new BLA. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance. In addition, new or modified government requirements, including new legislation, may be established that could delay or prevent regulatory approval of our product candidates under development or affect our ability to maintain product approvals we have obtained.

U.S. Market Exclusivity

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. 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.

Post-Approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as requirements relating to record keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. Manufacturers of products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. 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. 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.

As a condition of BLA approval, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the product. In addition, as a holder of an approved BLA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products.

Manufacturers 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 with a product or failure to comply with applicable regulatory requirements after approval may result in serious and extensive restrictions on a product or the manufacturer or holder of an approved BLA, as well as lead to potential market disruptions. These restrictions may include suspension of product manufacturing until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a “consent decree,” which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. Other potential consequences include interruption of production, issuance of warning letters or other enforcement letters, refusal to approve pending BLAs or supplements to approved BLAs, product seizure or detention, product recalls, fines, and injunctions or imposition of civil and/or criminal penalties.

In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation, correction, and reporting of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in production and quality control to maintain cGMP compliance.

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures, such as additional post-market clinical trials to assess new safety risks or distribution-related or other restrictions under a REMS. 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.

Regulations in the European Union

Review and Approval Process in the EU

In the EU, medicinal products can only be commercialized after a related marketing authorization ("MA"), has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application ("MA Application"), either under a centralized procedure administered by the EMA, or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the European Economic Area ("EEA") (which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use ("CHMP"), conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MA Application under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP.

Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines

Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines (“PRIME”) scheme, which provides incentives similar to the breakthrough therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. 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 potentially accelerated MA Application assessment once a dossier has been submitted.

In the EU, a “conditional” MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted “under exceptional circumstances” where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Post-authorization Requirements in the EU

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA 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.

All new MA Applications must include a risk management plan, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of periodic safety update reports, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that medicinal product promotional materials and advertising comply with the product's Summary of Product Characteristics ("SmPC") and may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20.

The three-year transition period ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

Health Care Laws and Regulations

Health care providers, including physicians, and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state health care laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, directly or indirectly, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the Foreign Corrupt Practices Act which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “ACA”), which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to health care items or services that are reimbursed by non-government third-party payors, including private insurers.

Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violations of such laws may result in significant penalties, including criminal, civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, integrity oversight and reporting obligations, diminished profits and future earnings, and the curtailment or restructuring of operations.

Pharmaceutical Insurance Coverage and Health Care Reform

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated health care costs. Significant uncertainty exists as to the coverage and reimbursement status of drug products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of such product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product candidate that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product candidate is approved. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drug products. For example, the U.S. Department of Health and Human Services ("HHS"), imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved drug products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the health care system in the United States.

In March 2010, the United States Congress enacted the ACA, which, among other things, included changes to the coverage and payment for drug products under government health care programs.

There have been judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA"), was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal

healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, the Centers for Medicare & Medicaid Services (“CMS”) and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission’s Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact “The Great Healthcare Plan,” to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers’ global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court’s *Loper Bright* decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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 health care programs.

We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of a biological product, some of a sponsor’s U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act 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 composed of a “testing phase” and a “review phase” (also referred to as an “approval phase”). The testing phase begins on the effective date of an IND and ends on the date a BLA or a New Drug Application (“NDA”) is initially submitted to FDA. The review phase is the period between the initial submission of the BLA or NDA and approval. The term of a patent may be extended for a period of time that is the sum of one-half of the time in the testing phase, plus all the time in the review phase, and minus any of the regulatory review period that occurs prior to the patent grant or where the sponsor did not act with due diligence. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The United States Patent and Trademark Office (“USPTO”), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, where possible we intend to apply for restoration of patent term for a patent covering the ZB Assets to add, if possible, patent life beyond its current expiration date. The ability to do this will depend on the length of the clinical trials and other factors involved in the filing of the relevant BLA.

Similar provisions for supplementary protection to compensate applicants for regulatory delays also exist in a number of territories, including Europe and Japan. Where possible we intend to apply for supplementary protection for the ZB Assets.

Data and Market Exclusivity

The ACA includes a subtitle called the 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 PHSa 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. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

At the present time, 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 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. The 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 recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

In the EEA, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator’s pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EEA, during a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization application can be submitted, and the innovator’s data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. 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 authorization, is held to bring a significant clinical benefit in comparison with existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity.

Another company may market another version of the product if such company obtained a marketing authorization based on a Marketing Authorization Application with a completely independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Pediatric Development

A biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance

with an FDA-issued “Written Request” for such a study. Similar provisions are also available in other territories, such as Europe. In the EEA, 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 drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO 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.

Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) 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.

Competition

The development and commercialization of product candidates in the biopharmaceutical industry are highly competitive and are subject to technological advancements resulting in numerous assets within drug classes. The immunology market is characterized by strong and increasing competition.

Our competitive landscape encompasses a spectrum of entities, ranging from startups to large-cap biopharmaceutical, specialty pharmaceutical, and biotechnology companies. These competitors are dedicated to developing diverse therapeutic modalities tailored for autoimmune diseases, including small molecules, antibodies, and cell therapy. We believe the key competitive factors that will affect the development and commercial success of the ZB Assets and any future product candidates include safety and efficacy, reliability, dosing and administration convenience, scope of marketing approval and marketing efforts, successful protection of intellectual property, reimbursement, and price.

There are a number of large companies that currently market products or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. More established companies may have a competitive advantage over us due to their greater size, resources, and institutional experience. These companies have greater experience and expertise in securing reimbursement, government contracts, relationships with key opinion leaders, conducting testing and clinical trials, obtaining and maintaining regulatory approvals and distribution relationships to market products, and marketing approved drugs. In addition, many of these companies have significantly greater financial resources and research, development and marketing capabilities than we do.

These competitors may also have products in similar or more advanced stages of development and may have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete.

Other potential competitors include academic institutions, government agencies, and public and private entities conducting research and seeking patent protection for alternative approaches to modulating inflammatory pathways.

Other drugs, non-pharmaceutical therapies, and alternative approaches to indications we may pursue for our drug candidates may compete with us both in the United States and elsewhere in the world. In addition, competition may also arise from off-label use of products approved for other indications, products accessed through gray markets, or product candidates available through clinical trials or expanded access.

Tibulizumab

If approved, tibulizumab would compete with currently available therapies and emerging product candidates in the indications we are pursuing.

Hidradenitis Suppurativa

In HS, three biologic therapies have been approved in the United States and certain other major markets for the treatment of moderate to severe HS in adults: HUMIRA® (adalimumab), COSENTYX® (secukinumab), and BIMZELX® (bimekizumab-bkzx). These agents target tumor necrosis factor alpha (“TNF α ”) or the interleukin-17 (“IL-17”) pathway.

Additional product candidates are in clinical development for HS, including therapies targeting the IL-17 pathway, agents modulating B cell signaling (including BTK inhibitors), therapies targeting interleukin-1 (“IL-1”) signaling, Janus kinase (“JAK”) pathways, and components of the complement system, as well as multi-pathway strategies such as bispecific antibodies and dual antagonists. Given the heterogeneous and multifactorial nature of HS, multiple approaches aimed at modulating inflammatory pathways are under investigation.

Systemic Sclerosis and SSc-Associated Interstitial Lung Disease (“SSc-ILD”)

In SSc and SSc-ILD, currently utilized therapies include immunosuppressive agents and biologics such as methotrexate, mycophenolate mofetil, BENLYSTA® (belimumab), UPLIZNA® (inebilizumab-cdon), and RITUXAN® (rituximab), among others.

OFEV® (nintedanib) and ACTEMRA® (tocilizumab) have been approved in the United States and certain other major markets to slow the decline in lung function associated with SSc-ILD. Multiple additional product candidates are in development for SSc and/or SSc-ILD, including agents targeting fibrosis, inflammation, and immune-mediated pathways.

Crebankitug

If crebankitug is approved, it may face competition from companies developing therapies targeting the IL-7, and/or TSLP pathways, as well as other approaches aimed at modulating T cell activation and immune homeostasis. Certain IL-7 receptor antagonists and TSLP-targeting agents are in clinical development, and at least one TSLP-targeting antibody has been approved in other inflammatory indications. Additional emerging therapies targeting related immune pathways may also compete in the indications we may pursue.

Torudokimab

If torudokimab is approved, competition may arise from various companies and partnerships actively engaged in clinical studies targeting IL-33 or the IL-33/ST2 signaling pathway.

People and Culture

Our global team, headquartered in Henderson, Nevada, comprises highly experienced members who have actively participated in research and development, including drug development, commercialization, business development, capital formation, and investor engagement across various industries.

As of December 31, 2025, we had 40 full-time employees. None of our employees are represented by a labor union.

We believe that our future success depends upon our continued ability to attract and retain highly skilled employees. We provide competitive salaries and bonuses, opportunities for equity ownership, and an employment package that promotes well-being, including health care and retirement planning. As part of our promotion and retention efforts, we also invest in ongoing employee development.

Legal Proceedings

We are not currently a party to any material legal proceedings. In the ordinary course of business, we are subject to legal proceedings, claims, and litigation.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an “emerging growth company” as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We will remain an emerging growth company until the earlier of: (i) December 31, 2026, (ii) the last day of the fiscal year in which we have more than \$1.235 billion in total annual gross revenue, or (iii) the date on which we are deemed to be a “large accelerated filer” under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which would occur if the market value of our common equity held by non-affiliates exceeds \$700.0 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our ordinary shares held by non-affiliates exceeds \$250.0 million as of the prior June 30, or (ii) our annual revenues exceeded \$100.0 million during such completed fiscal year and the market value of our ordinary shares held by non-affiliates exceeds \$700.0 million as of the prior June 30.

Corporate Information

JATT Acquisition Corp (“JATT”) was a Cayman Islands exempted company initially incorporated under the laws of the Cayman Islands on March 10, 2021. JATT completed its initial public offering of 13,800,000 units of JATT consummated on July 13, 2021 and in the over-allotment closing on July 19, 2021, each of which consisted of one Class A ordinary share, par value \$0.0001 per share, of JATT, and one-half of one redeemable warrant (the “IPO”). On March 20, 2023 (the “Closing Date”), we consummated a series of transactions (the “Business Combination”) contemplated by that certain Business Combination Agreement, dated June 16, 2022, as amended on September 20, 2022, November 14, 2022, and January 13, 2023 by and among Zura Bio Limited, a limited company incorporated under the laws of England and Wales (“Zura Bio UK”), JATT, JATT Merger Sub, a Cayman Islands exempted company and wholly owned subsidiary of JATT, JATT Merger Sub 2, a Cayman Islands exempted company and wholly owned subsidiary of JATT and Zura Bio Holdings Ltd, a Cayman Islands exempted company (the “Business Combination Agreement”), and JATT, as the registrant, changed its name to “Zura Bio Limited”.

Available Information

We file annual reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other information with the SEC. Our filings with the SEC are available on the SEC’s website at www.sec.gov. We also maintain a website at <http://www.zurabio.com>. We make available, free of charge, in the Investor Relations section of our website, documents we file with or furnish to the SEC, including our annual reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any exhibits and amendments to those reports. We make this information available as soon as reasonably practicable after we electronically file such materials with, or furnish such information to, the SEC. The other information found on our website is not part of this or any other report we file with, or furnish to, the SEC.

We may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures will be included on our website under the “Investors” section.

ITEM 1A. RISK FACTORS

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report and in other documents that we file with the SEC, in evaluating our business. Investing in our Class A Ordinary Shares involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks that we face. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have not completed any clinical trials, and have not taken a product through to commercialization.

We are a clinical-stage company with a limited operating history. To be cash flow positive and viable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including establishing our business model and key third-party relationships; completing preclinical studies and clinical trials of our product candidates; obtaining marketing approval for product candidates; manufacturing, marketing and selling those products for which we may obtain marketing approval; satisfying any post-marketing requirements; and otherwise monetizing products, for example by licensing or selling assets.

Our products are not approved for commercial sale. Since our inception in January 2022, we have incurred significant operating losses and have utilized substantial resources to in-license and plan for development of the ZB Assets, organize and staff our company, and provide other general and administrative support. We have not completed clinical trials, including global late-stage clinical trials. As is widespread practice in the life sciences industry, we will engage third-party clinical trial organizations to conduct preclinical and clinical trials. We cannot be certain that our planned preclinical and clinical trials will begin or be completed on time or at all. Furthermore, we cannot be certain whether our planned preclinical studies and clinical trials will be on budget or have significant cost overruns. We cannot predict whether product candidates will have the desired activity in the clinical trials or whether any side effects will be tolerable. In addition, we have not yet demonstrated an ability to obtain marketing approvals, manufacture a product to commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization.

Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to arrange for third-party contractors to do the following with respect to our product candidates:

- timely file and gain acceptance of investigational new drug applications to commence planned clinical trials or future clinical trials;
- timely initiate preclinical studies and clinical trials;
- timely enroll patients in clinical trials;
- successfully complete all safety and efficacy studies (preclinical and clinical) required to obtain U.S. and foreign regulatory approval;
- run additional clinical trials or other studies beyond those planned to support the approval and commercialization;
- identify appropriate human doses for clinical trials and commercial products;
- successfully manage the prevalence, duration, and severity of potential side effects or other safety issues, if any;
- obtain a positive readout from the clinical trials regarding therapeutic activity;
- successfully demonstrate safety and efficacy to the satisfaction of the FDA, EMA, or similar foreign regulatory;

- obtain the timely receipt of necessary marketing approvals from the FDA, EMA, and similar foreign regulatory authorities;
- manufacture sufficient volume and quality of clinical trial materials to enable the completion of our planned clinical trials;
- establish manufacturing capabilities or make arrangements with contract manufacturers for future clinical supply and commercial manufacturing;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community, and third-party payors;
- position our products to effectively compete with other therapies;
- obtain and maintain coverage and adequate reimbursement for our products;
- maintain a continued acceptable safety profile following approval;
- obtain and maintain regulatory exclusivity;
- obtain and maintain patent and trade secret protection; and
- enforce and defend our intellectual property rights and claims.

Furthermore, third parties may allege that they have intellectual property rights that could block our commercial activities and we may need to seek a license, which may not be available or may not be available at a reasonable price. We may also have a contractual dispute, such as a dispute related to patent inventorship or ownership, which may take significant resources, including the management team's time, to resolve.

Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, if any, the extent of any further losses or if or when we might achieve profitability. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history or track record of relative success. We may never succeed in these activities and, even if we succeed in commercializing the ZB Assets, we may never generate revenue that is significant enough to justify the investment in development, achieve profitability or otherwise successfully monetize product candidates. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable or otherwise successfully monetize the products could decrease the value of our shares and impair our ability to raise capital, reduce or eliminate our research and development efforts, or prevent the expansion of our business, or discontinue our operations. Further, we may encounter unexpected expenses, challenges and complications from known and unknown factors such as a global pandemic.

We have incurred losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from the ZB Assets and may never generate revenue or become profitable.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront costs and capital expenditures over a multi-year timeframe, and ultimately involve a risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable. We have no products approved for commercial sale, we have not generated any revenue to date, and we continue to incur research and development and other expenses related to our ongoing operations. We may not generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval from the FDA, EMA and similar foreign regulatory authorities of, and then successfully commercialize, the ZB Assets in one or more indications in one or more territories. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. If we are unable to raise further capital in the near-term, or partner with third parties that fund all or the vast majority of our costs and capital expenditures, then we may be unable to

continue operations. We do not expect to generate sufficient revenue through any means to fully fund our operations in the near-term. We cannot assure you that any additional financing that we are able to raise would not have a dilutive impact on your ownership interest.

We incurred a net loss of \$68.7 million for the fiscal year ended December 31, 2025. We expect to continue to incur significant losses for the foreseeable future. Even after finding a means to fund the foreseeable, and unforeseeable, costs to develop our product candidates, thereafter, the progress of our development, and the clinical results achieved, will affect, positively or negatively, the value of our company and accordingly our ability to raise capital. Favorable results may increase the value of the company, increasing our ability to raise capital. Unfavorable results are likely to decrease the value of the company and could impair our ability to raise more capital, which is necessary to maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our recurring losses from operations and financial condition could raise substantial doubt about our ability to continue as a going concern.

We expect to fund our operations from existing proceeds as well as through the future sale of equity, debt, borrowing under credit facilities or through potential collaborations with other companies or other strategic transactions.

If we need to raise additional capital and are unable to do so, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. In the future, in our own required quarterly assessments, we may conclude that there is a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern.

If we are unable to raise capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval from the FDA, EMA, and similar foreign regulatory authorities for, the ZB Assets. Even if one or more of the ZB Assets are approved for commercial sale, we anticipate incurring costs associated with sales, marketing, manufacturing and distribution activities to launch the ZB Assets. Our expenses could increase beyond expectations if we are required by the FDA, EMA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of the ZB Assets. Our future capital requirements depend on many factors, including factors that are not within our control. Based on our current operating plan, and after giving effect to the completion of the February 2026 public offering, we believe our existing cash and cash equivalents, will be sufficient to fund our operations through at least the end of 2028. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

We do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financing, collaborations and licensing arrangements or other sources. Such financing may dilute our shareholders or the failure to obtain such financing may restrict our operating activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a shareholder. Debt financing may result in the imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to the ZB Assets, or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by potential worsening global economic and political conditions and volatility in the credit and financial markets in the United States and worldwide. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Due to the significant resources required for the development of the ZB Assets, we must prioritize the pursuit of treatments for certain indications. We may expend our limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success.

We intend to develop treatments for patients with serious immune system disorders. Due to financial or other constraints, we may be required to limit the scope of our development plans. For example, we have prioritized and are currently conducting Phase 2 trials of tibilizumab in two indications, but have not initiated clinical trials for crebankitug or torudokimab. In the event that we are required to limit our development plans for one or more of the ZB Assets, we may be unable to initiate clinical trials with the same scope that we otherwise intended to pursue, or the geographies in which we initiate such trials.

Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular indications may not lead to the development of any viable commercial product and may divert resources away from other opportunities (including other indications) that later prove to have greater commercial potential or a greater likelihood of success. Even if the primary endpoints of such trials are met for one or more of the ZB Assets, there is no guarantee that such findings will justify initiation of Phase 3 trials. Even if the ZB Assets successfully conclude Phase 3 and other necessary clinical trials, and thereafter receive(s) marketing approval, they may not achieve market acceptance or commercial success. If we do not accurately evaluate the commercial potential or target market for the ZB Assets, we may relinquish valuable rights through future collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. We may make incorrect determinations regarding the viability or market potential of the ZB Assets or misread trends in our industry. Finally, our contractual obligations to make milestone payments to Pfizer and Lilly may impact our ability to fund the continued development of one or more of the ZB Assets.

We may in the future license additional assets, which may require us to expend additional resources and raise additional capital.

We may execute additional transactions to add to our pipeline. We have not yet entered into any agreements for any such additional in-licensing transactions. In the event that we do enter into any additional in-license agreements, it is likely that we will need to expend additional resources and raise additional capital. The ability to do so, to some extent, is subject to market, economic, financial, competitive, legislative, and regulatory factors as well as other factors that are beyond our control. There can be no assurance that our business will generate cash flow from operations, or that additional capital will be available to us, in amounts sufficient to enable us to fund our needs.

Risks Related to Anticipated Timing for Initiation, Enrollment, and Completion of Any Planned or Future Clinical Trials

We may not be able to initiate clinical trials if drug product is not timely available at clinical trial sites.

We may not be able to initiate clinical trials if drug product is not timely available at clinical trial sites. 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 to conclude as required by the FDA or foreign regulatory authorities. Additionally, certain clinical trials for our product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible participants or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Participant enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit participants. Participant enrollment and retention in clinical trials depends on many factors, including the size and nature of the patient population, the severity of the disease under investigation, the nature of the trial protocol, the existing body of safety and efficacy data for the product candidate, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of participants to clinical sites, the eligibility criteria for the trial, the ability to adequately monitor participants during a clinical trial, clinicians' and participants' perceptions as to the potential advantages of the product candidate being studied, and the risk that participants will drop out of a trial before completing all site visits. There are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner, particularly for any rare diseases we are pursuing. Furthermore, a number of factors could delay or prevent potential participants from participating in our clinical trials. For example, our efforts to build relationships with health care providers or patient communities may not succeed, which could result in delays in participant enrollment in our clinical trials. Delays or failures in planned participant enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. For example, in January 2026, we announced updated timing of topline results from our TibuSURE study, which are now anticipated in the first half of 2027. In addition, natural disasters or public health

epidemics may delay or prevent participants from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us or our partners from completing our clinical trials at all, and harm our ability to obtain approval. Further, if participants drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

Our inability to enroll, randomize, and retain a sufficient number of eligible patients for the duration of the trials would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs, may impact the robustness or quality of the resulting data, or may require us to abandon one or more clinical trials altogether.

Risks Related to the Clinical Development and Commercialization of Our Product Candidates

We have never successfully completed the regulatory approval process for any product candidates and we may be unable to do so for any product candidates we develop.

We have not yet demonstrated our ability to obtain regulatory approvals or arrange for a third party to do so on our behalf. If we are required to conduct additional preclinical studies or clinical trials of the ZB Assets beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies or clinical trials of the ZB Assets, or if the corresponding results are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval from the FDA, EMA or other regulatory authorities for our product candidates;
- not obtain regulatory approval at all and lose our right and ability under our licenses to further develop and commercialize the ZB Assets;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements from the FDA, EMA or other regulatory authorities; or
- have the product removed from the market after obtaining regulatory approval.

We are substantially dependent on the success of the ZB Assets, and our ongoing and anticipated clinical trials of the ZB Assets may not be successful.

Our future success is substantially dependent on our ability to successfully develop the ZB Assets for future marketing approval, and then successful commercialization.

The ZB Assets will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote the ZB Assets before we receive marketing approval from the FDA, EMA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of the ZB Assets will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, the manufacturing, marketing, distribution and sales efforts of any third parties with whom we choose to collaborate in the future. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of products, even if approved. If we are not successful in commercializing products, or are significantly delayed in doing so, our business will be materially harmed.

The results of preclinical studies and early clinical trials of the ZB Assets may not be predictive of the success of our later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA, or other foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that the ZB Assets are safe and effective before we can seek marketing approval. Demonstrations of efficacy or an acceptable safety profile in prior preclinical studies of the ZB Assets do not mean that future clinical trials will yield the same results, and the translational work that we need to

conduct may fail. For instance, we do not know whether the ZB Assets will perform in future preclinical studies or clinical trials as the ZB Assets have performed in preclinical studies and early clinical trials conducted by Pfizer and/or Lilly, as applicable.

The ZB Assets may fail to demonstrate in later-stage clinical trials sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other foreign regulatory authorities despite having progressed through preclinical studies and earlier stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety or efficacy results in preclinical studies or earlier-stage trials, which could prevent us from conducting the clinical trials we currently anticipate. In January 2026, we announced that we had expanded enrollment in the TibuSHIELD study in order to improve the study's power, but there can be no assurance that the study will be successful. There is no guarantee that the FDA, EMA, and other foreign regulatory authorities will consider the data obtained from prior trials sufficient to allow us to initiate clinical trials within the timelines we anticipate, or at all. Even if we are able to initiate our planned clinical trial on schedule, there is no guarantee that we will be able to complete such trial on the timelines we anticipate or that such trial will produce positive results. Any limitation on our ability to conduct clinical trials could delay or prevent regulatory approval or limit the size of the patient population that can be treated by the ZB Assets, if approved.

Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results.

Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any stage. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials, and the outcome of preclinical studies and early-stage clinical trials for a product candidate for a particular indication may not be predictive of the success of preclinical studies and early-stage clinical trials for the same product candidate for a different indication. Unexpectedly favorable results for the standard of care in any Phase 2 or Phase 3 trial could lead to unfavorable comparisons to the ZB Assets. Historically, placebo response rates in dermatologic conditions such as HS have been high and may complicate the interpretation of clinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain investor support for continued development and financing or regulatory authority marketing approval of their product candidates.

We cannot be sure that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. For example, in January 2026, we announced updated timing of topline results from our TibuSURE study, which are now anticipated in the first half of 2027, and our TibuSHIELD study, which are now anticipated in the fourth quarter of 2026, based on enrollment. We also cannot be sure that submission of an IND or similar application will result in the FDA, EMA, or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate timely or sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site, including delays relating to translation of materials for foreign clinical sites; failure to requalify drug substance or drug product for use in clinical trials; failure to demonstrate comparability of drug substance or drug product for regulatory authorization; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of the ZB Assets for use in clinical trials, or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's GCPs or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization ("CMO") and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; delays or failure in completing technology transfer for the ZB Assets; delays or failure in obtaining or releasing drug substance or drug product from licensors or third parties; licensors or third parties being unwilling or unable to perform quality control testing of drug substance or drug product; licensors or third parties being unwilling or unable to provide a right of reference to preclinical, manufacturing or clinical data for the ZB Assets; and licensors or third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory

authorities. 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, EMA, 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 ZB Assets, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of the ZB Assets beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of the ZB Assets, if the results of these trials 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.

Preliminary, interim data from our clinical trials that we announce or publish may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may disclose preliminary 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 data. We might also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, 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 ZB Assets and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, the ZB Assets may be harmed, which could harm our business, operating results, prospects or financial condition.

We may develop the ZB Assets in combination with other therapies, which exposes us to additional risks related to other agents or active pharmaceutical or biological ingredients used in combination with our product candidates.

In the future, we may develop the ZB Assets to be used with one or more approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other regulatory authorities could revoke approval of the therapy used in combination with our product candidates or that safety, efficacy, intellectual property, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

If the FDA or other regulatory authorities revoke their approval of these other therapies or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the therapies we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval.

We may also evaluate our future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or other regulatory authorities. We will not be able to market any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates, including the potential for serious adverse effects, delays in clinical trials and lack of FDA approval.

The ZB Assets may have a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit commercial potential.

Patients in previous trials for the ZB Assets experienced adverse events. If the ZB Assets are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or INDs, we may need to interrupt, delay or abandon development or limit development to more narrow uses or subpopulations in which such potential undesirable side effects or other characteristics may be less prevalent, less severe or more acceptable from a

risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trials or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the ZB Assets and may adversely affect our business, financial condition and prospects significantly.

Additionally, if the ZB Assets receive marketing approval, we or others may later identify undesirable side effects or adverse events caused by the ZB Assets. In such cases, regulatory authorities may suspend, limit or withdraw approvals of or seek an injunction against their manufacture or distribution, require additional warnings on the label, including “boxed” warnings, or issue safety alerts, require press releases or other communications containing warnings or other safety information, require us to change the way the ZB Assets is administered or conduct additional clinical trials or post-approval studies, require us to create a REMS which could include a medication guide outlining the risks of such side effects for distribution to patients or impose fines, injunctions or criminal penalties. We could also be sued and held liable for harm caused to patients, and our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the ZB Assets, if approved, and could seriously harm our business.

The ZB Assets are protein therapeutics and thus carry the risk of provoking immune responses. For example, the formation of anti-drug antibodies (“ADA”) were observed in the majority of patients who were dosed with crebankitug in a Phase 1b trial in T1D mellitus. There can be no assurance that ADAs will not develop in future studies that may reduce exposure or lead to adverse safety events. The development of ADA could also trigger hypersensitivity reactions that manifest as serious adverse events for the ZB Assets, including but not limited to anaphylaxis. If patients experience adverse events, including anaphylaxis, our trials could be delayed or stopped and our development programs may be halted entirely if this is observed during clinical development. Even if ADAs are not detected in early clinical trials, they may be detected after product launch and may significantly reduce the commercial potential or even result in the product being pulled from the market.

Risks Related to our Dependence on Third Parties or Their Actions

We intend to rely on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct preclinical studies or clinical trials required to develop our product candidates. We intend to rely on CROs, clinical trial sites, contractors, and other third parties to ensure the proper and timely conduct of our preclinical studies and clinical trials. We intend to rely upon CROs, contractors, and others to monitor, manage, and report data for our clinical trials, which includes data management, pharmacovigilance, biostatistical analysis and programming. Our reliance on the CROs, contractors, and others will not relieve us of our regulatory responsibilities.

We, our CROs, contractors, and other third parties we might engage will be required to comply with GLPs and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. Although we will rely on CROs, contractors, and others to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with our investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs, contractors, and others does not relieve us of our regulatory responsibilities. If we, CROs, contractors, and other third parties we engage fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials for approval. Accordingly, if our CROs, contractors, or others fail to comply with these regulations or fail to recruit a sufficient number of participants, we may be required to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, CROs, contractors, and other third parties we engage will not be our employees, and we will not control whether or not they devote sufficient time and resources to our programs. These CROs, contractors, and others 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 harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, contractors, and others, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. In addition, certain of our agreements with CROs, contractors, or other third parties provide for monetary and other limitations on their liability. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, 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 any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates.

If our relationships with any CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition, and prospects.

In addition, investigators for our 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. The FDA may conclude that a financial relationship between us and an investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA 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 and may ultimately lead to the denial of product approval.

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our product candidates. Reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost.

We have no or limited experience in drug formulation or manufacturing as a company, and we do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage and distribution, or testing. We will be dependent on third parties to manufacture the clinical supplies of our product candidates.

Further, we also will rely on contract manufacturers to supply us with sufficient quantities of our product candidates, to be used, if approved, for commercialization. We do not have long-term commercial supply agreements or commitments with a manufacturer to produce raw materials, active pharmaceutical ingredients or the finished products of our product candidates or the associated packaging. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, adverse macroeconomic or geopolitical developments such as a health epidemic or pandemic, or the ongoing conflicts in Ukraine and the Middle East, could impact our ability to procure sufficient supplies for the development of our products and product candidates. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Our reliance on contract manufacturers entails various risks, some of which we would not be subject to if we manufactured product candidates ourselves, including:

- inability to meet our drug specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP or similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components or finished drug product;
- lack of qualified backup suppliers for components or finished drug product purchased from a sole or single source supplier;

- misappropriation of proprietary information, including our trade secrets and know-how;
- the mislabeling of clinical supplies, potentially resulting, e.g., in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions;
- operations of our contract manufacturers or suppliers being disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

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

There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic and national security factors could lead to global trade restrictions and changes in trade policies and regulations that may adversely affect our business and operations.

Risks Related to Our Intellectual Property

Our business relies on certain licensing rights from Lilly for tibalizumab that can be terminated in certain circumstances. If we breach the agreement, or if we are unable to satisfy our obligations under which we license rights to tibalizumab from Lilly, we could lose the ability to develop and commercialize tibalizumab.

Our ability to continue to develop and commercialize tibalizumab is dependent on the use of certain intellectual property that is licensed to us from Lilly. The license sets forth certain terms and conditions for maintaining the license. In the event that the terms and conditions are not met or we become insolvent or bankrupt, the license may be terminated and we will no longer be able to develop and commercialize tibalizumab.

The 2023 Lilly License imposes upon us various diligence, payment and other obligations, as described in the section entitled “*Business — License Agreements — 2023 Lilly License.*”

If we fail to comply with any of our obligations under the 2023 Lilly License, Lilly may have the right to terminate the license agreement, in which event we would not be able to market any tibalizumab product.

If there is any dispute with Lilly regarding our rights under the 2023 Lilly License, including if we are unable to meet our milestone obligations or become insolvent or bankrupt, our ability to develop and commercialize tibalizumab may be adversely affected. Any uncured, material breach by us under the 2023 Lilly License could result in our loss of exclusive rights to tibalizumab and may lead to a complete termination of our product development efforts for tibalizumab.

Our business relies on certain licensing rights from Pfizer for crebankitug that can be terminated in certain circumstances. If we breach the agreement, or if we are unable to satisfy our obligations under which we license rights to torudokimab from Pfizer, we could lose the ability to develop and commercialize crebankitug.

We are party to a license agreement with Pfizer under which we were granted rights to certain patents, know-how and technology that are important and necessary to our business, including for crebankitug. Our rights to use these patents and employ the inventions claimed therein, as well as the exploitation of licensed technology and know-how, are subject to the continuation of, and our compliance with, the terms of our license agreement.

Our license agreement with Pfizer imposes upon us various diligence, payment and other obligations, including as described in the section entitled “*Business — License Agreements — Pfizer Agreement.*”

If we fail to comply with any of our obligations under the Pfizer Agreement, or we are subject to a bankruptcy or dissolution, Pfizer may have the right to terminate the license agreement, in which event we would not be able to market any crebankitug product.

We are heavily reliant upon the license from Pfizer to certain patent rights that are important or necessary to the development of crebankitug. Pfizer retains all rights not expressly granted by the license as well as retaining rights to make, have made, use and import crebankitug or any products containing crebankitug for all internal research, development and regulatory purposes, except that Pfizer does not have the right to conduct clinical trials to develop crebankitug or any products containing crebankitug.

We are responsible for filing, prosecuting (including in connection with any reexaminations, oppositions and the like) and maintaining the licensed patent rights and to provide Pfizer a reasonable opportunity to review and comment on proposed submissions to any patent office and reasonably consider any comments provided by Pfizer. We must notify Pfizer prior to permitting any patent right to go abandoned. Pfizer may then choose at its option to continue prosecution or maintenance of said patent right and the license granted to us will become nonexclusive as to that right. The patents and patent applications licensed by Pfizer were not drafted by us or our attorneys, and we have not controlled or had any input into the prosecution of these patents and patent applications. We cannot be certain that drafting or prosecution of those patents and patent applications were conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

Pursuant to the Pfizer Agreement, we are required to prepare a development plan and use Commercially Reasonable Efforts (as that term is defined in the Pfizer Agreement) to develop and seek regulatory approval for crebankitug in several countries and then to commercialize each product where regulatory approval is obtained. If we fail to comply with the obligations under our license agreement, or if we use the licensed intellectual property in an unauthorized manner, we may be required to pay damages and Pfizer may have the right to terminate the license. If our license agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidate covered by our agreement and those being tested or approved in combination with such product. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement.

Pursuant to the Pfizer Agreement, we have the first right, but not the obligation, to enforce the licensed patents at our expense. Without Pfizer’s consent, we may not settle any such initiated litigation that would (i) adversely affect the validity, enforceability or scope of any of the licensed patent rights, (ii) give rise to liability of Pfizer or its Affiliates, (iii) admit non-infringement of any licensed patent rights, or (iv) otherwise impair Pfizer’s rights in any licensed technology or the license agreement. If we decide not to enforce the licensed patents, our licensor has the option to enforce them and may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than is desirable. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

If there is any dispute with Pfizer regarding our rights under the Pfizer Agreement, including if we are unable to meet our milestone obligations or become insolvent or bankrupt, our ability to develop and commercialize crebankitug may be adversely affected. Any uncured, material breach by us under the Pfizer Agreement could result in our loss of exclusive rights to crebankitug and may lead to a complete termination of our product development efforts for crebankitug.

Our business relies on certain licensing rights from Lilly for torudokimab that can be terminated in certain circumstances. If we breach the agreement, or if we are unable to satisfy our obligations under which we license rights to torudokimab from Lilly, we could lose the ability to develop and commercialize torudokimab.

Our ability to continue to develop and commercialize torudokimab is dependent on the use of certain intellectual property that is licensed to us from Lilly. The license sets forth certain terms and conditions for maintaining the license. In the event that the terms and conditions are not met or we become insolvent or bankrupt, the license may be terminated and we will no longer be able to develop and commercialize torudokimab.

The 2022 Lilly License imposes upon us various diligence, payment and other obligations, as described in the section entitled “*Business — License Agreements — 2022 Lilly License.*”

If we fail to comply with any of our obligations under the 2022 Lilly License, Lilly may have the right to terminate the license agreement, in which event we would not be able to market any torudokimab product.

If there is any dispute with Lilly regarding our rights under the 2022 Lilly License, including if we are unable to meet our milestone obligations or become insolvent or bankrupt, our ability to develop and commercialize torudokimab may be adversely affected. Any uncured, material breach by us under the 2022 Lilly License could result in our loss of exclusive rights to torudokimab and may lead to a complete termination of our product development efforts for torudokimab.

Intellectual property disputes may impact our business and/or our ability to develop and commercialize the ZB Assets.

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or 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 have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate.

Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor’s rights.

In addition, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to seek alternative options, such as developing new product candidates with

design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

Our success depends in large part on our ability to obtain and maintain patent protection for the ZB Assets and their uses, components, formulations, methods of manufacturing and methods of treatment, as well as our ability to operate without infringing on or violating the proprietary rights of others. We have licensed rights, including composition of matter patent families, related to the ZB Assets. Licensing assets from third parties involves technical and scientific due diligence to assess the opportunity, the strength of the intellectual property protection for the asset and the ability to commercialize the asset. This due diligence is usually conducted over a relatively short period of time. It can be difficult to identify all the issues relevant to the assessment. Failure to identify all the relevant issues can impact negatively on the value of the asset.

Our intellectual property strategy is, where appropriate, to file new patent applications on inventions, including improvements to existing products/ candidates and processes to improve our competitive edge or to improve business opportunities. We continually assess and refine our intellectual property strategy to ensure appropriate protection and rights are secured. Thus, we may be able to file patent applications in the United States and abroad related to our novel discoveries and technologies, for example new uses/methods of treatment, new formulations and improvements to manufacturing methods, that are important to our business, as opportunities arise.

Identifying and seeking patent protection is expensive and time consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions where protection may be commercially advantageous, or we may financially not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information we regard as proprietary. Where possible, we seek to file for patent protection in commercial jurisdictions relevant to the product or technology; however, this is assessed on a case-by-case basis.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our future patent applications may not result in patents being issued which protect our technology or product candidates or which do not effectively prevent others from commercializing competitive technologies and product candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application or certain patent claims from being issued.

The issuance of a patent does not ensure that it is valid or enforceable. Therefore, even if we are issued a patent, it may not be valid or enforceable against third parties. Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by pharmaceutical and biotechnology companies. Thus, any of our patents, including patents that we may rely on to protect our market for approved products, may be held invalid or unenforceable by a court. If we are unable to successfully enforce our patents, we may be unable to exclude competitors from the marketplace, which may materially impact our business.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions claimed in our issued patents or future patent applications, or that we or our licensors were the first to file for protection of the corresponding inventions. As a result, we may not be able to obtain or maintain protection for certain inventions. Such patent protection may be of insufficient scope to achieve our business objectives.

In addition, the issuance of a patent does not necessarily give us the right to practice the patented invention. Third parties may have blocking patents that prevent marketing of our products or working our own technology. We endeavor to identify early third-party patents and patent applications which may block a product or technology, to minimize this risk. However, relevant patents or patent applications may be overlooked or missed, and we may need to obtain additional licenses from third parties to advance our research or commercialize the ZB Assets. We may fail to obtain any of these licenses on reasonable terms, or at all. If we are unable obtain a license, we may be required to expend significant time and resources to develop replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly.

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions, including the United States, Europe, China and Japan, the basic patent term is 20 years from the earliest filing date of a non-provisional patent application, subject to the payment of renewal fees. Some jurisdictions, including the United States, Europe and Japan, provide for up to an additional five years as a patent term extension for therapeutic products that require marketing approval. The requirements for this supplementary protection are set by the relevant authorities in the given jurisdiction. Products approved before the expiry of the basic patent term may benefit from such a patent term extension. It is our strategy to apply for such supplementary protection, where possible.

In addition to patent protection, statutory provisions in the United States, Europe and other jurisdictions may provide a period of clinical data exclusivity which may be followed by an additional period of market exclusivity to compensate for the time required for regulatory approval of our product candidates. Once the relevant criteria are satisfied, the protection applies. The length of protection depends on the jurisdiction and may also depend on the type of therapy.

Third parties may seek to market “similar” versions of our approved products, if any. Alternatively, third parties may seek approval to market their own products, similar or otherwise, that compete with our products. We may not be able to block the commercialization of these products, which may erode our commercial position in the marketplace.

If disputes over intellectual property and other rights that we have licensed, own in the future or co-own in the future prevent or impair our ability to maintain our licensing or exclusivity arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate.

We have limited geographical protection with respect to our licensed patents and may not be able to protect our intellectual property rights throughout the world.

We may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents worldwide can be prohibitively expensive and our intellectual property rights in some foreign jurisdictions may be less extensive than those in the United States.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In Europe, the expiration of an invention patent is 20 years from its filing date. Certain U.S. patents have a longer patent term pursuant to patent term adjustment (35 U.S.C. §154(b)).

Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries. For example, we may lack patent protection or pending patent applications in manufacturing countries such as China, India, and Singapore.

Even if patents are granted, they may be difficult to enforce in certain countries, for example, in China. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. 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 and financial condition may be adversely affected. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. While an inadvertent failure to make payment of fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-payment or non-compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our

licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates.

Issued patents covering one or more of our product candidates could be found invalid or unenforceable.

Any issued patents that we may license or own covering the ZB Assets 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. We may be subject to claims challenging the inventorship, ownership, validity, or enforceability of our patents and/or other intellectual property. Finally, changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect the ZB Assets. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market the ZB Assets under patent protection would be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage.

Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings. 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 the ZB Assets and compete directly with us. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize the ZB Assets.

We may not be able to maintain or enforce trade secret protection for our product candidates.

In addition to seeking patents, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation 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 may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A Ordinary Shares. 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. 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.

Patent terms may not protect our competitive position with respect to the ZB Assets for an adequate amount of time.

The life of a patent, and the protection it affords, is limited. Once patents covering the ZB Assets have expired, we may be open to competition from competitive products, including generics or biosimilars. 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 licensed and owned patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extensions in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. However, a patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug or its use it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug.

If and when the ZB Assets receive FDA approval, we expect to apply for patent term extension on patents covering those ZB Assets, there is no guarantee that the applicable authorities will agree with our assessment of whether such extension should be granted, and even if granted, the length of such extension. We may not be granted patent term extension either in the United States or in any foreign country 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 term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect or capitalize on the ZB Assets.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) could increase the uncertainties and costs surrounding the prosecution of our future owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and altered the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future legislation by the U.S. Congress, decisions by the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a

material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future. For example, in the case *Amgen v. Sanofi*, the Supreme Court held broad functional antibody claims invalid for lack of enablement. Similarly, in the case *Juno v. Kite*, the Federal Circuit held genus claims directed to CAR-T cells invalid for lack of written description for failing to provide disclosure commensurate with the scope of the claims. While we do not believe that any of the patents licensed or owned by us will be found wholly invalid based on these decisions, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

In Europe, a new unitary patent system came into effect on June 1, 2023. Under the unitary patent system, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (“UPC”). European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market the ZB Assets.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant third-party patents, the scope of said patent claims or the expiration of relevant patents, are complete, accurate or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of the ZB Assets. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent’s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. Our determination of the expiration date of any patent that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market the ZB Assets.

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 for technology covered by our patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering the ZB Assets or technology similar to ours. Any such patent application may have priority over our patent applications or patents, and if any such patent is granted, we may be required to obtain rights to those patents, which may not be available on reasonable terms or at all.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

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 such ownership rights.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing the ZB Assets or as a result of questions regarding co-ownership of potential joint inventions. Arbitration or litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we are unable to achieve ownership rights needed to assert a patent, we may be unable to use that patent to exclude a competitor from the marketplace. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against any of the above, such claims, arbitrations or litigations could result in substantial costs and be a distraction to management and other employees.

We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing the ZB Assets.

Our commercial success depends in part on avoiding infringing, misappropriating and otherwise violating the patents and other intellectual property and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, and administrative proceedings such as interferences, *inter partes* review and post grant review proceedings before the USPTO, and opposition proceedings before foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned or controlled by third parties, including our competitors, exist in the fields in which we are pursuing products and product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we or our licensors are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment relating to our products and product candidates and, because patent applications can take many years to issue, there may be currently pending third party patent applications which may later result in issued patents, in each case that our products and product candidates, their manufacture or use may infringe or be alleged to infringe.

If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon the ZB Assets and/or seek a license from the patent holder. Such a license may not be available on reasonable terms or at all. In addition, any intellectual property claims (e.g., patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds at a particular market price.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. If the third party is found not to infringe our asserted patents, then we may not be able to exclude them from the marketplace. Even if they are found to infringe our patents, a court may not grant an injunction to exclude them from the marketplace. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be sufficient.

Further, we may be required to protect our patents through procedures created to challenge the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. 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.

In addition, if any of the ZB Assets is found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain a license.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Our license from Pfizer is subject to retained rights.

Pfizer retains certain rights under its license agreement with us, including (a) the right to make, have made, use and import the underlying technology for all internal research, development and regulatory purposes; provided, that Pfizer shall not have the right to conduct clinical trials to develop the underlying technology in the treatment, diagnosis or prevention of diseases in humans, (b) the right to use the licensed patent rights and know-how for purposes other than those exclusively license to us under the Pfizer Agreement and (c) the rights that have been provided by Pfizer to (i) a reagent supplier to make or sell the underlying technology or (ii) a non-commercial entity to use the underlying technology, in each case in the form of non-cGMP samples of the underlying technology in milligram quantities solely as a research reagent.

Pfizer may also use for any purpose information in non-tangible form which may be retained by persons who have had access to crebankitug and the licensed know-how, including ideas, concepts or techniques contained therein.

It is difficult to monitor whether Pfizer limits its use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Our licenses from Lilly are subject to retained rights.

Lilly retains certain rights under its license agreements with us, including the right to use the underlying technology for internal research, development and regulatory purposes. It is difficult to monitor whether Lilly limits its use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

We may not be able to effectively secure first-tier technologies when competing against other companies or investors.

Our future success may require that we acquire patent rights and know-how to new or complementary technologies. However, we compete with a substantial number of other companies that may also compete for technologies we desire. In addition, many venture capital firms and other institutional investors, as well as other biotechnology companies, invest in companies seeking to commercialize various types of emerging technologies. Many of these companies have greater financial, scientific and commercial resources than us. Therefore, we may not be able to secure the technologies we desire. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and/or technologies.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether licensed or owned, 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 factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we may file or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensor) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensor) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;

- 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 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 and results of operation.

If approved, our product candidates that are regulated as biologics may face competition from biosimilars or interchangeables approved through an abbreviated regulatory pathway.

The BPCIA was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and 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. 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 develop and receive approval of a competing biologic, so long as their BLA does not rely on the reference product, sponsor’s data or submit the application as a biosimilar application. Any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of the ZB Assets is approved in the United States as a biological product under a BLA it would 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 the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. The approval of a biosimilar or interchangeable of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure.

Risks Related to Regulatory and Legal Compliance

The regulatory approval processes of the FDA, EMA, and other foreign regulatory authorities are complex, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for the ZB Assets, we may not be able to commercialize, or may be delayed in commercializing, the ZB Assets, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals in the U.S., EU and other jurisdictions is complex, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize the ZB Assets without first obtaining regulatory approval from the FDA in the United States and comparable foreign regulatory authorities outside of the United States. Before obtaining regulatory approvals for the commercial sale of the ZB Assets, we must demonstrate through complex and expensive preclinical studies and clinical trials that the ZB Assets are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. Further, the ZB Assets may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA, EMA, and comparable foreign regulatory authorities have discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Any of the ZB Assets could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities that is the ZB Assets are

safe and effective for their proposed indications; the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using products similar to the ZB Assets; we may be unable to demonstrate that the clinical and other benefits of the ZB Assets outweigh their safety risks; the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of the ZB Assets may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA, EMA, or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of the ZB Assets; the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical or commercial supplies; and the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Further, the approval requirements for the ZB Assets are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predicative of success elsewhere.

Of the large number of products in development, only a small percentage successfully complete the FDA, EMA, or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market the ZB Assets, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve the ZB Assets for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve the ZB Assets with a label that does not include the labeling claims necessary or desirable for the successful commercialization of the ZB Assets. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for the ZB Assets, we may not be able to commercialize, or may be delayed in commercializing, the ZB Assets and our ability to generate revenue could be materially impaired.

Disruptions at the FDA, EMA, the European Commission and other applicable U.S. and foreign government agencies and regulatory authorities caused by funding shortages, furloughs or other concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those authorities from performing normal business functions on which the operation of our business may rely, which could significantly harm our business, financial condition, results of operations and prospects.

The ability of the FDA, EMA, the European Commission or any other applicable foreign regulatory authority 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, ability to accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA, EMA, the European Commission, or any other applicable foreign regulatory authority's ability to perform routine functions. Average review times at the authorities have fluctuated in recent years as a result and could be delayed. In addition, government funding of the FDA and other government authorities 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 at the FDA and other agencies or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government authorities, which would adversely affect our business. For example, over the last several years, including during the recent government shutdown that began on October 1, 2025 and lasted 43 days and the government shutdown that lasted for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If, as a result of a prolonged government shutdown or otherwise, the FDA or other regulatory authorities are unable to timely conduct their regular inspections, reviews, or other regulatory activities, 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.

We will be subject to extensive 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 the ZB Assets.

Any regulatory approvals that we may receive for the ZB Assets will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the ZB Assets, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. In addition, if the FDA, EMA, or comparable foreign regulatory authorities approve the ZB Assets, the ZB Assets and the

activities associated with their respective development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA, EMA, and comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA, and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discover previously unknown problems with the ZB Assets, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the ZB Assets are manufactured, a regulatory authority may impose restrictions on the ZB Assets, the manufacturing facility or us, including requiring recall or withdrawal of the ZB Assets from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described herein may inhibit our ability to commercialize the ZB Assets and generate revenue and could require us to expend significant time and resources to respond and could generate negative publicity.

The FDA's, EMA's and other regulatory comparable authorities' policies may change and additional government regulations may be enacted that could prevent, limit, delay, increase the cost or risks of obtaining regulatory approval of our product candidates, including if as a result new or more costly or difficult to achieve clinical trial or manufacturing quality requirements are imposed. 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 regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer the ZB Assets at competitive prices which would seriously harm our business.

Sales of our product candidates in the United States, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Coverage policies and third-party payor reimbursement rates may change at any time. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, the U.S. Department of Health and Human Services (HHS), imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party payor reimbursement or a decision by a third-party payor to not cover any of our product candidates, if approved, could have a material adverse effect on our sales, results of operations and financial condition. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates if approved will be harmed.

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

If one or more of the ZB Assets is approved and we are found to have improperly promoted off-label uses, we may become subject to significant liability. If we cannot successfully manage the promotion of the ZB Assets, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers 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, commercial collaborators, principal investigators, CROs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities, whether intentionally or inadvertently. As we continue to grow and scale our operations, this risk increases. We have adopted a Code of Conduct and appropriate subject-specific policies applicable to all of our employees, but it is not always possible to promptly identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute the ZB Assets, if approved. See the section titled “Business — Government Regulation” for a more detailed description of the laws that may affect our ability to operate.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain regulatory approval.

The size of the potential market for the ZB Assets is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of the indications that may be addressable by the ZB Assets, which is derived from a variety of sources, including scientific literature and surveys of clinics. Our estimations may prove to be incorrect and the number of potential patients may turn out to be lower than expected. The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, the success of competing therapies and product pricing and reimbursement. Even if we obtain significant market share for our product candidates, because the potential target populations could be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Certain current and future relationships with customers and third party payors as well as certain of our business operations may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and information security laws and other privacy and information security laws. If we are unable to comply, or have not fully complied or are perceived to have not fully complied, with such laws, we could face significant penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Our operations may be directly, or indirectly through our relationships with customers, third party payors, healthcare providers, and others subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. The laws and regulations that may affect our ability to operate include, but may not be limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including Medicare or Medicaid, that are false or fraudulent;
- HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the HITECH and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf and their subcontractors that use, disclose, access, or otherwise process individually identifiable health information, and their covered subcontractors;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and further requires applicable manufacturers and applicable group purchasing organizations to report annually to the CMS ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as: anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; and state and local laws that require the registration of pharmaceutical sales representatives, many of which 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 (or perceived to be in violation) of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, litigation, significant civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, disgorgement, imprisonment, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business, including interrupting or stopping clinical trials, and our results of operations. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations, including continuing to build out a compliance program, will likely be costly.

Healthcare legislative and regulatory reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding healthcare systems that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes that could impact our ability to sell our products profitably. In particular, in 2010, the ACA was enacted, which, among other things, substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which

narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, the CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored-Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's recent Strategy Report released September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored-Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

There have been, and likely will continue to be, healthcare reform measures, including legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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

We and our external partners are subject to complex environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes, and the rehabilitation of contaminated sites. Our operations, including those performed by our external partners, may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we and/or our external partners may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are subject to laws and regulations related to privacy, data protection, information security and consumer protection across different markets where we conduct our business. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to laws and regulations related to, among other things, privacy, data protection, information security and consumer protection across different markets where we conduct our business. Such laws and regulations are constantly evolving and changing and are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an adverse effect on our business, operating results and financial operations. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security

incident or breach involving the potential or actual misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third party, could adversely affect our business, financial condition, and results of operations, including but not limited to investigation costs, material fines and penalties, compensatory, special, punitive, and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services, and/or credit restoration services or relief.

European data collection is also governed by restrictive regulations governing the use, processing and cross-border transfer of personal information. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in Europe, including personal health data, is subject to the EU General Data Protection Regulation (“EU GDPR”) and similar requirements in the United Kingdom (“UK GDPR”) (hereinafter the EU GDPR and UK GDPR are collectively referred to as “GDPR”), which impose strict requirements for processing the personal data of individuals within the EEA, such as Norway, Iceland, Liechtenstein and the United Kingdom. The GDPR is directly applicable in each EU member state and is extended to the EEA, while the UK GDPR applies to the United Kingdom of Great Britain and Northern Ireland. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR implements more stringent operational requirements than its predecessor legislation. 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. For example, the GDPR applies extraterritorially, requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for collecting and processing personal data (including data from clinical trials), requires the appointment of data protection officers, such as when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, including far reaching information rights and the right to erasure, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training, and audits. The GDPR provides that EU member states and EEA countries may establish their own laws and regulations that go beyond the GDPR in certain areas, such as regarding the mandatory appointment of data protection officers or further limiting the processing of personal data, including genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK’s International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

Our employees and personnel use generative artificial intelligence (“AI”) and/or automated decision-making technologies to perform their work, and the disclosure and use of personal information in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI and/or automated decision-making technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI and/or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

We cannot assure you that our third-party service providers with access to our or our customers’, suppliers’, trial patients’ and employees’ personally identifiable and other sensitive or confidential information will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage, and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. On February 20, 2026, the U.S. Supreme Court ruled that the President does not have authority under the International Emergency Economic Powers Act to impose broad tariffs without explicit congressional authorization, striking down major tariffs previously in place. In response to the U.S. Supreme Court ruling, the Trump administration imposed a new worldwide tariff effective for 150 days from February 24, 2026 and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response to previous and newly announced tariffs, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments and ongoing uncertainty regarding potential future shifts in federal trade policy and judicial interpretations of trade authorities have increased trade tensions and economic uncertainty and created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. Additionally, in April 2025, the Bureau of Industry and Security, U.S. Department of Commerce, initiated a Section 232 investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside of the United States pose a national security risk and should be subject to additional tariffs. This investigation may lead to new tariffs or trade restrictions to encourage domestic production.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our manufacturers and suppliers, including drug substances and drug products for tibalizumab, torudokimab, and crebankitug, are located outside of the United States, and our principal suppliers of critical raw materials are currently located in Italy, the Netherlands, and the United Kingdom. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Additionally, we are party to the Cell Line License Agreement with WuXi Biologics, which provides us with a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics’s know-how, cell line and biological materials to manufacture, have manufactured, use, sell and import certain products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement. See “*Business—License Agreements—Wuxi Biologics License.*” If we have product manufactured at WuXi Biologics in the future, we may face additional manufacturing and supply-chain risks due to the regulatory and political structure of the PRC, or as a result of the international relationship with the PRC, including but not limited to sanctions, tariffs and other restrictions that have been or may be imposed.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the

import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. As we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects. In addition, in the event Most-Favored-Nation pricing for pharmaceutical products is implemented and applicable to any of our product candidates that may receive regulatory approval, our revenue opportunities may be adversely affected.

The complexity of announced or future tariffs may also increase the risk that we or our suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described in this Annual Report.

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

We are dependent on our key personnel and anticipate hiring additional key personnel. If we are not successful in attracting and retaining qualified personnel, including consultants, 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 qualified managerial, scientific and medical personnel. We are dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, Chief Operating Officer, Chief Medical Officer, Chief Financial Officer and Chief Technology Officer. We have experienced numerous changes in management, and such frequent changes could be disruptive to our business.

If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts. We have relied upon and plan to continue to rely upon third parties, including consultants, to act in management roles. While we have agreements with such third parties, we do not have the same ability to influence their time commitment to us as we would if they were employees. Furthermore, we are dependent on our ability to attract, hire, relocate and retain qualified managerial, scientific and medical personnel from various jurisdictions. Therefore, immigration requirements may have a significant influence on our human resources planning. Immigration applications can take several months or more to be finalized. If we are unable to complete the requisite visa applications, either as a result of changing requirements or otherwise, our ability to successfully implement our business strategy could suffer, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on third parties, including consultants, independent clinical investigators and CROs to conduct and sponsor some of the clinical trials of our product candidates. Any failure by a third party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, academic partners, medical institutions, consultants and third-party CROs, to conduct our preclinical studies and clinical trials, including in some instances sponsoring such clinical trials, and to engage with regulatory authorities and monitor and manage data for our ongoing

preclinical and clinical programs. While we have, or will have, agreements governing the activities of such third parties, we will control only certain aspects of their activities and have limited influence over their actual performance.

Any of these third parties or consultants may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new contract research organization begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

We remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA and other regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our academic partners or CROs or if we or any of our academic partners or CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, 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 any other reasons, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us, our academic partners or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, with respect to investigator-sponsored trials that may be conducted, we do not control the design or conduct of these trials, and it is possible that the FDA or EMA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including the ability to obtain a license to obtain access to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we do not have control over the timing and reporting of the data from investigator-sponsored trials, nor do we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected. Additionally, the FDA or EMA may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or EMA may require us to obtain and submit additional preclinical, manufacturing, or clinical data.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.

We expect to experience significant growth in the number of our employees and/or number of consultants as well as the scope of our operations, particularly in the areas of drug development, clinical operations, regulatory affairs and, potentially, others. To manage our anticipated future growth, we must continue to implement and develop our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited

experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

Our internal computer systems, or those of any of the third parties with whom we work (including CROs, manufacturers, other contractors or consultants or potential future collaborators), may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of the third-parties with whom we work, such as CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties (including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, sophisticated nation states, and nation-state supported actors), which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data and cause program delays that could negatively impact our ability to meet our desired clinical development timelines.

Such cyber-attacks may include, but are not limited to, social-engineering attacks (including through deep fakes, which are increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. The likelihood and severity of these attacks may increase as we become more visible in the marketplace and approach significant milestones, such as key clinical data readouts or regulatory submissions.

We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of the ZB Assets could be delayed. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services.

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 data privacy and security obligations. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company or our customers could be leaked, disclosed, or revealed as a result of or in connection with our employees’, personnel’s, or vendors’ use of generative AI technologies.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

We currently rely, and plan to rely in the future, on third parties to conduct and support 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 regulatory approval of or commercialize the ZB Assets.

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract development and manufacturing organizations (“CDMOs”) and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. 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 studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. 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, EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations, even if responsibilities have been outlined in agreements with external partners, such as CROs. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to the ZB Assets. 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 regulatory approval of or successfully commercialize the ZB Assets.

We intend to rely on third parties to manufacture the ZB Assets. There can be no assurance that we will successfully negotiate future agreements with third-party manufacturers for the ZB Assets on acceptable terms or at all. Our business could be adversely affected if the third-party manufacturers are unable to produce the ZB Assets, fail to provide us with sufficient quantities of the ZB Assets or fail to do so at acceptable quality levels or prices.

We do not currently own or operate any facility that may be used to manufacture the ZB Assets (including any drug substance or finished drug product) and must rely on CDMOs to produce them for us. We have not yet validated the commercial scale and may not be able to do so for the ZB Assets for approval. For tibatuzumab, we do not currently own any cGMP compliant drug product and will not be able to conduct any clinical trials until we do. There can be no assurance that we will successfully negotiate agreements with CDMOs to manufacture future ZB Assets on acceptable terms or at all.

We have not participated in the manufacturing process of, and are completely dependent on, our contract manufacturing partners for manufacture of the ZB Assets and for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of the ZB Assets. If our partners do not successfully carry out their contractual duties, meet expected deadlines, or manufacture the ZB Assets in accordance with regulatory requirements, or if there are disagreements

between us and our CDMO, we will not be able to complete, or may be delayed in completing, the clinical trials required to support approval of the ZB Assets or the FDA, EMA or other regulatory agencies may refuse to accept our clinical or preclinical data. If the FDA, EMA, or a comparable foreign regulatory authority does not approve these facilities for the manufacture of the ZB Assets or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market the ZB Assets, if approved. Similarly, our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of the ZB Assets, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of the ZB Assets and harm our business and results of operations.

Moreover, if any CDMO on which we will rely are unable to produce the ZB Assets at all, or fail to manufacture quantities of the ZB Assets at quality levels necessary to meet our clinical requirements, or regulatory requirements at a scale sufficient to meet anticipated demand, and at a cost that allows us to continue development and to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. Our business could be similarly affected by business disruptions to our third-party providers with potential impacts on our future revenue and financial condition and our costs and expenses. If any CDMOs we contract with are unable to meet our timelines or cost and quantity demands, we may need to find additional CDMOs and negotiate new manufacturing agreements. We may also incur substantial fees if we contract with a CDMO to access a cell-line and we ultimately decide not to use that cell-line or that CDMO for the manufacturing of the ZB Assets and need to obtain resources elsewhere. Each of these risks could delay or prevent the commencement as well as the completion of our clinical trials or the approval of the ZB Assets by the FDA, including by causing us to have to rerun clinical studies, which would result in higher costs and could adversely impact the commercialization of the ZB Assets.

In addition, some third party CDMOs have intellectual property, such as patents and/or know-how for which they require an annual fee, milestones and/or royalties. These financial obligations increase the overall cost of goods and can reduce profitability or reduce the valuation of the product. We have such agreements in place, and may need additional agreements in the future.

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

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to the ZB Assets and/or our operations more broadly. Any of these relationships may require us to 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 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;
- 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 protect our intellectual property or proprietary information 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;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidate; and
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to such intellectual property or may require a license from the collaborator for such intellectual property in order to commercialize the product candidate and/or discourage generic competition.

As a result, if we enter into future 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. Furthermore, if conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Any delays in entering into future 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.

Our financial condition, results of operations and business reputation could be adversely affected by our recent internal review of certain agreements and other matters.

As previously disclosed, the audit committee of our board of directors formed an audit subcommittee to review our agreements and relationships with BAFFX17 and Stone Peach, among other matters, and engaged independent legal counsel to review the matters described therein. The review, the outcome of the review and other events arising in connection with these matters may materially adversely impact our financial condition and results of operations. See “Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Audit Subcommittee Investigation,” of this Annual Report for further information regarding the audit subcommittee review.

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

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biotechnology and biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event, or an employee or contractor may use social media to post information that is inaccurate, unauthorized or otherwise detrimental to our business, reputation or interests. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public’s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidate or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, we could fail to recognize actual or potential conflicts arising from the relationship or arrangement that our directors or executive officers have with another company. Our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We may identify material weaknesses in our internal control over financial reporting in the future or fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet periodic reporting obligations.

As a public company, we are required to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act and make an ongoing, formal assessment of the effectiveness of our internal controls over financial reporting.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will prevent or avoid control deficiencies that could lead to material weaknesses in our internal control over financial reporting in the future. Our current controls, and any new controls that we develop, may become inadequate because of changes in conditions in our business. Further, deficiencies in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods.

We have performed a formal evaluation of our internal control over financial reporting under the supervision and with the participation of management, including our principal executive officer and principal financial officer, as required by Section 404 of the Sarbanes-Oxley Act. We have not engaged an independent registered public accounting firm to perform an audit of our internal control over financial reporting as of any balance sheet date or for any period reported in our financial statements. We are required to evaluate and disclose changes made in our internal controls and procedures on a quarterly basis. Failure to comply with the Sarbanes-Oxley Act could potentially subject us to sanctions or investigations by the SEC, the applicable stock exchange or other regulatory authorities, which would require additional financial and management resources.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired, which may adversely affect investor confidence in Zura and, as a result, the market price of our ordinary shares.

As a public company, we are required to comply with the requirements of the Sarbanes-Oxley Act, including, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We continue to develop and refine our disclosure controls and other procedures that are designed to ensure that information we are required to disclose in the reports that we will file with the SEC are recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act, is accumulated and communicated to our management, including our principal executive and financial officers.

In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including dedicated to internal resources. We may also need to engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting. If any of these new or improved controls and systems do not perform as expected, we may experience material weaknesses in our controls. Moreover, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

Any failure to implement and maintain effective disclosure controls and procedures and internal control over financial reporting, including the identification of one or more material weaknesses, could cause investors to lose confidence in the accuracy and completeness of our financial statements and reports, which would likely adversely affect the market price of our ordinary shares. In addition, we could be subject to sanctions or investigations by the stock exchange on which our ordinary shares are listed, the SEC and other regulatory authorities.

Increasing regulatory focus on privacy and security issues and expanding laws and regulatory requirements could impact our business models and expose us to increased liability.

We are subject to global data protection, privacy and security laws, regulations and codes of conduct that relate to our business activities, which may include sensitive, confidential, and personal information. These laws, regulations and codes are inconsistent across jurisdictions and are subject to evolving and differing (sometimes conflicting) interpretations. Government officials and regulators, privacy advocates and class action attorneys are increasingly scrutinizing how companies collect, process, use, store, share and transmit personal data. This scrutiny can result in new and shifting interpretations of existing laws, thereby further impacting our business. For example, the GDPR in the European Economic Area, and the United Kingdom continues to be interpreted by European and U.K. courts in novel ways leading to shifting requirements, country specific differences in application and uncertain enforcement priorities. Under the GDPR, companies face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

More recently enacted laws globally, and new and emerging state laws in the United States on privacy, data and related technologies, such as the California Consumer Privacy Act (“CCPA”), the California Privacy Rights Act, the Colorado Privacy Act and the Virginia Consumer Data Protection Act, as well as industry self-regulatory codes and regulatory requirements, create new privacy and security compliance obligations and expand the scope of potential liability, either jointly or severally with our customers and suppliers. For example, the CCPA applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages.

As a security example, pursuant to the SEC’s Rules on Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure we are required to make certain disclosures related to material cybersecurity incidents and the reasonably likely impact of such an incident on Form 8-K and will be required to make certain other cybersecurity disclosures on Form 10-K. Determining whether a cybersecurity incident is notifiable or reportable may not be straightforward and any such mandatory disclosures could be costly and lead to negative publicity, loss of customer confidence in the effectiveness of our security measures, diversion of management’s attention and governmental investigations. We publish privacy policies and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, concerning data privacy, and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

While we made certain investments in readiness to comply with applicable requirements, the dynamic and evolving nature of these laws, regulations and codes, as well as their interpretation by regulators and courts, may affect our ability to implement our business models effectively and to adequately address disclosure requirements. These laws, regulations and codes may also impact our innovation and business drivers and may force us to bear the burden of more obligations. Perception of our practices, products, services or solutions, even if unfounded, as a violation of individual privacy, data protection rights or cybersecurity requirements, subjects us to public criticism, lawsuits (including class-action claims), government enforcement actions (e.g., fines, penalties, audits, inspections, investigations, audits), additional reporting requirements and/or oversight, bans or restrictions on processing personal data (including clinical trial data), orders to destroy or not use personal data (including clinical trial data), claims and other proceedings by regulators, industry groups or other third parties, all of which could disrupt or adversely impact our business and reputation and expose us to increased liability, fines and other punitive measures including interruptions or stoppages in our business operations (including clinical trials), inability to process personal data in certain jurisdictions, prohibition on sales of our products, services or solutions, restrictive judicial orders and disgorgement of data.

We face substantial competition, which may result in others discovering, developing, licensing or commercializing products before or more successfully than we do.

We face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Furthermore, pharmaceutical companies that develop and/or market products for the indications we are pursuing are likely to represent substantial competition. These include companies actively developing and/or marketing IL-7R inhibitors (such as Q32 Bio Inc. and OSE Immunotherapeutics SA), TSLPR inhibitors (such as Upstream Bio, Inc.), IL-33 inhibitors (such as Regeneron Pharmaceuticals, Inc. / Sanofi and AstraZeneca plc), ST2 inhibitors (such as Roche Holding AG / Genentech, Inc.), IL-17A inhibitors (such as MoonLake Immunotherapeutics, UCB SA, and Novartis AG), and BAFF inhibitors (such as GSK plc and Novartis AG). The above mechanisms may be of potential therapeutic use in one or more of the indications we plan to pursue in the Phase 2 program. If the ZB Assets do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors. Conversely, mixed or negative results from competitors developing comparable mechanisms of action may adversely affect the outlook for our product candidates.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize the ZB Assets. Our competitors may also develop drugs that are more effective, more convenient, more widely used or less costly or have a better safety profile than the ZB Assets and these competitors may also be more successful than us in manufacturing and marketing their products.

Furthermore, we also face competition more broadly across the market for existing cost-effective and reimbursable treatments for T-cell and B-cell mediated diseases, autoimmune diseases, and inflammatory diseases. The ZB Assets, if approved, may compete with these existing drug and other therapies but may not be competitive with them in price. We expect that if the ZB Assets are approved, they will be priced at a significant premium over biosimilar and generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for the ZB Assets will pose challenges.

Public health crises such as pandemics or similar outbreaks have affected and could continue to seriously and adversely affect our preclinical studies and anticipated clinical trials, business, financial condition and results of operations.

As a result of pandemics, related “shelter in place” orders and other public health guidance measures, we may experience disruptions that could seriously harm our business. Potential disruptions include but are not limited to: delays or difficulties in enrolling patients in, initiating or expanding our clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting health conditions or being forced to quarantine; interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed; recommendations by federal, state or local governments, employers and others or interruptions of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical trial endpoints; diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors; interruption or delays in the operations of the FDA, EMA, and comparable foreign regulatory authorities including delays in receiving approval from local regulatory authorities to initiate our planned clinical trials; interruption of, or delays in receiving, supplies of the ZB Assets due to staffing shortages, raw materials shortages, production slowdowns or stoppages and disruptions in delivery systems; and limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions.

Pandemics and other public health guided measures may also affect the ability of the FDA, EMA, and other regulatory authorities to perform routine functions. If global health concerns prevent the FDA, EMA, or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA, EMA, or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The extent to which pandemics evolve may affect our clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the pandemic, new or continued travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs, business closures or business disruptions. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

Pandemics and other similar disruptions may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Our business, operations, financial position, and clinical development plans and timelines could be materially adversely affected by international conflicts and economic sanctions.

Our financial position and operations may be materially and adversely affected by international conflicts, including military action (e.g., in Ukraine, Iran and the broader Middle East), civil disturbance (e.g., conflicts in Mexico) and economic sanctions imposed by certain governments. These conflicts may impact our ability to carry out clinical development activities in certain countries or regions. As our ability to continue to operate will be dependent on raising debt and equity finance, any adverse impact to those markets as a result of international conflict, including due to increased market volatility, decreased availability in third-party financing and/or a deterioration in the terms on which it is available (if at all), could negatively impact our business, operations or financial position. The extent of any potential impact is not yet determinable, however.

Third-party manufacturers in other countries may be subject to U.S. legislation or investigations, including the proposed BIOSECURE Act, sanctions, trade restrictions, and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, and could adversely affect our financial condition and business prospects. For example, the current U.S. federal government administration has recently proposed tariffs on certain U.S. imports, and China and other countries have responded with and/or threatened retaliatory tariffs on certain U.S. exports. We cannot predict what effects these tariffs and potential additional tariffs will have on our business, including in the context of escalating trade tensions. However, these tariffs and other trade restrictions could increase our operating costs, reduce our gross margins or otherwise negatively impact our financial results.

WuXi Biologics has historically been our sole supplier of torudokimab. We have moved our existing product from WuXi to the U.K. When we require additional product, we may find a new manufacturing facility for torudokimab. There is a risk that supplies of torudokimab may be significantly delayed by, or may become unavailable as a result of, finding a new manufacturer or business-related issues affecting WuXi Biologics, including manufacturing, equipment, process or regulatory issues. If we continue to have product manufactured at WuXi Biologics, we may also face additional manufacturing and supply-chain risks due to the regulatory and political structure of the PRC, or as a result of the international relationship with the PRC, including but not limited to sanctions and tariffs imposed by the U.S. government on WuXi. Although currently there has been no impact on our ability to obtain supply of torudokimab, there can be no assurance that operations would not be impacted in the future with a negative impact on the supply of, or use of, torudokimab.

Risks Related to Ownership of Our Class A Ordinary Shares

The market price of our securities may be volatile and may decline in the future.

Since the consummation of the Business Combination, the market value of our securities has fluctuated. Future fluctuations in the price of our securities could contribute to the loss of all or part of a shareholder’s investment. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. If an active market for our securities continues, the market price of our ordinary shares may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our ability to commercialize the ZB Assets, if approved;
- announcements regarding results of any clinical trials relating to our product candidates;
- unanticipated serious safety concerns related to the use of the ZB Assets;

- adverse regulatory decisions;
- changes in laws or regulations applicable to the ZB Assets, including but not limited to clinical trial requirements for approvals;
- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for the ZB Assets, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or shareholder litigation;
- our decision to initiate a clinical trial, not initiate a clinical trial or to terminate an existing clinical trial;
- our dependence on third parties;
- announcements of the introduction of new products by our competitors;
- market conditions and trends in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results or intellectual property rights of others;
- future issuances of ordinary shares or other securities;
- the recruitment or departure of key personnel;
- failure to meet or exceed any financial guidance or expectations regarding product development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- our failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- changes in financial estimates by us or by any securities analysts who might cover our shares;
- fluctuation of the market values of any of our potential strategic investments;
- issuances of debt or equity securities;
- compliance with our contractual obligations;
- sales of our Class A Ordinary Shares by us or our shareholders in the future;
- trading volume of our Class A Ordinary Shares;
- ineffectiveness of our internal controls;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- general political and economic conditions;

- effects of natural or man-made catastrophic events;
- effects of public health crises, pandemics and epidemics; and
- other events or factors, many of which are beyond our control.

Further, the equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of Class A Ordinary Shares, which could cause a decline in the value of Class A Ordinary Shares. Price volatility of Class A Ordinary Shares might worsen if the trading volume of Class A Ordinary Shares is low. In the past, shareholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' share. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of Class A Ordinary Shares.

We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the capital appreciation, if any, of our Class A Ordinary Shares.

We have not paid cash dividends on our Class A Ordinary Shares and we do not anticipate paying cash dividends on our Class A Ordinary Shares in the foreseeable future. The payment of dividends on our shares will depend on our ability to comply with relevant legal requirements as well as our earnings, financial condition and other business and economic factors affecting us at such time as the Board of Directors may consider relevant. Since we do not intend to pay dividends, a shareholder's ability to receive a return on such shareholder's investment will depend on any future appreciation in the market value of our Class A Ordinary Shares. There is no guarantee that our Class A Ordinary Shares will appreciate or even maintain the price at which our shareholders have purchased it.

Future sales and/or issuances of our securities could result in additional dilution of the percentage ownership of our existing shareholders and could cause our share price to fall.

If we or any of our existing shareholders sell our Class A Ordinary Shares, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences, and privileges senior to existing holders of our securities. Sales of a substantial number of our Class A Ordinary Shares in the public market, including the resale of the Class A Ordinary Shares held by our shareholders, could occur at any time. These sales, or the perception in the market that the holders of a large number of Class A Ordinary Shares intend to sell shares, could reduce the market price of our Class A Ordinary Shares. Pursuant to our Amended and Restated Registration and Shareholder Rights Agreement, dated March 20, 2023, by and among us and the shareholders party thereto (the "A & R Registration Rights Agreement"), certain shareholders are entitled to have a registration statement kept effective for a prolonged period of time such that registered resales of their Class A Ordinary Shares can be made.

Pursuant to our obligations under the A&R Registration Rights Agreement, we filed a resale shelf registration statement, which the SEC declared effective on September 14, 2023, as amended (the "Resale Registration Statement"), covering the resale of up to an aggregate of 21,248,364 Class A Ordinary Shares, 3,782,000 2023 Pre-Funded Warrants (as defined herein) and 3,782,000 Class A Ordinary Shares issuable upon the exercise of the 2023 Pre-Funded Warrants. Until such time that it is no longer effective, the Resale Registration Statement permits the resale of these shares for a significant period of time, the precise duration of which cannot be predicted. The resale, or expected or potential resale, of a substantial number of shares of our Class A Ordinary Shares in the public market could adversely affect the market price for our Class A Ordinary Shares and make it more difficult for you to sell your holdings at times and prices that you determine are appropriate. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the registration statement may continue for an extended period of time.

In addition, we currently have on file with the SEC a shelf registration statement on Form S-3 which allows us to offer and sell our ordinary shares, preference shares, debt securities, warrants and or units from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. In September 2024, we entered into a Sales Agreement (the "Sales Agreement") with Leerink Partners ("Leerink"), pursuant to which, from time to time, we may offer and sell through Leerink up to \$125.0 million of our Class A Ordinary Shares registered under the shelf registration statement pursuant to one or more "at the market" offerings. From time to time, we have issued and sold Class A Ordinary Shares pursuant to this agreement and as of the date of this filing, we have \$114.0 million of Class A Ordinary Shares remaining available for sale under the Sales Agreement. Sales of our Class A Ordinary Shares under the Sales Agreement with Leerink could be subject to business, economic or competitive uncertainties and contingencies, many of which

may be beyond our control, and which could cause actual results from the sale of our Class A Ordinary Shares to differ materially from expectations.

To the extent additional capital is raised through the sale and issuance of shares or other securities convertible into shares, the ownership interest of our shareholders will be diluted. Future issuances of our Class A Ordinary Shares or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our Class A Ordinary Shares and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of our Class A Ordinary Shares or the availability of our Class A Ordinary Shares for future sales will have on the trading price of our shares.

If certain holders of our Class A Ordinary Shares sell a significant portion of their securities, it may negatively impact the market price of our Class A Ordinary Shares and such holders still may receive significant proceeds.

Certain of our shareholders hold approximately 3,450,000 shares of our Class A Ordinary Shares that were originally purchased by JATT's sponsor, JATT Ventures, L.P, in a private placement prior to JATT's initial public offering at an effective purchase price of \$0.007 per share (the "Founder Shares") Accordingly, holders of the Founder Shares could sell their securities at a per-share price that is meaningfully less than the current market price of our Class A Ordinary Shares and still realize a significant profit from the sale of those securities that could not be realized by our other shareholders. As a result, holders of the Founder Shares may be more incentivized than our other shareholders to sell our Class A Ordinary Shares. If holders of the Founder Shares were to sell a significant portion of their securities, it may negatively impact the price of our Class A Ordinary Shares.

Our operating results have and may continue to fluctuate significantly.

We expect our operating results to be subject to quarterly, and possibly annual, fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- the addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting the ZB Assets, regulatory approvals, and the level of underlying demand for such products and purchasing patterns; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our ordinary shares to fluctuate substantially.

The absence, reduction, or unfavorable nature of securities or industry analyst coverage of our business, as well as unfavorable third-party reports or commentary and the existence of pre-funded warrants, could adversely affect the market price and trading volume of our Class A ordinary shares.

The trading market for our Class A Ordinary Shares is influenced by research reports, recommendations and other commentary published by securities or industry analysts that cover us or our business. We currently have research coverage from a limited number of analysts, and we cannot assure that additional analysts will initiate coverage of us or that existing coverage will be maintained. The scope, frequency and extent of analyst coverage may be limited due to factors beyond our control, including our market capitalization, operating history, clinical-stage development profile, capital structure or the nature of our business.

We may also be referenced in reports, analyses or other publications by third parties that do not formally cover us, including industry reports or market commentary. The content, accuracy and timing of information contained in such publications is outside of our control.

If a limited number of securities or industry analysts cover us, or if analysts that cover us issue unfavorable opinions regarding our business, business model, intellectual property, clinical trials, operating results or share performance, the market price or trading volume of our Class A ordinary shares may be adversely affected. In addition, if analysts reduce the frequency of their reports or fail to publish research on us on a regular basis, we may experience reduced visibility in the financial markets, which could adversely affect the market price or trading volume of our Class A ordinary shares.

We also have outstanding pre-funded warrants to purchase Class A ordinary shares. The existence of pre-funded warrants and the potential for their exercise may be reflected differently across analyst reports or third-party publications, which may contribute to investor uncertainty, share price volatility or changes in trading volume.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to the ZB Assets.

We may issue additional equity securities to fund future expansion and pursuant to equity incentive or employee benefit plans. We may also issue additional equity for other purposes. These securities may have the same rights as the Class A Ordinary Shares or, alternatively, may have dividend, liquidation or other preferences to the Class A Ordinary Shares. The issuance of additional equity securities will dilute the holdings of existing shareholders and may reduce the share price of the Class A Ordinary Shares.

Pursuant to the 2023 Zura Bio Limited Equity Incentive Plan, as amended (the “EIP”), we are authorized to grant equity awards to our employees, directors and consultants. In addition, pursuant to the 2023 Employee Stock Purchase Plan (“ESPP”), we are authorized to sell shares to our employees. As of December 31, 2025, a total of 12,859,090 and 4,029,898 Class A Ordinary Shares have been reserved for future issuance under the EIP and the ESPP, respectively. In addition, the EIP and ESPP provide for annual automatic increases in the number of shares reserved thereunder on January 1st of each year, unless our Board of Directors, or the appropriate committee thereof, elects not to increase the number of shares underlying the EIP and ESPP each year. Accordingly, on January 1, 2026, the shares reserved for future issuances under the EIP was increased by 5%. As a result of such annual increases, our shareholders may experience additional dilution, which could cause the price of our Class A Ordinary Shares to fall.

If we raise additional funds through collaboration, licensing or other similar arrangements, we may have to relinquish valuable rights to the ZB Assets, or grant licenses on terms unfavorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of the product candidates.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A Ordinary Shares.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A Ordinary Shares.

Anti-takeover provisions in the MAA and under Cayman Islands law could make an acquisition, which may be beneficial to our shareholders, more difficult and may prevent attempts by our shareholders to replace or remove our current management.

The Second Amended and Restated Memorandum and Articles of Association of Zura Bio Limited (the “MAA”) and the Companies Act (Revised) of the Cayman Islands (the “Cayman Islands Companies Act”) contain provisions that could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. Among other things, these provisions:

- allow the Board of Directors to authorize the issuance of preference shares, the terms of which may be established and the shares of which may be issued without shareholder approval, and which may include such preferred, deferred or other rights or restrictions, whether in regard to voting, dividends or other distributions, return of capital or other rights;

- provide that directors may only be removed (a) for cause by the vote of a majority of the other directors then in office or (b) by the affirmative vote of holders of at least two-thirds of the total voting power of all the then-outstanding Class A Ordinary Shares entitled to vote thereon, voting together as a single class;
- prohibit shareholder action by written resolution;
- provide that extraordinary general meetings may only be called by or at the direction of (a) the Chairman of the Board of Directors, the Board of Directors or the Chief Executive Officer or (b) members holding not less than 10% in par value of the issued shares which as at the date of the requisition for a meeting carry the right to vote at general meetings;
- provide that any alteration, amendment or repeal, in whole or in part, of any provision of the MAA by our shareholders will require the affirmative vote of the holders of at least two-thirds of the total voting power of all the then-outstanding Class A Ordinary Shares entitled to vote thereon, voting together as a single class; and
- establish advance notice requirements for appointment of directors to the Board of Directors and for proposing matters that can be acted upon by shareholders at general meetings.

These anti-takeover provisions and other provisions in the MAA and Cayman Islands law could make it more difficult for shareholders or potential acquirors to obtain control of the Board of Directors or initiate actions that are opposed by our then-current Board of Directors and could also delay or impede a merger, tender offer or proxy contest involving us. The existence of these provisions could negatively affect the price of our Class A Ordinary Shares and limit opportunities for a shareholder to realize value in a corporate transaction. In addition, if prospective takeovers are not consummated for any reason, we may experience negative reactions from the financial markets, including negative impacts on the price of our Class A Ordinary Shares.

The MAA designate the Cayman Islands as the exclusive forum for certain litigation that may be initiated by our shareholders and the federal district courts of the United States as the exclusive forum for litigation arising under the Securities Act, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to the MAA, unless we contest in writing to the selection of an alternative forum, the Courts of the Cayman Islands and any appellate court therefrom, will, to the fullest extent permitted by law, be the sole and exclusive forum for any claim or dispute arising out of or in connection with the MAA or otherwise relating to each shareholder's shareholding in Zura, including but not limited to (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our shareholders; (iii) any action asserting a claim arising pursuant to any provision of the Cayman Islands Companies Act, or the MAA; (iv) any action asserting a claim against us governed by the "internal affairs doctrine," (as such concept is recognized under the laws of the United States of America); *provided that*, for the avoidance of doubt, the foregoing forum selection provision will not apply to claims arising under the Securities Act, the Exchange Act or any other claim for which the federal district courts are, as a matter of the laws of the United States, the sole and exclusive forum for determination of such a claim.

The forum selection provisions in the MAA may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings and there is uncertainty as to whether a court would enforce such provisions. In addition, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If the enforceability of our forum selection provisions were to be challenged, we may incur additional costs associated with resolving such challenge. While we currently have no basis to expect any such challenge would be successful, if a court were to find its forum selection provisions to be inapplicable or unenforceable with respect to one or more of these specified types of actions or proceedings, we may incur additional costs associated with having to litigate in other jurisdictions, which could result in a diversion of the time and resources of our employees, management and Board of Directors, and could have an adverse effect on our business, financial condition and results of operations.

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

We are an emerging growth company, as defined in the JOBS Act. 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 periodic reports and proxy statements and

exemptions from the requirements of holding nonbinding advisory shareholder votes on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find Class A Ordinary Shares less attractive as a result, there may be a less active trading market for Class A Ordinary Shares and our share price may be more volatile.

We will remain an emerging growth company until the earlier of (i) December 31, 2026, (ii) the last day of the fiscal year in which we have more than \$1.235 billion in total annual gross revenues, (iii) the date on which we are deemed to be a large accelerated filer, which requires the market value of our ordinary shares that is held by non-affiliates to exceed \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 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 irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our business, financial condition and results of operations.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements.

We have and will continue to incur increased costs as a result of operating as a public company, and our management will devote substantial time to related compliance initiatives.

As a public company, we have and will continue to incur significant legal, accounting and other expenses that Legacy Zura did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations adopted, and to be adopted, by the SEC and The Nasdaq Capital Market (“Nasdaq”). Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive to obtain directors’ and officers’ liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. In addition, if our directors’ and officers’ liability insurance policy lapses, is cancelled, or is not renewed, we may be unable to secure new coverage or may only be able to do so at a significantly higher cost. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult to attract and retain qualified persons to serve on the Board of Directors, committees of the Board of Directors or as executive officers. Advocacy efforts by shareholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

Our enterprise resource planning system is intended to combine and streamline the management of our financial and accounting functions, enabling us to manage operations and track performance more effectively. Any disruptions or difficulties in using the enterprise resource planning system could adversely affect our controls and harm our business, financial condition and results of operations. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

As a public company, we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting. To achieve compliance with Section 404 within the prescribed period, we are engaging in a process to document and evaluate internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During

the course of testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. See above for additional information regarding a previously identified material weakness. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are 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 intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of our management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and there could be a material adverse effect on our business, financial condition and results of operations.

A failure to meet Nasdaq's continued listing requirements could result in a delisting of ordinary shares.

In order to continue to maintain the listing of our securities on Nasdaq, we are required to demonstrate ongoing compliance with Nasdaq's continued listing requirements. If we fail to satisfy Nasdaq's continued listing requirements, such as the minimum number of round-lot shareholders, the minimum dollar value of the public float, the total minimum capital, the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may or take steps to delist our Class A Ordinary Shares. We cannot assure you that we will be able to meet all continued listing requirements.

In the event of a delisting, we can provide no assurance that any action taken to restore compliance with listing requirements would allow our ordinary shares to become listed again, stabilize the market price or improve the liquidity of our ordinary shares, prevent our ordinary shares from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

We believe that we were a Passive Foreign Investment Company ("PFIC") for U.S. federal income tax purposes for the taxable year ended December 31, 2025, which could result in adverse U.S. federal income tax consequences to U.S. Holders.

If we are treated as a PFIC within the meaning of Section 1297 of the U.S. Internal Revenue Code of 1986, as amended (the "Code") for any taxable year (or portion thereof) during which a U.S. Holder (as defined below) holds our Class A Ordinary Shares (regardless of whether we remain a PFIC for subsequent taxable years), certain adverse U.S. federal income tax consequences, such as taxation at the highest marginal ordinary income tax rates on capital gains and on certain actual or deemed distributions, and interest charges on certain taxes treated as deferred, may apply to such U.S. Holder and such U.S. Holder might be subject to additional reporting requirements. Under certain circumstances, certain elections may be available to U.S. Holders of Class A Ordinary Shares to mitigate some of the adverse tax consequences resulting from PFIC treatment.

Based on the nature of our activities and the composition of our income and assets, we believe we were a PFIC for the taxable year ended December 31, 2025. Additionally, we may be a PFIC in the current taxable year or in any subsequent taxable year. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our Class A Ordinary Shares from time to time, which may fluctuate considerably. 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 how, and how quickly, we spend the cash we raise in any offering. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status.

If we were determined to be a PFIC, you may be unable to make certain advantageous elections with respect to your ownership of the Class A Ordinary Shares that could mitigate some of the adverse consequences of our PFIC status, or making such elections retroactively could have adverse tax consequences to you. We are representing to you, and there can be no assurance, that we will or will not be treated as a PFIC for any past, current, or future taxable year. We have not sought and will not seek any rulings from the United States Internal Revenue Service (the "IRS") or any opinion from any tax advisor as to such tax treatment. If we determine that we are a PFIC for any taxable year, upon written request by a U.S. Holder, we will endeavor to provide or make available to such U.S.

Holder such information as the IRS may require to enable the U.S. Holder to make and maintain a “qualified electing fund” election, but there can be no assurance that we will timely provide such required information. U.S. Holders should consult with, and rely solely upon, their tax advisors to determine the application of the PFIC rules to them and any resultant tax consequences.

For purposes of this discussion, a “U.S. Holder” is a person who, for U.S. federal income tax purposes, is a beneficial owner of our Class A Ordinary Shares and is (1) a citizen or individual resident of the United States; (2) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state thereof or the District of Columbia; (3) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or (4) a trust that (a) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code) or (b) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 1C. CYBERSECURITY

Risk management and strategy

Our information technology (IT) department with the help of third-party service providers helps identify, assess and manage our cybersecurity threats and risks by monitoring and evaluating our threat environment using various methods, including conducting scans of the threat environment, audits, and assessments. Our cybersecurity risk management processes have been designed to identify, assess, manage, mitigate, and respond to cybersecurity threats. This program will be integrated within our enterprise risk management system.

Depending on the environment, systems, and data at issue, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our information systems and data. For example, our cybersecurity risk management program is comprised of various components, such as:

- Maintaining certain data backup, disaster recovery, and business continuity capabilities designed to support timely restoration of our IT systems and data, which may include automated and encrypted backups, segregation of backup environments, defined recovery time and recovery point objectives for key systems, periodic restoration testing, and integration of recovery procedures with our incident response and cross-functional crisis management processes.
- Implementing certain security monitoring and access controls, which may include deployment of endpoint detection technologies, centralized security monitoring through a security operations function, and identity and access management processes designed to enforce least-privilege access, multi-factor authentication, privileged access management, and continuous monitoring of authentication activity.
- Requiring periodic employee cybersecurity training to mitigate the risk of phishing and social engineering attacks.
- Conducting periodic risk assessment of protections to mitigate cybersecurity threats.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, managed cybersecurity service providers, cybersecurity software providers, and dark web monitoring services.

We use third-party service providers to perform a variety of functions throughout our business, such as CROs and CMOs. We have a vendor management process to manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the information systems and data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider. This process may include reviewing the vendor’s written security program and conducting security assessment calls with the vendor’s personnel.

For a description of the risks from cybersecurity threats that may materially affect our company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report, including “Our internal computer systems, or those of any of the third parties with whom we work (including CROs, manufacturers, other contractors or consultants or potential future collaborators), may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.”

Governance

Our Board of Directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by our management, including our Vice President of IT who stays informed about and oversees prevention, detection, mitigation, and remediation efforts through regular communication and reporting channels within our organization. The Chief Legal Officer oversees the information security function and receives regular updates about information security.

Our Vice President of IT is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our Vice President of IT is also responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Chief Legal Officer. Our Chief Legal Officer works with the Vice President of IT to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response processes include reporting to the Audit Committee for certain cybersecurity incidents. The Chief Legal Officer and Audit Committee oversee the IT department and receive periodic updates concerning our significant cybersecurity threats and risk and the processes we have implemented to address them.

ITEM 2. PROPERTIES

We do not own any real property. We currently lease executive offices at 1489 W. Warm Springs Rd., #110, Henderson, Nevada and 8-10 Hill Street, London, W1J 5NG. We consider our current office space adequate for our current operations.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings, nor are we aware of any material pending or threatened litigation. In the ordinary course of business, we may be subject to legal proceedings, claims, and litigation.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information for Class A Ordinary Shares

Our Class A Ordinary Shares are listed for trading on The Nasdaq Capital Market under the symbol "ZURA".

Holders of Record

As of December 31, 2025, there were approximately 12 shareholders of record of our ordinary shares. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never declared or paid any cash dividends on our shares. We do not intend to pay cash dividends to our shareholders in the foreseeable future. Investors should not purchase our Class A Ordinary Shares with the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of the Board of Directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that the Board of Directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Persons

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information that management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and notes thereto as of December 31, 2025, included elsewhere in this Annual Report.

In addition to historical information, this discussion and analysis contains forward-looking statements. These forward-looking statements are subject to risks and uncertainties, including those discussed in the section titled "Risk Factors" in this Annual Report, that could cause actual results to differ materially from historical results or anticipated results. You should carefully read the information under "Cautionary Note Regarding Forward-Looking Statements" in this Annual Report. Unless the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" to "Zura," "we," "us," and "our" refer to Zura Bio Limited, a Cayman Islands exempted company, and its consolidated subsidiaries.

Overview

We are a clinical-stage biotechnology company developing novel and differentiated medicines for patients with autoimmune and inflammatory diseases, including serious and debilitating conditions with significant unmet medical need.

We were incorporated as a Cayman Islands exempted company on March 10, 2021. Our wholly owned subsidiary, Zura Bio Limited ("Zura Bio UK") was formed in the United Kingdom ("U.K.") on January 18, 2022. Prior to March 20, 2023, our operations were conducted through Zura Bio UK.

We have a limited operating history. Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital and entering into collaboration agreements for conducting manufacturing, and research and development activities. Our lead product candidate is in the clinical testing stage; however, prior to the initiation of TibuSHIELD and TibuSURE in May 2025 and December 2024, respectively, we had not conducted any clinical trials ourselves. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations through (i) the sale of equity, raising an aggregate of \$10.0 million of gross proceeds from the sale of our convertible preferred shares of Zura Bio UK through March 31, 2023; (ii) the issuance of a promissory note, receiving net proceeds of \$7.6 million in December 2022; (iii) proceeds from the Business Combination of \$56.7 million in March 2023 (iv) the sale of Class A Ordinary Shares and pre-funded warrants to purchase up to 3,782,000 Class A Ordinary Shares at a price of \$4.249 per pre-funded warrant for an aggregate purchase price of approximately \$16.1 million (the "2023 Pre-Funded Warrants") during the year ended December 31, 2023 (the "April 2023 Private Placement"), raising an aggregate of \$75.8 million of net cash proceeds; (v) the sale of Class A Ordinary Shares and pre-funded warrants to purchase up to 16,102,348 Class A Ordinary Shares at a price of \$3.107 per pre-funded warrant for an aggregate purchase price of \$50.0 million (the "2024 Pre-Funded Warrants") in April 2024 (the "April 2024 Private Placement") raising an aggregate of \$105.3 million of net cash proceeds; (vi) the sale of 1,500,000 Class A Ordinary Shares at a price of \$3.80 per share under the ATM (as defined below) for net proceeds of \$5.5 million, after sales agent commissions, in September 2024; and (vii) the sale of 3,000,000 Class A Ordinary Shares at a price of \$1.75 per share under the ATM for net proceeds of \$5.1 million, after sales agent commissions, in the first quarter of 2025.

Since our inception, we have incurred significant operating losses. Our net loss for the years ended December 31, 2025 and 2024 were \$68.7 million and \$52.4 million, respectively. As of December 31, 2025, we had an accumulated deficit of \$224.5 million. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue to advance the preclinical and clinical development of our product candidates;
- conduct our planned preclinical studies and clinical trials for our product candidates, as well as initiate and complete additional trials of future potential product candidates;
- scale up our clinical and regulatory capabilities;
- manufacture current good manufacturing practices, or cGMP, material for clinical trials or potential commercial sales;
- hire additional clinical, quality, regulatory, manufacturing, scientific and administrative personnel;

- establish a commercialization infrastructure and scale up manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- add operational, financial, and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, and other expenses in operating as a public company.

Business Combination

JATT Acquisition Corp (“JATT”) was a Cayman Islands exempted company initially incorporated under the laws of the Cayman Islands on March 10, 2021. On July 13, 2021, JATT completed its IPO. On March 20, 2023 (the “Closing Date”), we consummated a series of transactions contemplated by that certain Business Combination Agreement and JATT, as the registrant, changed its name to “Zura Bio Limited”.

On March 21, 2023, our Class A Ordinary Shares began trading on the Nasdaq under the symbol “ZURA”.

Shelf Registration and ATM Program

We filed a shelf registration statement on Form S-3 (the “Shelf Registration Statement”), which was declared effective September 17, 2024. Pursuant to the Shelf Registration Statement, we may offer and sell ordinary shares, preference shares, debt securities, warrants and or units having an aggregate public offering price of up to \$300.0 million. In connection with the filing of the Shelf Registration Statement, we also entered into a sales agreement (the “Sales Agreement”) with Leerink Partners LLC (“Leerink Partners”), relating to the sale of our Class A Ordinary Shares having an aggregate gross sales price of up to \$125.0 million, from time to time through Leerink Partners, acting as sales agent (the “ATM”). We incurred \$0.6 million of offering expenses in connection with establishing the ATM that reduced additional paid-in capital as of December 31, 2024. During the third quarter of 2024, we sold 1,500,000 Class A Ordinary Shares at a price of \$3.80 per share under the ATM, for net proceeds of \$5.5 million, after placement agent commissions. During the year ended December 31, 2025, we sold 3,000,000 Class A Ordinary Shares at a price of \$1.75 per share under the ATM, for net proceeds of \$5.1 million, after placement agent commissions. As of the date of this filing, we have \$114.0 million of Class A Ordinary Shares remaining available for sale under the Sales Agreement.

Exchange of Class A Ordinary Shares for Pre-Funded Warrants

In April 2025, we entered into share surrender and warrant agreements with certain affiliated shareholders (the “2025 Shareholders”), pursuant to which (i) the 2025 Shareholders surrendered an aggregate of 6,500,000 Class A Ordinary Shares owned by the 2025 Shareholders, for no consideration, which were immediately cancelled and retired, upon surrender; and (ii) we issued pre-funded warrants to purchase an aggregate of 6,500,000 Class A Ordinary Shares, with an exercise price of \$0.001 per share and no expiration date (the “2025 Share Exchange Warrants”). The 2025 Share Exchange Warrants are exercisable immediately and have substantially identical terms to the pre-funded warrants issued in 2024 in connection with our April 2024 subscription agreements.

April 2024 Private Placement

On April 18, 2024, we entered into subscription agreements (the “April 2024 Investor Agreements”) with certain institutional and other accredited investors pursuant to which we issued 18,732,301 Class A Ordinary Shares, par value \$0.0001 per share and pre-funded warrants (the “2024 Pre-Funded Warrants”) to purchase up to 16,102,348 Class A Ordinary Shares. Each Class A Ordinary Share was sold at a price of \$3.108 per Class A Ordinary Share and each 2024 Pre-Funded Warrant was sold at a price of \$3.107 per 2024 Pre-Funded Warrant for an aggregate purchase price of \$108.3 million.

On April 18, 2024, we also entered into subscription agreements (the “April 2024 Insider Agreements”) and together with the April 2024 Investor Agreements, the “April 2024 Private Placement”) with certain of our officers, directors and affiliates pursuant to

which we issued 1,357,827 Class A Ordinary Shares, par value \$0.0001 per share sold a purchase price of \$3.13 per Class A Ordinary Share for an aggregate purchase price of \$4.2 million.

The April 2024 Private Placement closed on April 22, 2024, from which we received gross proceeds of approximately \$112.5 million.

In July 2025, we issued 1,206,952 Class A Ordinary Shares in connection with the exercise of 2024 Pre-Funded Warrants. The gross proceeds received upon exercise of such pre-funded warrants were immaterial.

April 2023 Private Placement

On April 26, 2023, we entered into subscription agreements with certain accredited investors pursuant to which we issued 15,041,530 Class A Ordinary Shares, par value \$0.0001 per share and pre-funded warrants (the “2023 Pre-Funded Warrants” and, together with the 2024 Pre-Funded Warrants, the “Pre-Funded Warrants”) to purchase up to 3,782,000 Class A Ordinary Shares (the “April 2023 Private Placement”). Each Class A Ordinary Share was sold at a price of \$4.25 per Class A Ordinary Share and each 2023 Pre-Funded Warrant was sold at a price of \$4.249 per 2023 Pre-Funded Warrant for an aggregate purchase price of \$80.0 million. We received net proceeds of approximately \$75.8 million from the April 2023 Private Placement.

In July 2025, we issued 1,682,000 Class A Ordinary Shares in connection with the exercise of 2023 Pre-Funded Warrants. The gross proceeds received upon exercise of such pre-funded warrants were immaterial.

2023 Lilly License

On April 26, 2023, our consolidated subsidiary ZB17 LLC (“ZB17”) entered into a license agreement with Lilly (the “2023 Lilly License” and, together with the 2022 Lilly License (as defined below), the “Lilly Licenses”), for an exclusive license to develop, manufacture and commercialize tibilizumab. As consideration, we paid Lilly an upfront payment consisting of \$5.8 million during 2023 and issued 1,000,000 Class A Ordinary Shares at an aggregate fair value of \$7.8 million during the year ended 2023. During certain specified periods, Lilly shall have the exclusive right to evaluate certain clinical trial results and determine whether it wishes to negotiate an agreement for the further development and commercialization of ZB-106 by Lilly. If Lilly provides notice to the Company before the expiry of the applicable period that it wishes to seek to negotiate an agreement, the parties will have good faith negotiations regarding an agreement for further development and commercialization.

During 2024, ZB17 made an additional payment of \$5.0 million to Lilly, in connection with the receipt of certain know-how, data, information and materials that Lilly is required to provide under the license agreement.

The acquisition was accounted for as an asset acquisition, as substantially all of the fair value of the assets acquired is concentrated in a group of similar identifiable in-process research and development (“IPR&D”) assets. On the acquisition date, the molecule licensed had not yet received regulatory approval and the IPR&D did not have an alternative use. Accordingly, we recorded the entire cost of the 2023 Lilly License as a component of research and development in the consolidated statement of operations during the year ended December 31, 2023.

In consideration for the investment made by Stone Peach Properties, LLC (“Stone Peach”), we entered into a letter agreement with Stone Peach and ZB17, dated April 24, 2023, as amended by letter agreement dated November 21, 2023 (the “ZB17 Letter Agreement”), pursuant to which ZB17 granted Stone Peach the right, but not the obligation, to purchase 4.99% of the fully diluted equity of ZB17 for \$1.0 million (the “Stone Peach Call Right”). The Stone Peach Call Right was not exercisable until after the last patient is dosed in any single next clinical trial with tibilizumab and would expire one year from the date of first indication approval for tibilizumab by the United States Food and Drug Administration (“FDA”) or the European Medicines Agency (“EMA”). We recognized the Stone Peach Call Right at a grant-date fair value of \$1.5 million as a component of research and development in the consolidated statement of operations during the year ended December 31, 2023. The Stone Peach Call Right represented noncontrolling interest in our consolidated subsidiary, ZB17. As of December 31, 2024, the noncontrolling interest balance was \$1.5 million in the consolidated balance sheet. On December 29, 2025, the Company terminated the ZB17 Letter Agreement, and the noncontrolling interest was extinguished. See “Stone Peach Settlement and Release Agreement” below.

Additionally, beginning on May 1, 2023, Stone Peach received an annual payment of \$0.6 million, increasing by 10% annually, so long as we maintain our license for tibalizumab, to be paid on May 1st of each year. For the years ended December 31, 2025 and 2024, we recorded expenses of \$0.7 million and \$0.7 million, respectively, in research and development in the consolidated statement of operations for the annual payments. On December 29, 2025, we terminated the ZB17 Letter Agreement. See “—Stone Peach Settlement and Release Agreement” below.

A one-time payment of \$4.5 million for additional consideration due to Stone Peach upon acceptance from the FDA for our Investigational New Drug (“IND”) and commencement of our clinical trial for tibalizumab was recorded in research and development expenses in the consolidated statement of operations for the year ended December 31, 2024 and was paid in June 2025. This payment is included in accounts payable and accrued expenses in the consolidated balance sheet as of December 31, 2024.

A letter agreement, dated as of April 25, 2023, by and between BAFFX17, Ltd (“BAFFX17”) and us, and as amended by Amendment No. 1 on December 18, 2023 (the “BAFFX17 Letter Agreement”), provided that, as a finder’s fee for arranging the acquisition of the 2023 Lilly License, we would be required to make a one-time milestone payment of \$5.0 million to BAFFX17 upon the occurrence of either: (i) a change of control transaction, (ii) the closing of an issuance of equity or equity-linked securities by us of at least \$100.0 million (iii) the consummation of a sale of assets resulting in net proceeds in excess of \$100.0 million, or (iv) our fully diluted shares outstanding exceed 52,500,000 shares (on a split adjusted basis), as measured on April 24th of each year. As our fully diluted shares outstanding exceeded 52,500,000 shares prior to December 31, 2023, the \$5.0 million fee was previously accounted for in research and development expenses in the consolidated statement of operations for the year ended December 31, 2023, and is included in accounts payable and accrued expenses in the consolidated balance sheets as of December 31, 2024. On June 30, 2025, we received an invoice on behalf of BAFFX17 requesting a \$5.0 million milestone payment pursuant to the BAFFX17 Letter Agreement. We did not make such payment, and the BAFFX17 Letter Agreement was terminated on December 29, 2025. See “—BAFFX17 Settlement and Release Agreement” below.

In addition to the consideration paid and/or earned in 2025, 2024 and 2023, we are also obligated to make payments to Lilly (a) for four (4) development milestone payments up to an aggregate of \$155.0 million, and sales milestone payments up to an aggregate of \$440.0 million based on respective thresholds of net sales of products developed from tibalizumab; and (b) over a multi-year period (twelve years, or upon the later expiration of regulatory exclusivity of tibalizumab in a country) for an annual earned royalty at a marginal royalty rate in the mid-single digits to low-double digits, with increasing royalty percentage rates depending on net sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of years (collectively, the “2023 Lilly Contingent Payments”). As of December 31, 2025, none of the 2023 Lilly Contingent Payments are due and accordingly will not be recorded in our financial statements until they are due. Prior to the BAFFX17 Settlement Agreement and Stone Peach Settlement Agreement described below, we were also obligated to make payments (a) to BAFFX17 for a fee equal to 3% of any milestone or royalty payments due to Lilly pursuant to the terms of either the 2022 Lilly License or the 2023 Lilly License; (b) to Stone Peach for a one-time milestone payment of \$25.0 million upon either (i) certain equity-related transactions, or (ii) the receipt of regulatory approval from the applicable regulatory authority for any new indication in the applicable jurisdiction; and (c) to Stone Peach for a royalty of 2% of the aggregate net sales of any products developed from the compound. See “—BAFFX17 Settlement and Release Agreement” and “—Stone Peach Settlement and Release Agreement” below.

2022 Lilly License

On December 8, 2022, our consolidated subsidiary, Z33 Bio Inc. (“Z33”) entered into a license agreement with Lilly (the “2022 Lilly License”) pursuant to which Lilly granted Z33 an exclusive (even as to Lilly) license to develop, manufacture, and commercialize torudokimab. As consideration, we paid Lilly an upfront fee of \$7.0 million during 2022 and issued Lilly 550,000 Class A Ordinary Shares at an aggregate fair value of \$4.5 million upon the Closing Date of the Business Combination during the year ended December 31, 2023.

A letter agreement dated December 8, 2022, as amended on November 21, 2023 (the “Z33 Letter Agreement” and, together with the ZB17 Letter Agreement, the “Stone Peach Letter Agreements”) by and between Stone Peach, us and Z33, provided that, as a finder’s fee in connection with arranging the acquisition, Z33 issued to Stone Peach 4,900,222 shares of Z33’s series seed preferred shares (the “Z33 Series Seed Preferred Shares”), which was included in the measurement of the cost of the acquired asset. We had the right, but not the obligation, to purchase up to 50% of the Z33 Series Seed Preferred Shares issued to Stone Peach at a price per share of \$2.448869 for a period of two years from the date of the agreement (the “Call Option”). Pursuant to the Z33 Letter Agreement, Stone Peach had the right, but not the obligation to sell up to 50% of the Z33 Series Seed Preferred Shares issued to Stone Peach to us for a price per share of \$2.040724 (the “Put Option”). In April 2023, we agreed to exercise our Call Option and we amended the settlement terms to settle the Call Option by issuing 2,000,000 Class A Ordinary Shares (the “Amended Terms”). In November 2023, the Amended

Terms were voided and our rights and obligations under the Call Option reverted to those in the original agreement (the “Second Amended Terms”). In connection with the Second Amended Terms, we also provided Stone Peach with the right, but not the obligation, to sell up to 50% of the Z33 Series Seed Preferred Shares issued to Stone Peach to Zura in exchange for 2,000,000 Class A Ordinary Shares (the “Put Right”). Stone Peach was permitted to exercise its Put Option and Put Right at any time between April 24, 2024 and April 24, 2028 under the new agreement. Each of the Amended Terms and the Second Amended Terms were considered an extinguishment and reissuance of the Z33 Series Seed Preferred Shares, and the Z33 Series Seed Preferred Shares are remeasured to the greater of the redemption value or the initial fair value, less noncontrolling shareholder’s interest in net loss of Z33, at each subsequent reporting period. The Z33 Series Seed Preferred Shares represented redeemable noncontrolling interest in our consolidated subsidiary, Z33. On December 29, 2025, we terminated the Z33 Letter Agreement, and the redeemable noncontrolling interest was extinguished. See “—Stone Peach Settlement and Release Agreement” below.

In addition to the consideration paid and transferred in 2022 and shares issued in 2023, we paid \$3.0 million to Lilly in December 2025, as a financing by Z33 with gross proceeds exceeding \$100.0 million did not occur by December 7, 2025. We are also obligated to make payments to Lilly for (a) 10 commercial, development and regulatory milestone payments up to an aggregate of \$155.0 million and sales milestone payments up to an aggregate of \$440.0 million based on respective thresholds of net sales of products developed from the licensed molecule; and (b) an annual earned royalty at a marginal royalty rate in the mid-single to low-double digits, with increasing royalty percentage rates based on Net Sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of the year (collectively, “the “2022 Lilly Contingent Payments”). As of December 31, 2025, none of the 2022 Lilly Contingent Payments are due and accordingly will not be recorded in our financial statements until they are due.

Pfizer Agreement

On March 22, 2022, we entered into a license agreement and a Series A-1 Subscription and Shareholder’s Agreement (collectively, the “Pfizer Agreement”) with Pfizer. Under the Pfizer Agreement, we acquired a license for crebankitug, in exchange for \$5.0 million in cash and 2,702,083 shares (as adjusted by the exchange ratio established in the Business Combination Agreement) of our Series A-1 convertible preferred shares, representing a 20% interest in us. The Pfizer Agreement was accounted for as an asset acquisition, as substantially all of the \$7.5 million value transferred to us was allocated to in-process research and development. On the acquisition date, the compound licensed had not yet received regulatory approval and the in-process research and development did not have an alternative use.

In addition to the consideration transferred during 2022, we are obligated to make payments to Pfizer for (a) twelve (12) development and regulatory milestone payments aggregating up to \$70.0 million and sales milestone payments up to an aggregate of \$525.0 million based on respective thresholds of net sales of products (developed from the licensed compound) (the “Products”); and (b) an annual earned royalty at a marginal royalty rate in the mid-single digits to low double digits (less than 20%), based on thresholds of net sales of Products (collectively, the “Pfizer Contingent Payments”). Royalties are payable on a country-by-country basis for a certain period of years or upon the later expiration of regulatory exclusivity of our Products in a country.

We recorded the first \$1.0 million development milestone, included in the Pfizer Contingent Payments, as a component of research and development in the consolidated statement of operations during the year ended December 31, 2023. This amount was fully paid to Pfizer during the year ended December 31, 2024. As of December 31, 2025, no additional Pfizer Contingent Payments are due and accordingly no additional Pfizer Contingent Payments will be recorded in our financial statements until they are due.

The Pfizer Agreement also had an anti-dilution provision to allow Pfizer to maintain an 18% interest in us. Immediately prior to the Closing Date of the Business Combination, additional share options and restricted share units were issued to certain employees, executives, and directors that would result in the dilution of Pfizer’s ownership in us. In accordance with the anti-dilution provision of the Pfizer Agreement, Pfizer was issued additional Series A-1 convertible preferred shares upon the closing of the Business Combination that were immediately converted to 267,939 Class A Ordinary Shares. Following the Business Combination, the anti-dilution provision is no longer in effect.

Athantor Letter Agreement

On December 29, 2025, in connection with the termination of the Stone Peach Letter Agreements, as described in Note 5 to our consolidated financial statements located in “*Item 15—Exhibits and Financial Statement Schedules—Financial Statements*,” we entered into a letter agreement with Athantor Capital, an exempted company incorporated under the laws of the Cayman Islands with limited liability (“Athantor”) (the “Athantor Agreement”), pursuant to which we issued to Athantor 8,657,402 Class A Ordinary Shares (the “Athantor Shares”). Athantor is also entitled to piggyback registration rights pursuant to which Athantor has the right to include

Athanor Shares in certain registered offerings by us or if we propose to file a registration statement under the Securities Act of 1933, as amended (the “Securities Act”), with respect to the registration of equity securities, as set forth in the Athanor Agreement.

In addition, pursuant to the terms of the Athanor Agreement, we paid Athanor an upfront fee in an amount equal to \$7.3 million and shall pay a one-time milestone payment in the amount of \$25.0 million after the occurrence of the earliest of the following events: (i) we or ZB17 undergoes a Change of Control (as defined in the Athanor Agreement), (ii) the consummation by us or ZB17 of a sale of assets resulting in net proceeds in excess of \$500.0 million, or (iii) First Indication Regulatory Approval (as defined in the Athanor Agreement). In addition, pursuant to the terms of the Athanor Agreement, we agreed to pay an amount equal to 2% of Net Sales (as defined in the Athanor Agreement) for the Product (as defined in the Athanor Agreement) to the extent such Net Sales (collectively, the “Net Sales Payments”) are the subject of a royalty payment under the 2023 Lilly License.

The Athanor Agreement contains representations, warranties and covenants by the parties in addition to the terms described above and shall remain in effect on a country-by-country basis until the expiration of the obligation to pay the Net Sales Payments.

Stone Peach Settlement and Release Agreement

In connection with the termination of the Stone Peach Letter Agreements, on December 29, 2025, we and Stone Peach, Baljit Lehal and Kanwarjeet “Shawn” Tucker (the “Stone Peach Parties”) entered into a Settlement and Release Agreement (the “Stone Peach Settlement Agreement”). Pursuant to the Stone Peach Settlement Agreement, the Stone Peach Parties acknowledged that, as between us and any of the Stone Peach Parties, each of (i) the Stone Peach Letter Agreements, (ii) that certain Z33 Founder Issuance Agreement, dated December 8, 2022, between Z33 and Stone Peach, (iii) that certain Series Seed Preferred Stock Investment Agreement, dated December 8, 2022, between us and Stone Peach and (iv) that certain Confidentiality and Non-Circumvention Agreement dated December 13, 2022, between us and Stone Peach (such agreements, the “Stone Peach Agreements”) are terminated and therefore rendered null and void, and unenforceable in part or in whole by any of the Stone Peach Parties. In addition, pursuant to the Stone Peach Settlement Agreement, the Stone Peach Parties provided a general release of us and our affiliates, together with our predecessors, successors, and assigns and past, present and future officers, directors, shareholders, members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest from and against any and all claims under the Stone Peach Agreements along with any other complaints, claims, causes of action, rights or damages which the Stone Peach Parties have or may have had against us or any of our affiliates.

BAFFX17 Settlement and Release Agreement

On December 29, 2025, we and BAFFX17, Asim Mohammed and Lahmber Singh (the “BAFFX17 Parties”) entered into a Settlement and Release Agreement (the “BAFFX17 Settlement Agreement”). Pursuant to the BAFFX17 Settlement Agreement, we and the BAFFX17 Parties agreed and acknowledged that the BAFFX17 Agreement was terminated and therefore rendered null and void and unenforceable in part or in whole by any BAFFX17 Party. In addition, pursuant to the BAFFX17 Settlement Agreement, the BAFFX17 Parties provided a general release of us and our affiliates, together with the our predecessors, successors, and assigns and past, present and future officers, directors, shareholders, members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest from and against any and all claims under the BAFFX17 Agreements along with any other complaints, claims, causes of action, rights or damages which the BAFFX17 Parties have or may have had against us or any of our affiliates.

Audit Subcommittee Investigation

As previously disclosed, the audit committee of our Board of Directors formed the Audit Subcommittee, comprised solely of disinterested and independent directors, to review our agreements and relationships with Stone Peach and BAFFX17, among other matters. The Audit Subcommittee was assisted by independent legal counsel and a third-party due diligence firm. The Audit Subcommittee’s internal review is complete, and the results are discussed below.

Through legal counsel, the Audit Subcommittee engaged in extensive fact finding, including reviewing relevant documents and communications. Following a detailed review of this information, and based on the advice of independent legal counsel, the Audit Subcommittee determined (1) that it was in the best interests of us and its shareholders to replace the Stone Peach Agreements with the more commercially advantageous Athanor Agreement and (2) to terminate or void the agreements between us and our subsidiaries, on the one hand, and Stone Peach or BAFFX17, on the other hand. Consistent with the determination of the Audit Subcommittee, we negotiated, with the assistance of management and legal counsel, the Athanor Agreement as well as the Stone Peach Settlement Agreement and the BAFFX17 Settlement Agreement, which terminated all outstanding agreements between the parties and, in the case of the settlement agreements, contain broad releases of claims against us, its subsidiaries and affiliates by Stone Peach, BAFFX17 and

their respective principals. The Athanor Agreement, the Stone Peach Settlement Agreement and the BAFFX17 Settlement Agreement were approved by the Audit Subcommittee and the Board of Directors.

The internal review found no issue with our agreements and relationships with Stone Peach and BAFFX17 that had an impact on our financial results under accounting principles generally accepted in the United States of America (“U.S. GAAP”) or on the financial statements included in our previously filed quarterly or annual reports. Additionally, the internal review found no instances of misconduct by our current employees relating to the agreements or relationships. The internal review also included an analysis of our internal controls over financial reporting and disclosure controls and procedures, and as part of our process of continuous improvement, we plan to implement certain additional controls and procedures, which are not expected to materially affect our existing controls and procedures.

Impact of Global Economic Trends

Macroeconomic conditions, including uncertainties associated with the changes to and by the U.S. federal government administration, the ongoing conflicts in Iran and the broader Middle East, the ongoing conflict between Ukraine and Russia, conflicts in Mexico, international trade policies (including tariffs, sanctions and trade barriers), economic slowdowns, public health crises, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets, rising interest rates and financial and credit market fluctuations, volatility in the capital markets or other evolving macroeconomic developments, continue to have direct and indirect impacts on our business and could in the future materially impact our results of operations and financial condition. Recent tariffs and trade restrictions have increased costs and complexity for many businesses, which may also have an adverse impact on our business. See “*Part I, Item 1A. Risk Factors—International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects*” for more information. We continue to actively monitor the impact of these macroeconomic factors on our results of operations, financial condition and cash flows. The extent of the impact of these factors on our operational performance and financial condition, including our ability to execute our business strategies and initiatives in the expected timeframe, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact our business.

Components of Operating Results

Operating Expenses

Research and Development Expenses

Research and development (“R&D”) expenses consist of all direct and indirect operating expenses incurred to support our clinical development programs, including research activities conducted in support of such programs, manufacturing activities, consulting fees for clinical and manufacturing advisory services, contract research organization (“CRO”) costs, costs related to manufacturing materials for preclinical and clinical studies, payroll and benefits (including share-based compensation for employees supporting clinical development activities), licensing fees, and data and study acquisition costs. Expenses are recognized as the related goods are delivered or the services are performed.

R&D expenses include the cost of IPR&D assets purchased in an asset acquisition transaction. IPR&D assets are expensed provided that the acquired asset did not also include processes or activities that would constitute a “business” as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Acquired IPR&D payments, including upfront payments, transaction fees and subsequent pre-commercial milestone payments, are immediately expensed in the period in which they are incurred. Research and development costs incurred after the acquisition are expensed as incurred. R&D expenses also include the remeasurement of the research and development license consideration liability. The research and development license consideration liability represented an obligation to issue either preferred shares of our subsidiary or Class A Ordinary Shares to Lilly as consideration for the 2022 Lilly License, which was ultimately settled through the issuance of Class A Ordinary Shares upon the closing of the Business Combination.

Research and development expenses could include:

External Expenses:

- external research and development expenses incurred under agreements with CROs, investigative sites and consultants to conduct our clinical trials;
- costs related to manufacturing material for preclinical studies and clinical trials, including fees paid to CMOs;
- milestone payments under our licensing agreements;
- laboratory supplies and research materials;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance and equipment.

Internal Expenses:

- employee-related expenses, including salaries, bonuses, benefits, share-based compensation and other related costs for those employees involved in research and development efforts.

A significant portion of our research and development costs have been external expenses. We utilize third-party contractors for our research and development activities. We track these external expenses on an individual program basis within our portfolio, when they are specific to an individual program, once a clinical product candidate or program has been identified.

We use CMOs for our manufacturing activities and we do not have our own laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development. We track our manufacturing activities on a portfolio basis when we have multiple programs in a portfolio, but do not track these activities on a program basis within the portfolio, as these costs are deployed across multiple programs within a portfolio.

Our internal research and development costs are primarily personnel-related costs. We do not track internal costs on a portfolio or program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We plan to substantially increase our research and development expenses for the foreseeable future as we develop our product candidates and manufacturing processes and conduct discovery and research activities for our clinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical studies of our product candidates due to the inherently unpredictable nature of clinical development. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to how we pursue our product candidates and how much funding to direct to each program on an ongoing basis in response to the results of future clinical trials, regulatory developments and our ongoing assessments as to commercial potential. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase as we commence, continue and expand our clinical trial activities. Our future expenses may vary significantly each period based on factors such as:

- expenses incurred to conduct preclinical studies required to advance our product candidates into clinical trials;
- per patient clinical trial costs, which may vary based on the number of doses that patients receive;
- the number of patients who enroll in each clinical trial;
- the number of clinical trials required for approval;

- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in clinical trials and follow-up;
- the phase of development of the product candidate;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all;
- the cost of insurance, including product liability insurance, in connection with clinical trials;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

General and administrative (“G&A”) expenses primarily consist of professional fees for legal, accounting, and consulting costs relating to corporate matters, as well as salaries and related costs for personnel in executive and administrative functions and board of director fees, including share-based compensation.

We anticipate that our G&A expenses will increase in the future as we continue to support research and development activities and incur increased costs of operating as a public company. These costs include increased headcount to support expanded operations and infrastructure.

Additionally, we anticipate increased costs associated with maintaining compliance with Nasdaq rules and SEC requirements such as accounting, audit, legal and consulting services, as well as director and officer liability insurance, investor and public relations activities.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the periods presented (in thousands):

	For the Year Ended December 31,		\$ Change	% Change
	2025	2024		
Operating expenses:				
Research and development	\$ 42,082	\$ 24,401	\$ 17,681	72 %
General and administrative	33,164	30,788	2,376	8 %
Total operating expenses	<u>75,246</u>	<u>55,189</u>	<u>20,057</u>	<u>36 %</u>
Loss from operations	(75,246)	(55,189)	(20,057)	36 %
Other (income)/expense, net:				
Interest income	(6,336)	(7,998)	1,662	(21)%
Change in fair value of private placement warrants	—	5,240	(5,240)	(100)%
Other income, net	(260)	(28)	(232)	* %
Total other income, net	<u>(6,596)</u>	<u>(2,786)</u>	<u>(3,810)</u>	<u>137 %</u>
Loss before income taxes	(68,650)	(52,403)	(16,247)	31 %
Income tax benefit	—	—	—	— %
Net loss before redeemable noncontrolling interest	(68,650)	(52,403)	(16,247)	31 %
Accretion of redeemable noncontrolling interest to redemption value	4,868	—	4,868	* %
Adjustment of redeemable noncontrolling interest	831	7,017	(6,186)	(88)%
Deemed dividend on extinguishment of noncontrolling interest and redeemable noncontrolling interest	(36,402)	—	(36,402)	* %
Net loss attributable to Class A Ordinary Shareholders of Zura	<u>\$ (99,353)</u>	<u>\$ (45,386)</u>	<u>\$ (53,967)</u>	<u>119 %</u>

* Percentage change not meaningful

Operating Expenses

Research and development expenses (in thousands):

The following table summarizes our research and development expenses for the periods presented (in thousands):

	For the Year Ended December 31,		\$ Change	% Change
	2025	2024		
External expenses:				
Direct expenses by program:				
Tibulizumab Portfolio				
Tibulizumab SSc Program	\$ 10,650	\$ 2,393	8,257	345 %
Tibulizumab HS Program	9,990	552	9,438	* %
Tibulizumab Combined (SSc and HS) Programs	5,718	12,875	(7,157)	(56)%
Total Tibulizumab Portfolio	<u>26,358</u>	<u>15,820</u>	<u>10,538</u>	<u>67 %</u>
Additional product candidates (crebankitug and torudokimab)	4,393	1,543	2,850	185 %
Unallocated expenses	1,938	1,271	667	52 %
Internal expenses:				
Personnel expenses (including share-based compensation)	9,393	5,767	3,626	63 %
Total research and development expense	<u>\$ 42,082</u>	<u>\$ 24,401</u>	<u>\$ 17,681</u>	<u>72 %</u>

* Percentage change not meaningful

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Research and development expenses increased by \$17.7 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase was primarily due to:

- a \$9.4 million and \$8.3 million increase in costs as we advance our Phase 2 clinical trials evaluating tibulizumab in adults with SSc and HS, respectively, driven by costs incurred for CRO fees to support the conduct of our clinical trials;
- a \$3.6 million increase in compensation, including share-based compensation, driven by increased personnel in research and development functions;
- a \$2.9 million increase related to our additional product candidates (crebankitug and torudokimab), driven by a one-time milestone of \$3.0 million recognized in the year ended December 31, 2025; and
- \$0.7 million increase in unallocated non-portfolio specific research and development expenses due to our growth to support our advancement of our Phase 2 clinical trials and other product candidates.

This increase was partially offset by a \$7.2 million decrease in costs for tibulizumab that was not specific to an indication, primarily driven by the derecognition of the \$5.0 million obligation due to BAFF (see “ - *BAFFX17 Settlement and Release Agreement*” above) in the year ended December 31, 2025, and a one-time milestone of \$4.5 million recognized in the year ended December 31, 2024.

We anticipate that research and development expenses will continue to increase in the future as we conduct research and development activities.

General and administrative expenses

General and administrative expenses increased by \$2.4 million for the year ended December 31, 2025 as compared to the year ended December 31, 2024. The increase was primarily due to an increase in professional fees for legal costs to support our growing organization as we advance our Phase 2 clinical trials evaluating tibulizumab in SSc and HS.

Other Expense (Income)

Interest income

Interest income decreased by \$1.7 million for the year ended December 31, 2025 as compared to the year ended December 31, 2024. This is primarily due to a decrease in our cash and cash equivalents balance during the year ended December 31, 2025 as compared to the year ended December 31, 2024.

Change in fair value of private placement warrants

Revaluation loss on the liability-classified Private Placement Warrants assumed in the Business Combination was \$5.2 million during the year ended December 31, 2024. During the year ended December 31, 2024, the Private Placement Warrants were recorded at their settlement value upon completion of the Warrant Exchange, which was the fair value of the Class A Ordinary Shares exchanged for the Private Placement Warrants. There were no Private Placement Warrants outstanding as of December 31, 2024 and December 31, 2025.

Other income, net

Other income, net remained relatively consistent for the year ended December 31, 2025 as compared to the year ended December 31, 2024.

Accretion of redeemable noncontrolling interest to redemption value

Accretion of redeemable noncontrolling interest to redemption value was \$4.9 million for the year ended December 31, 2025 resulting from the remeasurement of the Z33 Series Seed Preferred Shares to redemption value. After the modification of the terms of the Z33 Series Seed Preferred Shares issued to Stone Peach (see “—2022 Lilly License” above), the Z33 Series Seed Preferred Shares are recorded at the greater of the redemption value or the initial fair value, less noncontrolling shareholder’s interest in net loss of Z33. The redeemable noncontrolling interest was remeasured prior to extinguishment on December 29, 2025 (see “—Stone Peach Settlement and Release Agreement” above). As of December 31, 2024, the redemption value was below the initial fair value, less noncontrolling shareholder’s interest in net loss of Z33, resulting in no accretion of the redeemable noncontrolling interest when remeasuring the Z33 Series Seed Preferred Shares to its redemption value.

Adjustment of Redeemable Noncontrolling Interest

After the modification of the terms of the Z33 Series Seed Preferred Shares issued to Stone Peach (see “—2022 Lilly License” above), the Z33 Series Seed Preferred Shares are recorded at the greater of the redemption value or the initial fair value, less noncontrolling shareholder’s interest in net loss of Z33. For the year ended December 31, 2025, there was a \$0.8 million adjustment to the redeemable noncontrolling interest recognized as an adjustment to net loss attributable to Class A Ordinary Shareholders of Zura as a result of the extinguishment of 50% of the redeemable noncontrolling interest upon the exercise of the Put Option in the third quarter of 2025. For the year ended December 31, 2024, the adjustment of redeemable noncontrolling interest from redemption value to carrying value of \$7.0 million resulted from a decrease in the redemption value of the Z33 Series Seed Preferred Shares below its initial fair value, less the noncontrolling shareholder’s interest in net loss of Z33, as of December 31, 2024.

Deemed dividend on extinguishment of noncontrolling interest and redeemable noncontrolling interest

Deemed dividend on extinguishment of noncontrolling interest and redeemable noncontrolling interest was \$36.4 million for the year ended December 31, 2025 resulting from the Company entering into the Athanor Agreement and Stone Peach Settlement Agreement effective December 29, 2025 (see “—Athanor Agreement” and “—Stone Peach Settlement and Release Agreement” above). The deemed dividend was recorded as the difference between the fair value of the new instruments issued under the Athanor Agreement and the carrying amount of our prior obligations that we were relieved of per the Stone Peach Settlement Agreement.

Liquidity and Capital Resources

Overview

Since our inception, we have not generated any revenue and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2025, we had cash and cash equivalents of \$109.4 million. We have funded our operations through (i) the sale of equity, raising an aggregate of \$10.0 million of gross proceeds from the sale of our convertible preferred shares of Zura Bio UK through March 31, 2023; (ii) the issuance of a promissory note, receiving net proceeds of \$7.6 million in December 2022; (iii) proceeds from the Business Combination of \$56.7 million in March 2023; (iv) the April 2023 Private Placement, raising an aggregate of \$80.0 million of gross proceeds from the sale of Class A Ordinary Shares and 2023 Pre-Funded Warrants during the year ended December 31, 2023; (v) the April 2024 Private Placement, raising an aggregate of \$112.5 million of gross proceeds from the sale of Class A Ordinary Shares and 2024 Pre-Funded Warrants in April 2024; (vi) the sale of 1,500,000 Class A Ordinary Shares at a price of \$3.80 per share under the ATM for net proceeds of \$5.5 million, after placement agent commissions, in September 2024; and (vii) the sale of 3,000,000 Class A Ordinary Shares at a price of \$1.75 per share under the ATM for net proceeds of \$5.1 million, after placement agent commissions, in the first quarter of 2025.

We have experienced operating losses and cash outflows from operations since inception and will require ongoing financing in order to continue our research and development activities and business operations. We have not earned any revenue or reached successful commercialization of our products. Our future operations are dependent upon our ability to finance our cash requirements which will allow us to continue our research and development activities and the commercialization of our products. There can be no assurance that we will be successful in continuing to finance our operations.

Capital Requirements

To date, we have not generated revenue from any source, including the commercial sales of our approved drug products, and we do not expect to generate revenue from the commercial sales of our approved drug products for at least the next few years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be adversely affected. We do not know when, or if, we will generate any revenue from the commercial sales of our approved drug products, and we do not expect to generate revenue from the commercial sales of our approved drug products unless and until we obtain regulatory approval of, and commercialize, our product candidates.

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research and development, and seek marketing approval for our product candidates, as well as administrative costs associated with supporting our operations. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company.

We will also be responsible to Pfizer and Lilly for significant future contingent payments under the Pfizer Agreement and the Lilly Licenses upon the achievement of certain development, regulatory, and sales milestones, as well as ongoing royalties on net commercial sales. The size and timing of these milestone payments will vary greatly depending upon a number of factors, and it is therefore difficult to estimate the total payments that could become payable to Pfizer and Lilly and when those payments would be due. If we achieve all of the milestones, we would be obligated to pay multimillion dollar development and regulatory milestone payments and sales milestone payments. We will be required to pay certain of these milestone payments prior to the time at which we are able to generate sufficient revenue, if any, from commercial sales of any of our product candidates. In addition to milestone payments, we are also required to pay Pfizer and Lilly under the Pfizer Agreement and Lilly Licenses, respectively, ongoing royalties in the mid-single digits to low double-digits percentage range based upon thresholds of net sales of products.

Based on our current business plans, and after giving effect to the completion of the February 2026 public offering, we believe that our existing cash, cash equivalents and investments should be sufficient to fund our operating expenses and capital requirements through at least the end of 2028. Our estimate as to how long we expect our existing cash and cash equivalents to be able to fund our operating expenses and capital requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which are beyond our control, could result in less cash available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Because of the numerous risks and uncertainties associated with the research, development and commercialization of pharmaceutical drug products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the timing and amount of our milestone payments to Pfizer under the Pfizer Agreement and to Lilly under the Lilly Licenses;
- our headcount growth and associated costs as we expand our research and development capabilities and establish and expand our commercial infrastructure and operations;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distributions, for any of our product candidates for which we receive marketing approval;
- royalty payments to Pfizer under the Pfizer Agreement and Lilly under the Lilly Licenses;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many 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 our product candidates that we do not expect to be commercially available in the near term, if at all, and are subject to successful clinical development and regulatory approval. Accordingly, we may 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. To the extent that we raise additional capital through securities or debt financing, the terms of these securities or this debt may restrict our ability to operate. Any financing, if available, may involve covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Cash Flows

	For the Years Ended December 31,	
	2025	2024
Net cash used in operating activities	\$ (64,815)	\$ (28,076)
Net cash used in investing activities	(113)	(5,075)
Net cash (used in) provided by financing activities	(2,163)	109,843
Net increase in cash and cash equivalents	<u>\$ (67,091)</u>	<u>\$ 76,692</u>

Cash flows from operating activities

Net cash used in operating activities increased by \$36.7 million to \$64.8 million for the year ended December 31, 2025 from \$28.1 million for the year ended December 31, 2024. The increase is primarily due to an increase in our cash net loss of \$16.2 million. Non-cash charges decreased by \$14.5 million due to decreased share-based compensation expense of \$4.7 million driven by a modification of our former CEO's awards in 2024, a decrease in the change in fair value on the Private Placement Warrants of \$5.2 million, and a gain on extinguishment of the BAFFX17 liability of \$5.0 million. Working capital changes increased cash used in operations by \$6.7 million of cash for operating activities, resulting from an increase in cash used in paying accounts payable and accrued expenses for the year ended December 31, 2025.

Cash flows from investing activities

Cash used in investing activities for the year ended December 31, 2025 was \$0.1 million, which was related to equipment purchased during the period.

Cash used in investing activities for the year ended December 31, 2024 was \$5.1 million, which was related to the \$5.0 million cash consideration paid to acquire the 2023 Lilly License and \$0.1 million of equipment purchased during the period.

Cash flows from financing activities

Cash used in financing activities for the year ended December 31, 2025 was \$2.2 million, which consisted of consideration paid for the Athanor Agreement of \$7.3 million, partially offset by proceeds of \$5.1 million, after commissions, for the sale of Class A Ordinary Shares under our ATM.

Cash provided by financing activities for the year ended December 31, 2024 was \$109.8 million, which consisted of \$62.5 million of proceeds from the issuance of Class A Ordinary Shares in connection with the April 2024 Private Placement, \$50.0 million of proceeds from the issuance of 2024 Pre-Funded Warrants in connection with the April 2024 Private Placement and net proceeds of \$5.5 million, after commissions, for the sale of Class A Ordinary Shares under our ATM, partially offset by transaction costs incurred in connection with the 2024 Private Placement and establishing the ATM of \$7.2 million and \$0.6 million, respectively.

Contractual Obligations and Other Commitments

We have or will enter into agreements in the normal course of business with contract research organizations, contract manufacturing organizations and other vendors for research and development services for operating purposes, which are generally cancelable upon written notice. Some third party CMOs have intellectual property, such as patents and/or know-how with an annual fee and royalty bearing license to its customers that forms part of the manufacturing agreement.

Lonza License

In July 2022, we entered into a license agreement (the “Lonza License”) with Lonza Sales AG (“Lonza”) for a worldwide nonexclusive license for Lonza’s gene expression system in exchange for varying considerations depending on a number of factors such as whether we enter further into manufacturing agreements with Lonza or with a third party, and whether we enter into sublicense agreements with third parties (including up to middle six-figure annual payments per sublicense upon commencement of a sublicense, as well as royalties of up to low-single digit percentages of net sales of certain products over a commercially standard double-digit multi-year term). The Lonza License will remain in effect until terminated. We are free to terminate the Lonza License at any time upon 60 days’ notice, with or without cause. Lonza may terminate the Lonza License for cause upon a breach by us or for other commercially standard reasons. During October 2023, we began manufacturing drug substance with another third party. As a result of manufacturing with a third party other than Lonza, under the terms of the Lonza License we had a license fee of \$0.4 million due to Lonza in the fourth quarter of 2023 and annually thereafter. The \$0.4 million Lonza License fee was recorded as research and development expense and paid in each of the years ended December 31, 2025 and 2024.

WuXi Biologics License

In July 2023, we entered into a biologics master services agreement (the “WuXi Biologics MSA”) with WuXi Biologics and its Affiliates (“WuXi Biologics”). Under the WuXi Biologics MSA, we are obligated to pay WuXi Biologics a service fee and all non-cancellable obligations in the amount specified in each work order associated with the agreement for the provision of services.

The WuXi Biologics MSA may be terminated upon 30 days’ written notice by either party. Each work order under the WuXi Biologics MSA terminates upon completion of the services under such work order, or earlier under certain circumstances: (i) by us upon 3 months’ written notice for reasonable cause, (ii) by WuXi if the services cannot be reasonably performed due to technical difficulties, or (iii) immediately by either party if a material breach is uncured for 30 days. Termination fees may apply under (i) and in the case of our material breach in (iii).

In July 2023, we entered into a cell line license agreement (the “Cell Line License Agreement”) with WuXi Biologics. The Cell Line License Agreement provides us with a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics’s know-how, cell line, and biological materials to manufacture, have manufactured, use, sell and import certain products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the “WuXi Biologics Licensed Products”). In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of \$150,000. Additionally, if we manufacture all of our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer (the “Royalty”). If we manufacture part of our commercial supplies of the WuXi Biologics Licensed Products with WuXi Biologics or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon three months’ prior written notice and its payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 30 days after written notice, or (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure. As of December 31, 2025, there are no payments currently due under the Cell Line License Agreement.

We have not included future milestone or royalty payments or other contractual payment obligations as the timing and amount of such obligations are unknown or uncertain and are contingent upon the initiation, continuation, and/or successful completion of future activities.

Critical Accounting Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us 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, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate research and development costs incurred during the period, which impacts the amount of accrued expenses and prepaid balances related to such costs as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and service providers to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. To date, our estimated accruals have not differed materially from actual costs incurred.

External costs consist primarily of payments to third parties in connection with our process development, manufacturing and clinical development activities. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We allocate external costs by program and functional area. Internal costs consist primarily of employee-related costs including salaries, related benefits and share-based compensation expense for employees engaged in research and development functions. We do not allocate internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

Share-Based Compensation

We recognized share-based compensation expense for all share-based awards. The fair value of the equity instruments at the date of grant, net of actual forfeitures when they occur, is recognized to share-based compensation expense on a straight-line basis over the requisite service period. When the terms and conditions are modified before they vest, any increase in the fair value of the shares, measured immediately before and after the modification, is also charged to the consolidated statements of operations.

The grant date fair value of our restricted shares, restricted share units and share options with a nominal exercise price is determined based on the share price of our Class A Ordinary Shares. The grant date fair value of our share options is estimated using the Black-Scholes option pricing model. This model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

Expected volatility—Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a publicly traded set of peer companies. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the

equivalent period of the calculated expected term of the share-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

Expected term—The expected term represents the period that the share-based awards are expected to be outstanding. We have opted to use the “simplified method” for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally between 5 to 10 years.

Risk-Free Interest Rate—The risk-free rate assumption is based on the United States Treasury yield in effect at the time of the grant with maturities consistent with the expected term of our options.

Dividend Yield—We have never paid dividends on our ordinary shares and have no plans to pay dividends on our ordinary shares. Therefore, we used an expected dividend yield of zero.

Redeemable Noncontrolling Interest

Our consolidated subsidiary Z33 issued the Z33 Series Seed Preferred Shares to Stone Peach as a finder’s fee for the 2022 Lilly License pursuant to the Z33 Letter Agreement. As the Z33 Letter Agreement to issue the Z33 Series Seed Preferred Shares included embedded put and call features, the shares issued to Stone Peach represented redeemable noncontrolling interest that we were required to initially measure at fair value at issuance. The Z33 Letter Agreement and the Stone Peach Letter Agreements were amended in both April 2023 and November 2023. The amendments were accounted for as extinguishments and reissuances of the Z33 Series Seed Preferred Shares which triggered us to remeasure the fair value of the Z33 Series Seed Preferred Shares at those points in time. Subsequent to the amendments, the Series Seed Preferred Shares were remeasured at the end of each reporting period to the greater of the redemption value or the initial carrying value, decreased for the noncontrolling interest’s share of Z33’s net loss.

The fair value of the shares without the embedded features was first determined using an option pricing model which utilizes inputs which are highly subjective assumptions and generally require significant judgement. These assumptions include expected volatility, expected term, the underlying value of Z33’s equity, a discount for lack of control, and a discount for lack of marketability.

We then valued the embedded put and call features utilizing the Black-Scholes option pricing model utilizing inputs which are highly subjective and require significant judgement, including expected volatility, expected term, and the fair value of a Z33 Series Seed Preferred Share. On December 29, 2025, we terminated the Z33 Letter Agreement and the respective call and put rights relating to Z33’s Series Seed Preferred Shares were extinguished. See “—*Athanor Letter Agreement*” below.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements located in “*Item 15—Exhibits and Financial Statement Schedules—Financial Statements*” in this Annual Report for a description of recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition and results of operations.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Upon the Closing Date, we remained an emerging growth company and may elect to extend the transition period for complying with new or revised accounting standards, which delays the adoption of these accounting standards until they would apply to private companies.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements in addition to any required unaudited interim financial statements, with correspondingly reduced disclosure in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;

- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registrations statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on financial statements.

We would cease to qualify as an emerging growth company on the date that is the earliest of: (i) December 31, 2026, (ii) the last day of the fiscal year in which we have more than \$1.235 billion in total annual gross revenues, (iii) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our Class A Ordinary Shares that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, or (iv) the date on which we have issued more than \$1.0 billion of non-convertible debt over the prior three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. We have taken advantage of certain reduced reporting requirements in this Annual Report. Accordingly, the information contained herein may be different than you might obtain from other public companies in which you hold equity interests.

We are also a “smaller reporting company” as defined under the Securities Act and Exchange Act. We may continue to be a smaller reporting company so long as either (i) the market value of Class A Ordinary Shares held by non-affiliates is less than \$250.0 million or (ii) our annual revenue was less than \$100.0 million during the most recently completed fiscal year and the market value of Class A Ordinary Shares held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in this Annual Report and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company under the requirements of (ii) above, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a “smaller reporting company”, we are not required to provide the information otherwise required by this Item 7A.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements, together with the report of our independent registered public accounting firm, required by this item are set forth beginning on page F-1 of this Annual Report.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of December 31, 2025, our Chief Executive Officer and Chief Financial Officer carried out an evaluation with the participation of management of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2025.

Management's Report on Internal Controls Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Securities Exchange Act of 1934 that occurred during the quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

A control system, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

No Attestation Report of Registered Public Accounting Firm

This Annual Report does not contain an attestation report of our registered public accounting firm due to an exemption for "emerging growth companies."

ITEM 9B. OTHER INFORMATION

Insider Trading Arrangements

During the quarter ended December 31, 2025, no directors or executive officers entered into, modified or terminated, contracts, instructions or written plans for the sale or purchase of our securities that were intended to satisfy the affirmative defense conditions of Rule 10b5-1.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Other than as set forth below, the information required by this item will be included in the definitive proxy statement for our 2026 annual general meeting of shareholders (the “AGM”), which will be filed with the SEC within 120 days of our 2025 fiscal year end.

Our Code of Ethics (the “Code”), which applies to all directors, officers and employees, is available on our Investor Relations website, investors.zurabio.com. The information on, or otherwise accessible through, our website does not constitute a part of this Annual Report. We intend to satisfy the disclosure requirements regarding any applicable amendment to or waiver from the Code by posting such information on our Investor Relations website rather than by filing a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in our definitive proxy statement for our AGM and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The information required by this item will be included in the definitive proxy statement for our AGM and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in the definitive proxy statement to our 2026 Annual General Meeting of Shareholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in the definitive proxy statement to our 2026 Annual General Meeting of Shareholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Form 10-K:

(1) Financial Statements: The financial statements as set forth under Item 8 of this Annual Report are incorporated herein.

(2) Financial Statement Schedules:

All schedules have been omitted because they are not required, not applicable, not present in amounts sufficient to require submission of the schedule, or the required information is otherwise included in our consolidated financial statements and related notes.

(3) Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report.

Exhibit	Description
2.1	Business Combination Agreement, dated as of June 16, 2022, by and among JATT, Merger Sub, Merger Sub 2, Holdco and Zura Bio Limited (incorporated by reference to Exhibit 2.1 of JATT's Current Report on Form 8-K (File No. 001-40598), filed with the SEC on June 17, 2022).
2.2	First Amendment dated as of September 20, 2022 to the Business Combination Agreement by and among JATT, Merger Sub, Merger Sub 2 and Holdco and Zura Bio Limited (incorporated by reference to Exhibit 2.2 of JATT's Form S-4/A (File No. 333-267005), filed with the SEC on October 25, 2022).
2.3	Second Amendment dated as of November 14, 2022 to the Business Combination Agreement by and among JATT, Merger Sub, Merger Sub 2, Holdco and Zura Bio Limited (incorporated by reference to Exhibit 2.2 of JATT's Current Report on Form 8-K (File No. 001-40598), filed with the SEC on November 15, 2022).
2.4	Third Amendment dated as of January 13, 2023 to the Business Combination Agreement by and among JATT Acquisition Corp, JATT Merger Sub, JATT Merger Sub 2, Zura Holdings, Ltd. and Zura Bio Limited (incorporated by reference to Exhibit 2.1 of JATT's Current Report on Form 8-K (File No. 001-40598), filed with the SEC on January 19, 2023).
3.1	Second Amended and Restated Memorandum and Articles of Association of Zura Bio Limited (incorporated by reference to Exhibit 3.1 to Zura's Form 8-K (File No. 001-40598), filed with the SEC on March 24, 2023).
4.1	Specimen Share Certificate of Zura Bio Limited (incorporated by reference to Exhibit 4.5 of JATT's Form S-4 (File No. 333-267005) filed with the SEC on August 19, 2022).
4.2	Form of Pre-Funded Warrant to Purchase Ordinary Shares (incorporated herein by reference to Exhibit 4.1 to Zura Bio Limited's Current Report on Form 8-K, filed with the SEC on May 3, 2023).
4.3	Form of Pre-Funded Warrant to Purchase Ordinary Shares (incorporated herein by reference to Exhibit 4.1 to Zura Bio Limited's Current Report on Form 8-K, filed with the SEC on August 21, 2024).
4.4	Form of Pre-Funded Warrant to purchase Ordinary Shares (incorporated by reference to Exhibit 4.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on April 23, 2024).
4.5	Form of Pre-Funded Warrant to purchase Ordinary Shares (incorporated by reference to Exhibit 4.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on April 17, 2025).
4.6	Form of Pre-Funded Warrant to purchase Ordinary Shares (incorporated by reference to Exhibit 4.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on February 26, 2026).
4.7	Description of Zura Bio Limited's securities (incorporated by reference to Exhibit 4.6 to Zura Bio Limited's Annual Report on Form 10-K filed with the SEC on March 25, 2025).
10.1+	License Agreement between Zura Bio Limited and Lonza Sales AG, dated July 22, 2022 (incorporated by reference to Exhibit 10.17 of JATT's Form S-4/A (File No. 333-267005) filed with the SEC on February 17, 2023).
10.2+	License, Development and Commercialization Agreement, dated as of December 8, 2022, by and between Eli Lilly and Company and Z33 Bio Inc (incorporated by reference to Exhibit 10.22 of JATT's Form S-4/A (File No. 333-267005) filed with the SEC on February 17, 2023).
10.3†	Zura Bio Limited 2023 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 of Zura Bio Limited's Registration Statement on Form S-8 (File No. 333-272842) filed with the SEC on June 22, 2023).

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10.4†	Zura Bio Limited 2023 Employee Share Purchase Plan (incorporated by reference to Exhibit 99.2 of Zura Bio Limited's Registration Statement on Form S-8 (File No. 333-272842) filed with the SEC on June 22, 2023).
10.5	Share Option Award Agreement (incorporated by reference to Annex C of the Definitive Proxy Statement on Schedule 14A filed with the SEC on May 19, 2023).
10.6††+	License, Development and Commercialization Agreement between ZB17 LLC and Eli Lilly and Company, dated April 26, 2023 (incorporated by reference to Exhibit 10.38 to the Registration Statement filed with the SEC on August 25, 2023).
10.7†	Offer Letter, dated March 2, 2023, to Amit Munshi, (incorporated by reference to Exhibit 10.28 of JATT's Form 10-Q (File No. 001-40598) filed with the SEC on May 12, 2023).
10.8†††+	Service Agreement between Zura Bio Limited and Kiran Nistala (incorporated by reference to Exhibit 10.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on December 6, 2023).
10.9†	Employment Agreement between Zura Bio Limited and Robert Lisicki (incorporated by reference to Exhibit 10.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on January 8, 2024).
10.10	Share Surrender and Warrant Agreement, dated as of August 15, 2024, by and among Zura Bio Limited and certain investors party thereto (incorporated by reference to Exhibit 10.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on August 21, 2024).
10.11	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on April 23, 2024).
10.12	Sales Agreement, by and between Zura Bio Limited and Leerink Partners LLC, dated September 3, 2024 (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3 filed with the SEC on September 3, 2024).
10.13	Amended and Restated Registration Rights Agreement dated March 20, 2023, by and among Zura Bio Limited, the Sponsor and the parties thereto (incorporated by reference to Exhibit 10.2 of the Company's Current Report Form 8-K (File No. 001-40598) filed with the SEC on March 24, 2023).
10.14	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.13 of the Company's Current Report on Form 8-K (File No. 001-40598), filed with the SEC on March 24, 2023).
10.15†	Share Option Award Agreement (incorporated by reference to Annex C of the Definitive Proxy Statement on Schedule 14A filed with the SEC on May 19, 2023).
10.16†	Letter Agreement, dated as of December 8, 2022, by and among Zura Bio Limited and Stone Peach Properties LLC (incorporated by reference to Exhibit 10.27 of JATT's Form S-4/A (File No. 333-267005) filed with the SEC on December 14, 2022).
10.17	Offer Letter Agreement with Kim Davis, dated November 22, 2022 (incorporated by reference to Exhibit 10.39 to the Form S-1/A filed with the SEC on August 11, 2023).
10.18	Share Surrender and Warrant Agreement, dated as of April 16, 2025, by and among Zura Bio Limited and Venrock Healthcare Capital Partners EG, L.P., Venrock Healthcare Capital Partners III, L.P., and VHCP Co-Investment Holdings III, LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-40598) filed with the SEC on April 17, 2025).
10.19	Share Surrender and Warrant Agreement, dated as of April 17, 2025, by and between Zura Bio Limited and AI Biotechnology, LLC (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-40598) filed with the SEC on April 17, 2025).
10.20†	Offer Letter with Eric Hyllengren dated June 27, 2025 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K (File No. 001-40598) filed with the SEC on July 1, 2025).
10.21†	Settlement Agreement, by and between Zura Bio Limited and Verender Badial, dated as of June 27, 2025 (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-40598) filed with the SEC on July 1, 2025).
10.22†	Zura Bio Limited Executive Severance Benefit Plan (incorporated by reference to Exhibit 10.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on September 30, 2025).
10.23#	Letter Agreement, dated December 29, 2025, by and between Zura Bio Limited and Athanor Capital (incorporated by reference to Exhibit 10.1 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on January 2, 2026).
10.24	Settlement and Release Agreement, dated December 29, 2025, by and between Zura Bio Limited and the Stone Peach Parties (incorporated by reference to Exhibit 10.2 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on January 2, 2026).
10.25	Settlement and Release Agreement, dated December 29, 2025, by and between Zura Bio Limited and the BAFFX17 Parties (incorporated by reference to Exhibit 10.3 to Zura Bio Limited's Current Report on Form 8-K filed with the SEC on January 2, 2026).

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10.26†	Separation Agreement, by and between Zura Bio Limited and Robert Lisicki, dated January 21, 2026 (incorporated by reference to Exhibit 10.1 to Zura Bio Limited’s Current Report on Form 8-K filed with the SEC on January 26, 2026).
10.27†#	Offer Letter with Sandeep Kulkarni, dated January 21, 2026 (incorporated by reference to Exhibit 10.2 to Zura Bio Limited’s Current Report on Form 8-K filed with the SEC on January 26, 2026).
10.28†	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 of the Company’s Form 10-Q (File No. 001-40598) filed with the SEC on November 13, 2025).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 of the Company’s Form 10-K (File No. 001-40598) filed with the SEC on March 25, 2025).
21.1*	List of Subsidiaries of Zura Bio Limited.
23*	Consent of WithumSmith+Brown, PC, independent registered public accounting firm of Zura.
24.1*	Power of Attorney (included on signature page).
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief 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	Clawback Policy (incorporated by reference to Exhibit 97.1 of the Company’s Annual Report on Form 10-K filed on March 28, 2024).
101.INS	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101.

† Indicates management contract or compensatory plan or arrangement.

†† The Registrant has redacted provisions or terms of this Exhibit pursuant to Regulation S-K Item 601(b)(10)(iv). While portions of the Exhibits have been omitted, these Exhibits include a prominent statement on the first page of each redacted Exhibit that certain identified information has been excluded from the exhibit because it is both not material and is the type that the Registrant treats as private or confidential. The Registrant agrees to furnish an unredacted copy of the Exhibit to the SEC upon its request.

Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

+ Portions of this Exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K.

* Filed herewith.

** Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 19, 2026

Zura Bio Limited
By: /s/ Sandeep Kulkarni

Sandeep Kulkarni
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Sandeep Kulkarni and Eric Hyllengren, and each of them, as his or her true and lawful attorneys-in-fact and agents, each 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 on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact and agents, or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

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 in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
/s/ Sandeep Kulkarni Sandeep Kulkarni	Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2026
/s/ Eric Hyllengren Eric Hyllengren	Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2026
/s/ Amit Munshi Amit Munshi	Director, Chairman of the Board of Directors	March 19, 2026
/s/ Someit Sidhu Someit Sidhu	Director	March 19, 2026
/s/ Steve Schoch Steve Schoch	Director	March 19, 2026
/s/ Jennifer Jarrett Jennifer Jarrett	Director	March 19, 2026
/s/ Dan Becker Dan Becker	Director	March 19, 2026
/s/ Parvinder Thiara Parvinder Thiara	Director	March 19, 2026
/s/ Ajay Nirula Ajay Nirula	Director	March 19, 2026
/s/ Mark Eisner Mark Eisner	Director	March 19, 2026

ZURA BIO LIMITED

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Zura Bio Limited:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Zura Bio Limited (the “Company”) as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in redeemable noncontrolling interest and shareholders’ equity, and cash flows for each of the two years in the period ended December 31, 2025, and the related consolidated 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 each of the two years in the period ended December 31, 2025, 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 entity’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ WithumSmith+Brown, PC

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

East Brunswick, New Jersey
March 19, 2026

PCAOB ID Number 100

PART I—FINANCIAL INFORMATION**Item 1. Financial Statements.****Zura Bio Limited****Consolidated Balance Sheets
(In thousands, except share data)**

	December 31,	
	2025	2024
Assets		
Current assets		
Cash and cash equivalents	\$ 109,407	\$ 176,498
Prepaid expenses and other current assets	2,903	2,246
Total current assets	112,310	178,744
Property and equipment, net	126	91
Other assets	1,512	698
Total assets	<u>\$ 113,948</u>	<u>\$ 179,533</u>
Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	\$ 12,410	\$ 19,514
Total current liabilities	12,410	19,514
Total liabilities	12,410	19,514
Commitments and contingencies (Note 9)		
Redeemable noncontrolling interest	—	11,663
Shareholders' Equity		
Class A Ordinary Shares, \$0.0001 par value; 300,000,000 shares authorized as of December 31, 2025 and 2024; 73,680,710 and 65,297,530 shares issued and outstanding as of December 31, 2025 and 2024, respectively	7	7
Additional paid-in capital	326,078	302,705
Accumulated deficit	(224,547)	(155,897)
Total Zura Bio Limited shareholders' equity	101,538	146,815
Noncontrolling interest	—	1,541
Total shareholders' equity	101,538	148,356
Total liabilities, redeemable noncontrolling interest and shareholders' equity	<u>\$ 113,948</u>	<u>\$ 179,533</u>

See accompanying notes to consolidated financial statements.

Zura Bio Limited**Consolidated Statements of Operations**
(In thousands, except share and per share data)

	For the Years Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	\$ 42,082	\$ 24,401
General and administrative	33,164	30,788
Total operating expenses	75,246	55,189
Loss from operations	(75,246)	(55,189)
Other (income)/expense, net		
Interest income	(6,336)	(7,998)
Change in fair value of private placement warrants	—	5,240
Other income, net	(260)	(28)
Total other income, net	(6,596)	(2,786)
Loss before income taxes	(68,650)	(52,403)
Income tax benefit	—	—
Net loss	(68,650)	(52,403)
Adjustment of redeemable noncontrolling interest	831	7,017
Accretion of redeemable noncontrolling interest to redemption value	4,868	—
Deemed dividend on extinguishment of noncontrolling interest and redeemable noncontrolling interest	(36,402)	—
Net loss attributable to Class A Ordinary Shareholders of Zura	\$ (99,353)	\$ (45,386)
Net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	\$ (1.06)	\$ (0.60)
Weighted-average Class A Ordinary Shares used in computing net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	94,160,138	75,070,761

See accompanying notes to consolidated financial statements.

Zura Bio Limited

Consolidated Statements of Changes in Redeemable Noncontrolling Interest and Shareholders' Equity
(In thousands, except share data)

	Redeemable Noncontrolling Interest	Class A Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Noncontrolling Interest	Total Shareholders' Equity
		Shares	Amount				
Balance as of December 31, 2023	\$ 18,680	43,593,678	\$ 4	\$162,820	\$ (103,494)	\$ 1,541	\$ 60,871
Issuance of Class A Ordinary Shares in connection with April 2024 Private Placement, net of \$7.2 million of transaction costs	—	20,090,128	2	55,221	—	—	55,223
Issuance of Pre-Funded Warrants in connection with April 2024 Private Placement	—	—	—	50,030	—	—	50,030
Issuance of Pre-Funded Warrants in exchange for Class A Ordinary Shares	—	(4,000,000)	—	—	—	—	—
Issuance of Class A Ordinary Shares in exchange for Private Placement Warrants	—	1,718,108	—	6,230	—	—	6,230
Issuance of Class A Ordinary Shares in exchange for Public Warrants	—	2,064,082	—	—	—	—	—
Issuance of Class A Ordinary Shares in connection with a sale under the ATM, net of \$0.2 million of commissions	—	1,500,000	1	5,533	—	—	5,534
ATM transaction costs	—	—	—	(626)	—	—	(626)
Issuance of Class A Ordinary Shares for restricted stock units, net of shares withheld for taxes	—	331,534	—	(318)	—	—	(318)
Share-based compensation	—	—	—	16,798	—	—	16,798
Adjustment of redeemable noncontrolling interest from redemption value to carrying value	(7,017)	—	—	7,017	—	—	7,017
Net loss	—	—	—	—	(52,403)	—	(52,403)
Balance as of December 31, 2024	\$ 11,663	65,297,530	\$ 7	\$302,705	\$ (155,897)	\$ 1,541	\$ 148,356
Issuance of Class A Ordinary Shares in connection with sales under the ATM, net of \$0.2 million of commissions	—	3,000,000	—	5,093	—	—	5,093
Issuance of Pre-Funded Warrants in exchange for Class A Ordinary Shares	—	(6,500,000)	(1)	1	—	—	—
Issuance of Class A Ordinary Shares upon exercise of Pre-Funded Warrants	—	2,888,952	1	2	—	—	3
Issuance of Class A Ordinary Shares for share option exercises and restricted share units, net of shares withheld for taxes	—	336,826	—	66	—	—	66
Issuance of Class A Ordinary Shares in connection with the Athanor Agreement	—	8,657,402	—	46,318	—	—	46,318
Partial extinguishment of redeemable noncontrolling interest	(5,831)	—	—	831	—	—	831
Accretion of redeemable noncontrolling interest to redemption value	4,868	—	—	(4,868)	—	—	(4,868)
Extinguishment of noncontrolling interest and redeemable noncontrolling interest	(10,700)	—	—	(36,402)	—	(1,541)	(37,943)
Share-based compensation	—	—	—	12,332	—	—	12,332
Net loss	—	—	—	—	(68,650)	—	(68,650)
Balance as of December 31, 2025	\$ —	73,680,710	\$ 7	\$326,078	\$ (224,547)	\$ —	\$ 101,538

See accompanying notes to consolidated financial statements.

Zura Bio Limited

**Consolidated Statements of Cash Flows
(In thousands)**

	For the Years Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss before redeemable noncontrolling interest	\$ (68,650)	\$ (52,403)
Adjustments to reconcile net loss before redeemable noncontrolling interest to net cash used in operating activities		
Share-based compensation expense	12,332	16,798
Change in fair value of private placement warrants	—	5,240
Depreciation and amortization	49	9
Foreign exchange transaction gain	84	(27)
Gain on extinguishment of BAFFX17 liability	(5,000)	—
Other non-cash items, net	4	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(657)	(1,209)
Other assets	(814)	(698)
Accounts payable and accrued expenses	(2,163)	4,214
Net cash used in operating activities	(64,815)	(28,076)
Cash flows from investing activities		
Purchase of fixed assets	(113)	(75)
Purchase of research and development license	—	(5,000)
Net cash used in investing activities	(113)	(5,075)
Cash flows from financing activities		
Proceeds from issuance of Ordinary Shares in connection with April 2024 Private Placement, net of \$7.2 million of transaction costs	—	55,223
Proceeds from issuance of Pre-Funded Warrants in connection with April 2024 Private Placement	—	50,030
Proceeds from issuance of Class A Ordinary Shares in connection with a sale under the ATM, net of \$0.2 million of commissions	5,093	5,534
ATM transaction costs	—	(626)
Issuance of Class A Ordinary Shares upon exercise of Pre-Funded Warrants	3	—
Proceeds from exercise of stock options	107	—
Restricted stock units withheld to pay employee withholding taxes	(41)	(318)
Consideration paid for Athanor Agreement	(7,325)	—
Net cash (used in) provided by financing activities	(2,163)	109,843
Net increase in cash and cash equivalents	(67,091)	76,692
Cash and cash equivalents, beginning of period	176,498	99,806
Cash and cash equivalents, ending of period	<u>\$ 109,407</u>	<u>\$ 176,498</u>
Supplemental Disclosure		
Cash paid for taxes	\$ —	\$ —
Cash paid for interest	\$ —	\$ —
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Issuance of Class A Ordinary Shares in exchange for private placement warrants	\$ —	\$ 6,230
Issuance of shares in conjunction with Athanor agreement	\$ 46,318	\$ —
Adjustments to redeemable noncontrolling interest	\$ —	\$ 7,017
Accretion of redeemable noncontrolling interest to redemption value	\$ 4,868	\$ —
Purchase of property and equipment included in accounts payable and accrued expenses	\$ —	\$ 25
Extinguishment of noncontrolling interest and redeemable noncontrolling interest	\$ 18,072	\$ —

See accompanying notes to consolidated financial statements.

Zura Bio Limited

Notes to Consolidated Financial Statements

(Tabular amounts in thousands, except share and per share data)

1. Organization and Description of Business

Zura Bio Limited, a Cayman Islands exempted company, formerly known as JATT Acquisition Corp (“JATT”), together with its subsidiaries (collectively, the “Company”, “Zura” or “Zura Bio”), is a clinical-stage biotechnology company developing novel and differentiated medicines for patients with autoimmune and inflammatory diseases, including serious and debilitating conditions with significant unmet medical need. These diseases are often chronic, biologically complex and difficult to treat, and many patients do not achieve durable disease control with currently available therapies. The Company’s strategic focus is to identify immune-mediated diseases in which translational and clinical evidence supports the role of specific biological pathways in disease pathogenesis. The Company is currently developing one clinical-stage product candidate in ongoing Phase 2 trials while evaluating development opportunities for its pipeline of clinical-stage assets, focusing on indications with unmet needs and commercial potential.

Business Combination

On March 20, 2023 (the “Closing Date”), the Company consummated a series of transactions (the “Business Combination”), pursuant to the terms of a business combination agreement (the “Business Combination Agreement”), dated as of June 16, 2022 (as amended on September 20, 2022, November 14, 2022, and January 13, 2023), by and among JATT, JATT Merger Sub, JATT Merger Sub 2, Zura Bio Holdings Ltd., and Legacy Zura, pursuant to which JATT changed its name to “Zura Bio Limited”.

On March 20, 2023, the Company’s Class A ordinary shares (“Class A Ordinary Shares”) began trading on the Nasdaq under the symbol “ZURA”.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use the extended transition period for complying with new or revised accounting standards, and as a result of this election, the consolidated financial statements may not be comparable to companies that comply with public company Financial Accounting Standards Board (“FASB”) standards’ effective dates. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an emerging growth company. The Company expects to no longer be an emerging growth company effective December 31, 2026.

Liquidity

The Company has incurred operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. The Company has an accumulated deficit of \$224.5 million and \$155.9 million as of December 31, 2025 and 2024, respectively, and a net loss of \$68.7 million and \$52.4 million for the years ended December 31, 2025 and 2024, respectively. The Company’s existing sources of liquidity as of December 31, 2025 include \$109.4 million in cash and cash equivalents.

Prior to the Business Combination, the Company historically funded operations primarily with issuances of convertible preferred shares and a promissory note. Upon the closing of the Business Combination, the Company received \$56.7 million in net cash proceeds. Additionally, the Company has received \$10.0 million, \$105.3 million and \$75.8 million, respectively, in net cash proceeds in connection with the ATM (as defined herein), April 2024 Private Placement (as defined herein) and April 2023 Private Placement (as defined herein). The Company’s cash requirements include, but are not limited to, clinical development, product manufacturing costs and working capital requirements. The Company expects such operating losses and negative cash flows from operations will continue but has sufficient liquidity to fund its operations over the next twelve months.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements (the "consolidated financial statements") have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and include the accounts of its consolidated subsidiaries. Other shareholders' interests in the Company's subsidiaries, Z33 Bio, Inc. ("Z33") and ZB17 LLC ("ZB17"), are shown in the consolidated financial statements as redeemable noncontrolling interest and noncontrolling interest, respectively. All intercompany balances and transactions have been eliminated in consolidation.

Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Significant estimates and assumptions reflected in the consolidated financial statements relate to and include, but are not limited to, accrued research and development expenses, the fair value of share-based compensation, the fair value of redeemable noncontrolling interest, and the valuation allowance of deferred tax assets resulting from net operating losses.

Risks and Uncertainties

The Company is subject to risks common to early-stage companies in the biotechnology industry, including, but not limited to, development by the Company or its competitors of technological innovations, risks of failure of clinical studies, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to transition from preclinical manufacturing to commercial production of products.

The Company's future product candidates will require approvals from the United States Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a material adverse impact on the Company.

The Company has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of \$250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

Segments

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") in making decisions regarding resource allocation and assessing performance. The Company's CODM is the Chief Executive Officer. The Company and the CODM views its operations and manages its business in one operating segment, developing novel medicines for immune and inflammatory disorders. The Company has business activities in different regions that are managed on a consolidated basis.

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The accounting policies of the Company's segment are the same as those described within this footnote. The CODM uses net loss, that is reported in the consolidated statements of operations to assess performance for the Company's segment and decide how to allocate resources. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. The following tables represent information provided to the chief operating decision maker:

	Year Ended December 31,	
	2025	2024
Research and development expenses:		
Wages and benefits	\$ 7,381	\$ 3,543
Tibulizumab SSc Program	10,650	2,393
Tibulizumab HS Program	9,990	552
Tibulizumab Combined (SSc and HS) Programs	5,718	12,875
Additional product candidates (crebankitug and torudokimab)	4,393	1,543
Unallocated research and development expenses	1,938	1,271
General and administrative expenses:		
Wages and benefits	10,635	6,395
Other general and administrative expenses	12,163	9,810
Stock-based compensation	12,332	16,798
Other segment items*	(6,550)	(2,777)
Net loss	\$ 68,650	\$ 52,403

*Other segment items include Depreciation and amortization, Interest income, Change in fair value of private placement warrants, and Other income (net).

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company had \$106.3 million and \$170.7 million in cash equivalents as of December 31, 2025 and 2024, respectively.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset. Computer and office equipment are depreciated over three years. Expenditures for repairs and maintenance are recorded to expense as incurred.

Research and Development

Research and development ("R&D") expenses consist of all direct and indirect operating expenses supporting the processes and manufacturing in development, including consulting fees for clinical and manufacturing advisory services, contract research organization ("CRO") costs, costs related to manufacturing material for preclinical studies, payroll and benefits, which includes share-based compensation for research and development employees, licensing fees, and data and study acquisition costs. Expenses are recognized as an expense as the related goods are delivered or the services are performed. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

R&D expenses include the cost of in-process research and development ("IPR&D") assets purchased in an asset acquisition transaction. IPR&D assets are expensed provided that the acquired asset did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has not established alternative future use. Acquired IPR&D payments, including upfront payments, transaction fees and subsequent pre-commercial milestone payments, are immediately expensed in the period in which they are incurred. Research and development costs incurred after the acquisition are expensed as incurred.

R&D Incentive Credits

The Company is eligible to obtain certain R&D incentive credits (the “R&D Credits”), through participation in the United Kingdom’s (“U.K.”) R&D Small and Medium Enterprise (“SME”) and the Research and Development Expenditure Credit (“RDEC”) tax relief programs.

The R&D Credits are calculated as a percentage of qualifying R&D expenses incurred as part of research projects. The R&D Credits are used as tax credits for the Company with the resulting amount being payable in cash by the U.K. government (tax authority) to the Company. The R&D Credits are subject to future audits by the U.K. tax authority within defined periods.

Although the incentive credits are administered through the local tax authority, the Company has accounted for the incentives outside of the scope of FASB Accounting Standards Codification (“ASC”) Topic 740, Income Taxes, since the incentives are not linked to the Company’s taxable income and can be realized regardless of whether the Company has generated taxable income in the respective jurisdictions. The Company accounts for these incentive credits as a government grant which analogizes with International Accounting Standards 20 (“IAS 20”), Accounting for Government Grants and Disclosure of Government Assistance.

In accordance with IAS 20, the Company will recognize the R&D Credits when it has reasonable assurance that the R&D Credits will be received. As the Company has only filed two claims under the tax relief programs as of December 31, 2025, it has determined that reasonable assurance will be met upon cash receipt. For the year ended December 31, 2025, the Company recorded \$0.3 million in other income, net in the consolidated statement of operations for R&D Credits received in May 2025. In April 2025, the Company filed an additional claim for an R&D Credit for \$1.0 million that was not received as of December 31, 2025.

Share-Based Compensation

The Company accounts for all share-based payments to employees and non-employees, including grants of share options, share options with non-market performance conditions (“PSOs”), share options with market-based performance conditions, restricted share units (“RSUs”), and restricted share awards (“RSAs”) based on their respective grant date fair values. RSUs, RSAs and share options that vest immediately and have a nominal exercise price are valued based on the fair value of the Company’s Class A Ordinary Shares on the date of grant. The Company estimates the fair value of share option grants using the Black-Scholes option-pricing model. The assumptions used in calculating the fair value of share-based awards represent management’s best estimates and involve inherent uncertainties and the application of management’s judgment. These assumptions include:

Expected volatility—Due to our limited operating history and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a publicly traded set of peer companies. The historical volatility data was computed using the daily closing prices for the selected companies’ shares during the equivalent period of the calculated expected term of the share-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

Expected term—The expected term represents the period that the share-based awards are expected to be outstanding. We have opted to use the “simplified method” for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally between 5 to 10 years.

Risk-Free Interest Rate—The risk-free rate assumption is based on the United States Treasury yield in effect at the time of the grant with maturities consistent with the expected term of our options.

Dividend Yield—We have never paid dividends on our ordinary shares and have no plans to pay dividends on our ordinary shares. Therefore, we used an expected dividend yield of zero.

The Company expenses share-based compensation related to share options with only service conditions over the requisite service period on a straight-line basis. The Company records share-based compensation expense for the PSOs when the Company’s management deems it probable that the performance conditions will be satisfied. The Company estimates the fair value of share option grants with market-based performance conditions using a Monte-Carlo simulation model. For share option grants with market-based performance conditions, the Company recognizes share-based compensation expense as the requisite service is rendered by the employee, regardless of when, if ever, the market-based performance conditions are satisfied. The share-based compensation costs are recorded in research and development and general and administrative expenses in the consolidated statements of operations based upon the respective employee’s or non-employee’s role within the Company. Forfeitures are recorded as they occur.

Income Taxes

Income taxes are recorded in accordance with ASC 740, Income Taxes. ASC 740 requires a company to use the asset and liability method of accounting for income taxes, whereby deferred tax assets are recognized for deductible temporary differences, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effect of changes in tax laws and rates on the date of enactment.

Under ASC 740, a tax position is recognized as a benefit only if it is “more likely than not” that the tax position would be sustained in a tax examination, with a tax examination being presumed to occur. The amount recognized is the largest amount of tax benefit that is greater than 50% likely of being realized on examination. For tax positions not meeting the “more likely than not” test, no tax benefit is recorded. The Company does not have any material uncertain tax positions for any of the reporting periods presented. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as part of income tax expense.

On July 4, 2025, President Trump signed H.R. 1, the annual reconciliation bill commonly referred to as the “One Big Beautiful Bill Act” (“OBBBA”) into law. The OBBBA makes permanent many of the provisions previously enacted as part of the 2017 Tax Cut and Jobs Act that were set to expire at the end of 2025 and includes other changes to certain U.S. corporate tax provisions including (i) the restoration of immediate expensing for domestic research and development expenditures, (ii) the reinstatement of 100% bonus depreciation for qualified property and (iii) favorably modifying the section 163(j) interest limitation (similar to EBITDA). FASB Topic 740, “Income Taxes”, requires the tax effects of changes in tax laws or rates be recognized in the period in which the law is enacted. The enactment of the OBBBA did not have a material impact on our effective tax rate as of December 31, 2025.

Warrants

In connection with the Business Combination, the Company assumed JATT’s public warrant and private placement warrant liabilities. As a result of the recapitalization, the settlement provisions of the Public Warrants (as defined herein) no longer preclude equity classification and the Public Warrants were reclassified to equity following the Business Combination. The Public Warrants and Private Placement Warrants (as defined herein) were exchanged for Class A Ordinary Shares during the year ended December 31, 2024 (the “Warrant Exchange”). See Note 6.

In connection with each of the April 2024 Private Placement and April 2023 Private Placement (each as defined herein), the Company issued pre-funded warrants.

Classification of the Public Warrants and Pre-Funded Warrants (as defined herein) as equity instruments and the Private Placement Warrants as liability instruments is based on management’s analysis of the guidance in ASC 815, *Derivatives and Hedging*. The Company measured the private placement warrant liability at fair value each reporting period and at settlement value, based on the fair value of the Class A Ordinary Shares exchanged, upon the Warrant Exchange, with the change in fair value recorded as other (expense) income in the consolidated statements of operations. Upon completion of the Warrant Exchange, the warrant liability was extinguished and the Class A Ordinary Shares were recorded at fair value in shareholders’ equity. The Company measured the Public Warrants at the fair value of the equity instruments as of the Closing Date of the Business Combination. The Company measured the Pre-Funded Warrants at the fair value of the equity instruments as of the date of the April 2023 Private Placement, the April 2024 Private Placement, the Share Exchange, or the 2025 Share Exchange (as defined herein), as applicable. See Note 6.

Noncontrolling Interest

During April 2023, ZB17, a consolidated subsidiary of the Company, issued a share-based payment award to a third party in connection with 2023 Lilly License representing a noncontrolling interest. A noncontrolling interest in a subsidiary is considered an ownership interest in a majority-owned subsidiary that is not attributable to the parent. The Company includes noncontrolling interest as a component of total shareholders’ equity in the Company’s consolidated balance sheets. The option to acquire ZB17 ownership interests does not provide the option-holder with rights to participate in the profits and losses of the subsidiary prior to the exercise of the option. Following the Athanor Agreement, the noncontrolling interest in the Company’s consolidated balance sheet was extinguished as of December 31, 2025. See Note 5.

Redeemable Noncontrolling Interest

In 2022, Z33, a consolidated subsidiary of the Company, issued 4,900,222 shares of its series seed preferred shares (the “Z33 Series Seed Preferred Shares”) to Stone Peach representing a redeemable noncontrolling interest. The Z33 Series Seed Preferred Shares issued to Stone Peach contained put features and were considered redeemable until the exercise or the expiration of the put features. The redeemable noncontrolling interests were classified outside of permanent equity in the consolidated balance sheets. The redeemable noncontrolling interest was measured at the end of each reporting period as the higher of (1) its initial carrying amount, increased or decreased for the noncontrolling interest’s share of Z33’s net income or loss, or (2) the redemption price, with any changes included in accretion of noncontrolling interest to redemption value in the consolidated statements of operations. Following the Athanor Agreement, the redeemable noncontrolling interest in the Company’s consolidated balance sheet was extinguished as of December 31, 2025. See Notes 5 and 10.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss attributable to Class A Ordinary Shareholders by the weighted-average number of both Class A Ordinary Shares and Pre-Funded Warrants outstanding during the period. As the Company has a net loss, basic and diluted net loss per share was the same for each period presented as the inclusion of all potentially dilutive securities outstanding would have been anti-dilutive.

As of the periods presented, potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, were as follows:

	December 31,	
	2025	2024
Shares issuable upon exercise of options to purchase Class A Ordinary Shares	14,110,191	10,175,633
Shares issuable upon exercise of Z33 Series Seed Preferred Shares Put Right	—	2,000,000
Shares issuable upon vesting of restricted share units	573,282	859,923
Restricted share awards	249,997	374,995
Total	14,933,470	13,410,551

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (“ASU 2023-09”), ASU 2023-09 to enhance the transparency and decision usefulness of income tax disclosures. The amendments in the ASU address investor requests for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. We adopted this standard on a retrospective basis for our 2025 annual reporting. Refer to Note 8, *Income Taxes* for the disclosures required by this guidance.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (“ASU 2024-03”). This ASU requires disclosure, in the notes to financial statements, of the nature of certain expenses included in the income statement. ASU 2024-03 will be effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2024-03 and expects to adopt it for the year ending December 31, 2027.

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*, which establishes guidance on the recognition, measurement, and presentation of government grants received by business entities. The amendments in ASU 2025-10 are effective for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual reporting periods, with early adoption permitted. The guidance can be applied under a modified prospective approach, a modified retrospective approach, or a full retrospective approach. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements and disclosures.

3. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis. The Company determines fair value based upon the exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as determined by either the principal market or the most advantageous market. Inputs used in the valuation techniques to derive fair values are classified based on a three-level hierarchy. These levels are:

Level 1: Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2: Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3: Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Financial instruments consist of cash and cash equivalents, prepaid and other current assets, and accounts payable and accrued expenses. The carrying values of the Company’s cash, prepaid and other current assets, and accounts payable and accrued expenses approximate their fair value due to the short-term maturity of these instruments.

The following table presents information about the Company’s financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2025 and 2024, and the fair value hierarchy of the valuation techniques utilized:

	December 31, 2025			Total
	Level 1	Level 2	Level 3	
Financial assets:				
Cash equivalents	\$ 106,310	\$ —	\$ —	\$ 106,310

	December 31, 2024			Total
	Level 1	Level 2	Level 3	
Financial assets:				
Cash equivalents	\$ 170,743	\$ —	\$ —	\$ 170,743

There were no transfers into or out of Level 1, Level 2, or Level 3 during the year ended December 31, 2025 and 2024.

Private Placement Warrants

In August 2024, pursuant to the Warrant Exchange, the Company exchanged all of the outstanding private placement warrants to purchase 6,899,996 Class A Ordinary Shares (the “Private Placement Warrants”) for Class A Ordinary Shares. The Private Placement Warrants were originally assumed in connection with the Business Combination in 2023. See Note 6. The Private Placement Warrants were measured at fair value on a recurring basis. Because the transfer of Private Placement Warrants to non-permitted transferees would result in the Private Placement Warrants having substantially the same terms as the Public Warrants, the Company determined that the fair value of each Private Placement Warrant is consistent with that of a Public Warrant. Accordingly, the Private Placement Warrants are classified as Level 2 financial instruments. Upon completion of the Warrant Exchange, the Private Placement Warrants were remeasured to settlement value which was determined based on the fair value of the Class A Ordinary Shares issued in exchange for the Private Placement Warrants. The following table provides a summary of changes in the estimated fair value of the Private Placement Warrants:

	For the Year Ended December 31, 2024	
Balance, beginning of year	\$	990
Assumption of private placement warrants		—
Change in fair value		5,240
Exchange of private placement warrants for Class A Ordinary Shares		(6,230)
Balance, end of year	\$	—

There were no Private Placement Warrants outstanding as of December 31, 2025 and December 31, 2024. For the year ended December 31, 2024, the Company recorded a loss of \$5.2 million, from the change in fair value of the Private Placement Warrants in change in fair value of private placement warrants in the consolidated statements of operations.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses are composed of the following as of December 31, 2025 and 2024:

	December 31,	
	2025	2024
Accrued research and development costs	\$ 6,575	\$ 7,100
Accrued 2023 Lilly License costs	—	9,500
Accrued bonus	3,319	1,713
Accounts payable	1,279	733
Accrued professional fees	559	318
Other accrued expenses	678	150
Total accounts payable and accrued expenses	\$ 12,410	\$ 19,514

5. License Agreements

2023 Lilly License

On April 26, 2023, ZB17 entered into a license agreement with Lilly (the “2023 Lilly License” and, together with the 2022 Lilly License (as defined below), the “Lilly Licenses”), for an exclusive license to develop, manufacture and commercialize tibulizumab. As consideration, we paid Lilly an upfront payment consisting of \$5.8 million during 2023 and issued Class A Ordinary Shares at an aggregate fair value of \$7.8 million during the year ended 2023. During 2024, ZB17 made an additional payment of \$5.0 million to Lilly in connection with the receipt of certain know-how, data, information and materials that Lilly is required to provide under the license agreement.

The acquisition was accounted for as an asset acquisition as substantially all of the fair value of the assets acquired is concentrated in a group of similar identifiable IPR&D assets. On the acquisition date, the molecule licensed had not yet received regulatory approval and the IPR&D did not have an alternative use. Accordingly, the Company expensed the entire cost of the 2023 Lilly License in research and development in the consolidated statement of operations during the year ended December 31, 2023.

In consideration for the investment made by Stone Peach Properties, LLC (“Stone Peach”), the Company entered into a letter agreement with Stone Peach and ZB17, dated April 24, 2023, as amended by letter agreement dated November 21, 2023 (the “ZB17 Letter Agreement”), pursuant to which ZB17 granted Stone Peach the right, but not the obligation, to purchase 4.99% of the fully diluted equity of ZB17 for \$1.0 million (the “Stone Peach Call Right”). The Stone Peach Call Right was not exercisable until after the last patient is dosed in any single next clinical trial with tibulizumab and would expire one year from the date of first indication approval for tibulizumab by the United States Food and Drug Administration (“FDA”) or the European Medicines Agency (“EMA”). We recognized the Stone Peach Call Right at a grant-date fair value of \$1.5 million as a component of research and development in the consolidated statement of operations during the year ended December 31, 2023. The Stone Peach Call Right represented a noncontrolling interest in our consolidated subsidiary, ZB17. On December 29, 2025, the Company terminated the ZB17 Letter Agreement, and the noncontrolling interest was extinguished as of December 31, 2025. See “—Stone Peach Settlement and Release Agreement” below. As of December 31, 2024, the noncontrolling interest balance was \$1.5 million in the consolidated balance sheet.

Additionally, beginning on May 1, 2023, Stone Peach received an annual payment of \$0.6 million initially, and increasing by 10% annually, so long as the Company maintains its license for tibulizumab, to be paid on May 1st of each year. The Company records expense for these annual payments when they become due. For each of the years ended December 31, 2025 and 2024, the Company recorded \$0.7 million in research and development in the consolidated statement of operations for the annual payments. On December 29, 2025, the Company terminated the ZB17 Letter Agreement. See “—Stone Peach Settlement and Release Agreement” below.

The Company recorded a one-time payment of \$4.5 million for additional consideration due to Stone Peach upon approval from the FDA for its Investigational New Drug (“IND”) and commencement of the clinical trial for tibulizumab in research and development in the consolidated statement of operations for the year ended December 31, 2024 and was paid in June 2025. The payment is included in accounts payable and accrued expenses in the consolidated balance sheet as of December 31, 2024.

A letter agreement, dated as of April 25, 2023, by and between BAFFX17, Ltd (“BAFFX17”) and the Company, and as amended by Amendment No. 1 on December 18, 2023 (the “BAFFX17 Letter Agreement”), provided that, as a finder’s fee for arranging the acquisition of the 2023 Lilly License, the Company agreed to make a one-time milestone payment of \$5.0 million to BAFFX17, Ltd (“BAFFX17”) upon the occurrence of either: (i) a change of control transaction, (ii) the closing of an issuance of equity or equity-linked securities by the Company of at least \$100.0 million, (iii) the consummation of a sale of assets resulting in net proceeds in excess of \$100.0 million, or (iv) the Company’s fully diluted shares outstanding exceed 52,500,000 shares (on a split adjusted basis) as measured on April 24th of each year. As the Company’s fully diluted shares outstanding exceeded 52,500,000 shares prior to December 31, 2023, the \$5.0 million fee was recorded in research and development in the consolidated statement of operations for the year ended December 31, 2023, and is included in accounts payable and accrued expenses in the consolidated balance sheets as of December 31, 2024. On June 30, 2025, the Company received an invoice on behalf of BAFFX17 requesting a \$5.0 million milestone payment pursuant to the BAFFX17 Letter Agreement. The Company did not make such payment and the BAFFX17 Letter Agreement was terminated on December 29, 2025. See “—BAFFX17 Settlement and Release Agreement” below.

In addition to the consideration paid and/or earned in 2025, 2024 and 2023, the Company is obligated to make payments to Lilly (a) for four (4) development milestone payments up to an aggregate of \$155.0 million, and sales milestone payments up to an aggregate of \$440.0 million based on respective thresholds of net sales of products developed from tibilizumab; and (b) over a multi-year period (twelve years, or upon the later expiration of regulatory exclusivity of ZB-106 in a country) for an annual earned royalty at a marginal royalty rate in the mid-single digits to low-double digits, with increasing royalty percentage rates depending on net sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of years (collectively, the “2023 Lilly Contingent Payments”). As of December 31, 2025, none of the 2023 Lilly Contingent Payments are due and accordingly will not be recorded in the Company’s financial statements until they are due. Prior to the BAFFX17 Settlement Agreement and Stone Peach Settlement Agreement described below, we were also obligated to make payments (a) to BAFFX17 for a fee equal to 3% of any milestone or royalty payments due to Lilly pursuant to the terms of either the 2022 Lilly License or the 2023 Lilly License; (b) to Stone Peach for a one-time milestone payment of \$25.0 million upon either (i) certain equity-related transactions, or (ii) the receipt of regulatory approval from the applicable regulatory authority for any new indication in the applicable jurisdiction; (c) to Stone Peach for a royalty of 2% of the aggregate net sales of any products developed from the compound. See “—BAFFX17 Settlement and Release Agreement” and “—Stone Peach Settlement and Release Agreement” below.

2022 Lilly License

On December 8, 2022, the Company’s consolidated subsidiary, Z33, entered into a license agreement with Lilly (the “2022 Lilly License”) pursuant to which Lilly granted Z33 an exclusive (even as to Lilly) license to develop, manufacture, and commercialize torudokimab. As consideration, the Company paid Lilly an upfront fee of \$7.0 million during 2022 and issued 550,000 Class A Ordinary Shares upon the closing of the Business Combination (subject to certain lock-up provisions) (the “Lilly License Fee”). During 2022, the Company recorded expense for the entire cost of the Lilly License Fee. Prior to the Business Combination, the obligation to issue shares represented contingent consideration and was classified as a liability in the consolidated balance sheet (research and development license consideration liability), which was settled upon the issuance of shares upon the closing of the Business Combination.

A letter agreement dated December 8, 2022, as amended on November 21, 2023 (the “Z33 Letter Agreement” and, together with the ZB17 Letter Agreement, the “Stone Peach Letter Agreements”) by and between Stone Peach, the Company and Z33, provided that, as a finder’s fee in connection with arranging the acquisition, Z33 issued to Stone Peach Properties, LLC (“Stone Peach”) 4,900,222 shares of Z33 Series Seed Preferred Shares, which was included in the measurement of the cost of the acquired asset. The Company has the right, but not the obligation to purchase up to 50% of the Series Seed Preferred Shares issued to Stone Peach at a price per share of \$2.448869 for a period of two years from the date of the agreement (the “Call Option”). Pursuant to the Z33 Letter Agreement, Stone Peach had the right, but not the obligation to sell up to 50% of the Series Seed Preferred Shares issued to Stone Peach to the Company for a price per share of \$2.040724 (the “Put Option”). In April 2023, the Company agreed to exercise its Call Option and the Company amended the settlement terms to settle the Call Option by issuing 2,000,000 Class A Ordinary Shares (the “Amended Terms”). In November 2023, the Amended Terms were voided and the Company’s rights and obligations under the Call Option reverted to those in the original agreement (the “Second Amended Terms”). In connection with the Second Amended Terms, the Company also provided Stone Peach with the right, but not the obligation to sell up to 50% of the Series Seed Preferred Shares issued to Stone Peach to the Company in exchange for 2,000,000 Class A Ordinary Shares (the “Put Right”). Stone Peach was permitted to exercise its Put Option and Put Right at any time between April 24, 2024 and April 24, 2028 under the new agreement. Each of the Amended Terms and the Second Amended Terms were considered an extinguishment and reissuance of the Z33 Series Seed Preferred Shares, and the Z33 Series Seed Preferred Shares were remeasured to the greater of the redemption value or the initial fair value, less noncontrolling shareholder’s interest in net loss of Z33, at each subsequent reporting period. The Z33 Series Seed Preferred Shares represented redeemable noncontrolling interest in the Company’s consolidated subsidiary, Z33.

In July 2025, the Company received a request from Stone Peach to exercise the Put Option pursuant to which Stone Peach would sell 50% of its Series Seed Preferred Shares in Z33 for \$5.0 million. Additionally, in July 2025, the Company received a further request from Stone Peach to exercise the Put Right pursuant to which Stone Peach would sell 50% of its Series Seed Preferred Shares in Z33 in exchange for 2,000,000 of the Company's Class A Ordinary Shares. Upon exercise, the obligation to settle the Put Option in cash was recorded in accounts payable and accrued expenses and additional paid-in capital. The obligation to settle the Put Right in Class A Ordinary Shares represented redeemable noncontrolling interest and was included in accounts payable and accrued expenses on the condensed consolidated balance sheet as of September 30, 2025. On December 29, 2025, the Company terminated the Z33 Letter Agreement and the redeemable noncontrolling interest and obligation to settle the Put Right were extinguished as of December 31, 2025. See "—Stone Peach Settlement and Release Agreement" below.

We paid an additional \$3.0 million to Lilly in December 2025 because a financing by Z33 with gross proceeds exceeding \$100.0 million did not occur by December 7, 2025. We are also obligated to make payments to Lilly for (a) 10 commercial, development and regulatory milestone payments up to an aggregate of \$155.0 million and sales milestone payments up to an aggregate of \$440.0 million based on respective thresholds of net sales of products developed from the licensed compound, if any; and (b) an annual earned royalty at a marginal royalty rate in the mid-single to low-double digits, with increasing royalty percentage rates based on net sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of the year, if any year (collectively, the "2022 Lilly Contingent Payments"). The Company will account for these contingent milestone payments when they become due. As of December 31, 2025, none of the 2022 Lilly Contingent Payments are due and accordingly will not be recorded in the Company's financial statements until they are due.

Pfizer Agreement

On March 22, 2022, the Company entered into a license agreement and a Series A - 1 Subscription and Shareholder's Agreement (collectively, the "Pfizer Agreement") with Pfizer. Under the Pfizer Agreement, the Company acquired a license for crebankitug in exchange for \$5.0 million in cash and 2,702,083 shares (as adjusted by the exchange ratio established in the Business Combination Agreement) of the Company's Series A - 1 convertible preferred shares, representing a 20% interest in the Company. In accordance with Accounting Standards Codification ("ASC") 805, *Business Combinations*, the Pfizer Agreement is accounted for as an asset acquisition, as substantially all of the \$7.5 million value transferred to the Company was allocated to IPR&D. On the acquisition date, the compound licensed had not yet received regulatory approval and the IPR&D did not have an alternative use.

In addition to the consideration transferred during 2022, the Company is obligated to make payments to Pfizer for (a) twelve (12) future development and regulatory milestone payments aggregating up to \$70.0 million and sales milestone payments up to an aggregate of \$525.0 million based on respective thresholds of net sales of products (developed from the licensed compound) (the "Products"), if any; and (b) an annual earned royalty at a marginal royalty rate in the mid-single digits to low double digits (less than 20%), based on thresholds of net sales of the Company's Products, if any (collectively, the "Pfizer Contingent Payments"). Royalties are payable on a country-by-country basis for a certain period of years or upon the later expiration of regulatory exclusivity of the Company's Products in a country.

The Company recorded the first \$1.0 million development milestone, included in the Pfizer Contingent Payments, as a component of research and development in the consolidated statement of operations during the year ended December 31, 2023. This amount was fully paid to Pfizer during the year ended December 31, 2024. As of December 31, 2025, no additional Pfizer Contingent Payments are due and accordingly no additional Pfizer Contingent Payments will be recorded in the Company's financial statements until they are due.

Lonza License

In July 2022, the Company entered into a license agreement (the "Lonza License") with Lonza Sales AG ("Lonza") for a worldwide non-exclusive license for Lonza's gene expression system in exchange for varying considerations depending on a number of factors such as whether the Company enters further into manufacturing agreements with Lonza or with a third party, and whether the Company enters into sublicense agreements with third parties (including up to middle six-figure annual payments per sublicense upon commencement of a sublicense, as well as royalties of up to low-single digit percentages of net sales of certain products over a commercially standard double-digit multi-year term). The Lonza License will remain in effect until terminated. The Company is free to terminate the Lonza License at any time upon 60 days' notice, with or without cause. Lonza may terminate the Lonza License for cause upon a breach by the Company or for other commercially standard reasons.

During October 2023, the Company began drug substance manufacturing with another third party. As a result of manufacturing with a third party other than Lonza, under the terms of the Lonza License the Company had a license fee of \$0.4 million due to Lonza in the fourth quarter of 2023 and annually thereafter. The Company recorded \$0.4 million for the Lonza License in research and development in the consolidated statements of operations for the years ended December 31, 2025 and 2024. During each of the years ended December 31, 2025 and 2024, \$0.4 million was paid for the Lonza License.

WuXi Biologics License

In July 2023, the Company entered into a cell line license agreement (the “Cell Line License Agreement”) with WuXi Biologics and its Affiliates (“WuXi Biologics”) for certain of WuXi Biologics’s know-how, cell line, and biological materials to manufacture, have manufactured, use, sell and import certain products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the “WuXi Biologics Licensed Products”). If the Company manufactures all of its commercial supplies of bulk drug product for WuXi Biologics Licensed Products with a manufacturer other than WuXi Biologics or its affiliates, the Company is required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer (the “Royalty”). If the Company manufactures part of its commercial supplies of the WuXi Biologics Licensed Products with WuXi Biologics or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis. The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon three months’ prior written notice and its payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by the Company that remains uncured for 30 days after written notice, or (iii) by WuXi Biologics if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure. As of December 31, 2025, there are no payments currently due under the Cell Line License Agreement.

Athamor Letter Agreement

On December 29, 2025, in connection with the termination of the Stone Peach Letter Agreements, the Company entered into a letter agreement with Athamor Capital, an exempted company incorporated under the laws of the Cayman Islands with limited liability (“Athamor”) (the “Athamor Agreement”), pursuant to which the Company issued to Athamor 8,657,402 Class A Ordinary Shares (the “Athamor Shares”). Athamor is also entitled to piggyback registration rights pursuant to which Athamor has the right to include Athamor Shares in certain registered offerings by the Company or if the Company proposes to file a registration statement under the Securities Act of 1933, as amended (the “Securities Act”), with respect to the registration of equity securities, as set forth in the Athamor Agreement.

In addition, pursuant to the terms of the Athamor Agreement, the Company agreed to pay Athamor an upfront fee in an amount equal to \$7.3 million within thirty days of execution of the Athamor Agreement and a one-time milestone payment in the amount of \$25.0 million after the occurrence of the earliest of the following events: (i) we or ZB17 undergoes a Change of Control (as defined in the Athamor Agreement), (ii) the consummation by the Company or ZB17 of a sale of assets resulting in net proceeds in excess of \$500.0 million, or (iii) First Indication Regulatory Approval (as defined in the Athamor Agreement). In addition, pursuant to the terms of the Athamor Agreement, the Company agreed to pay an amount equal to 2% of Net Sales (as defined in the Athamor Agreement) for the Product (as defined in the Athamor Agreement) to the extent such Net Sales (collectively, the “Net Sales Payments”) are the subject of a royalty payment under that certain license agreement dated as of April 26, 2023, by and between ZB17 and Lilly. The upfront fee was paid as of December 31, 2025.

The Athamor Agreement contains representations, warranties and covenants by the parties in addition to the terms described above and shall remain in effect on a country-by-country basis until the expiration of the obligation to pay the Net Sales Payments.

Stone Peach Settlement and Release Agreement

In connection with the termination of the Stone Peach Letter Agreements, on December 29, 2025, the Company and Stone Peach, Baljit Lehal and Kanwarjeet “Shawn” Tucker (the “Stone Peach Parties”) entered into a Settlement and Release Agreement (the “Stone Peach Settlement Agreement”). Pursuant to the Stone Peach Settlement Agreement, the Stone Peach Parties acknowledged that, as between the Company and any of the Stone Peach Parties, each of (i) the Stone Peach Letter Agreements, (ii) that certain Z33 Founder Issuance Agreement, dated December 8, 2022, between Z33 and Stone Peach, (iii) that certain Series Seed Preferred Stock Investment Agreement, dated December 8, 2022, between the Company and Stone Peach and (iv) that certain Confidentiality and Non-Circumvention Agreement dated December 13, 2022, between the Company and Stone Peach (such agreements, the “Stone Peach Agreements”) are terminated and therefore rendered null and void, and unenforceable in part or in whole by any of the Stone Peach Parties. In addition, pursuant to the Stone Peach Settlement Agreement, the Stone Peach Parties provided a general release of the Company and its affiliates, together with the Company’s predecessors, successors, and assigns and past, present and future officers, directors, shareholders,

members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest from and against any and all claims under the Stone Peach Agreements along with any other complaints, claims, causes of action, rights or damages which the Stone Peach Parties have or may have had against the Company or any of the Company's affiliates.

BAFFX17 Settlement and Release Agreement

On December 29, 2025, the Company and BAFFX17, Asim Mohammed and Lahmber Singh (the "BAFFX17 Parties") entered into a Settlement and Release Agreement (the "BAFFX17 Settlement Agreement"). Pursuant to the BAFFX17 Settlement Agreement, we and the BAFFX17 Parties agreed and acknowledged that a certain letter agreement by and between BAFFX17 and the Company dated April 25, 2023, as amended by letter agreement dated December 18, 2023 (the "BAFFX17 Agreements") are terminated and therefore rendered null and void and unenforceable in part or in whole by any BAFFX17 Party. In addition, pursuant to the BAFFX17 Settlement Agreement, the BAFFX17 Parties provided a general release of the Company and its affiliates, together with the Company's predecessors, successors, and assigns and past, present and future officers, directors, shareholders, members, partners, attorneys, agents, employees, managers, representatives, assigns and successors in interest from and against any and all claims under the BAFFX17 Agreements along with any other complaints, claims, causes of action, rights or damages which the BAFFX17 Parties have or may have had against the Company or any of the Company's affiliates. As the Company has been relieved of the liability by BAFFX17, the reversal of the previously recorded \$5.0 million one-time milestone payment obligation was recorded as a decrease to accounts payable and accrued expenses on the consolidated balance sheet and a decrease to research and development expenses on the consolidated statement of operations for the year-ended December 31, 2025.

6. Shareholders' Equity

On March 16, 2023, in connection with the closing of the Business Combination and effective upon the Closing Date, the Company authorized 300,000,000 Class A Ordinary Shares, par value of \$0.0001 and 1,000,000 preferred shares, par value of \$0.0001.

Shelf Registration and ATM Program

The Company filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement"), which was declared effective on September 17, 2024. Pursuant to the Shelf Registration Statement, the Company may offer and sell ordinary shares, preference shares, debt securities, warrants and or units having an aggregate public offering price of up to \$300.0 million. In connection with the filing of the Shelf Registration Statement, the Company also entered into a sales agreement (the "Sales Agreement") with Leerink Partners LLC ("Leerink Partners"), relating to the sale of the Company's Class A Ordinary Shares having an aggregate gross sales price of up to \$125.0 million, from time to time through Leerink Partners, acting as sales agent (the "ATM"). The Company incurred \$0.6 million of offering expenses in connection with establishing the ATM that reduced additional paid-in capital as of December 31, 2024.

During the year ended December 31, 2024, the Company sold 1,500,000 Class A Ordinary Shares at a price of \$3.80 per share under the ATM, for net proceeds of \$5.5 million, after placement agent commissions.

During the year ended December 31, 2025, the Company sold 3,000,000 Class A Ordinary Shares at a price of \$1.75 per share under the ATM, for net proceeds of \$5.1 million, after sales agent commissions.

As of December 31, 2025, \$114.0 million of Class A Ordinary Shares remained available for sale under the Sales Agreement.

April 2024 Private Placement

On April 18, 2024, the Company entered into subscription agreements (the "Investor Agreements") with certain institutional and other accredited investors pursuant to which the Company agreed to issue 18,732,301 Class A Ordinary Shares at a price of \$3.108 per share and pre-funded warrants to purchase up to 16,102,348 Class A Ordinary Shares (the "2024 Pre-Funded Warrants") at a price of \$3.107 per 2024 Pre-Funded Warrant for an aggregate purchase price of \$108.3 million. Each 2024 Pre-Funded Warrant has an exercise price of \$0.001 per Class A Ordinary Share and is exercisable for one Class A Ordinary Share at any time or times on or after April 22, 2024, until exercised in full.

On April 18, 2024, the Company also entered into subscription agreements (the "Insider Agreements" and together with the Investor Agreements, the "April 2024 Private Placement") with certain officers, directors and affiliates of the Company pursuant to which the Company issued 1,357,827 Class A Ordinary Shares at a price of \$3.13 per share for an aggregate purchase price of \$4.2 million.

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The April 2024 Private Placement closed on April 22, 2024, from which the Company received total gross proceeds of approximately \$112.5 million, before deducting transaction costs of \$7.2 million.

During the year ended December 31, 2025, 1,206,952 Class A Ordinary Shares were issued in connection with the exercise of 2024 Pre-Funded Warrants. As of December 31, 2025, 14,895,396 of the 2024 Pre-Funded Warrants remained outstanding.

April 2023 Private Placement

On April 26, 2023, the Company entered into its second PIPE subscription agreement (the “April 2023 Private Placement”) with certain accredited investors pursuant to which the Company issued 15,041,530 Class A Ordinary Shares, par value \$0.0001 per share and pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 3,782,000 Class A Ordinary Shares. Each Class A Ordinary Share was sold at a price of \$4.25 per Class A Ordinary Share and each Pre-Funded Warrant was sold at a price of \$4.249 per Pre-Funded Warrant for an aggregate purchase price of \$80.0 million. Each 2023 Pre-Funded Warrant has an exercise price of \$0.001 per Class A Ordinary Share and is exercisable for one Class A Ordinary Share at any time or times on or after April 26, 2023 until exercised in full.

During the year ended December 31, 2025, 1,682,000 Class A Ordinary Shares were issued in connection with the exercise of 2023 Pre-Funded Warrants. As of December 31, 2025, 2,100,000 of the 2023 Pre-Funded Warrants remained outstanding.

Warrant Exchange

On July 12, 2024, the Company commenced an exchange offer (the “Exchange Offer”) and consent solicitation (the “Consent Solicitation”) relating to its outstanding warrants that it assumed in connection with the business combination, including (i) public warrants to purchase 5,910,000 Class A Ordinary Shares (the “Public Warrants”) that were held by JATT, and (ii) Private Placement Warrants that were held by JATT shareholders (together with the Public Warrants, the “IPO warrants”). The Company offered to all holders of the IPO warrants the opportunity to receive 0.30 Class A ordinary shares in exchange for each outstanding IPO warrant tendered by the holder and exchanged pursuant to the Exchange Offer. Concurrently with the Exchange Offer, the Company also solicited consents from holders of the IPO warrants to amend that certain warrant agreement, dated as of July 16, 2021, by and between the Company and Continental Stock Transfer & Trust Company, as warrant agent (the “Warrant Agreement”) to permit the Company to require that each IPO warrant outstanding upon the closing of the Exchange Offer be exchanged for 0.27 Class A ordinary shares, which is a ratio 10% less than the exchange ratio applicable to the Exchange Offer. Pursuant to the terms of the Warrant Agreement, all except certain specified modifications or amendments required the vote or written consent of holders of at least a majority of the outstanding public warrants and a majority of the outstanding private placement warrants.

On August 12, 2024, the Company completed the Exchange Offer and Consent Solicitation and issued 2,011,017 Class A Ordinary Shares in exchange for 6,703,428 Public Warrants and 1,224,167 Class A Ordinary Shares in exchange for 4,080,580 Private Placement Warrants. In connection with its completion of the Exchange Offer, the Company entered into an amendment, dated August 12, 2024 (the “Warrant Amendment”), to the Warrant Agreement to provide the Company with the right to mandatorily exchange the Company’s remaining outstanding IPO warrants for Class A ordinary shares at an exchange ratio of 0.27 Class A ordinary shares for each IPO warrant. On August 27, 2024, in accordance with the Warrant Amendment, the Company issued 547,006 Class A Ordinary Shares in exchange for the 196,568 outstanding Public Warrants and 1,829,420 outstanding Private Placement Warrants. As a result, there are no outstanding IPO warrants as of December 31, 2024 and December 31, 2025. In connection with the Warrant Exchange, the Company paid out a de minimis amount of cash in lieu of fractional shares.

The Company incurred approximately \$1.6 million of costs directly related to the Warrant Exchange, consisting primarily of dealer manager fees and professional, legal, filing, regulatory, and other costs, which are included in general and administrative expenses for the year ended December 31, 2024.

Exchange of Class A Ordinary Shares for Pre-Funded Warrants

In April 2025, the Company entered into share surrender and warrant agreements with certain affiliated shareholders (the “2025 Shareholders”), pursuant to which (i) the 2025 Shareholders surrendered an aggregate of 6,500,000 Class A Ordinary Shares owned by the 2025 Shareholders, for no consideration, which were immediately cancelled and retired, upon surrender; and (ii) the Company issued pre-funded warrants to purchase an aggregate of 6,500,000 Class A Ordinary Shares (the “2025 Share Exchange Warrants”) (such transaction, the “2025 Share Exchange”) with an exercise price of \$0.001 per share and no expiration date. The 2025 Share Exchange Warrants are exercisable immediately and have substantially identical terms to the form of 2024 Pre-Funded Warrant (see above). As of December 31, 2025, all of the 2025 Share Exchange Warrants remained outstanding.

On August 15, 2024, the Company entered into a share surrender and warrant agreement (the “Share Exchange Agreement”) with certain affiliated shareholders (the “Shareholders”), pursuant to which (i) the Shareholders surrendered an aggregate of 4,000,000 Class A Ordinary Shares owned by the Shareholders, for no consideration, which were immediately cancelled and retired, upon surrender; and (ii) the Company issued pre - funded warrants to purchase an aggregate of 4,000,000 Ordinary Shares, with an exercise price of \$0.001 per share (the “Share Exchange Warrants”) (the “Share Exchange”). The Share Exchange Warrants are exercisable immediately and have substantially identical terms to the form of 2024 Pre-Funded Warrant (see above). A holder of the Share Exchange Warrants (together with its affiliates and other attribution parties) may not exercise any portion of a Share Exchange Warrant to the extent that immediately prior to or after giving effect to such exercise the holder would beneficially own more than 9.99% of the Company’s outstanding Class A Ordinary Shares immediately after exercise, which percentage may be increased or decreased to any other percentage specified not in excess of 9.99% at the holder’s election upon 61 days’ notice to the Company subject to the terms of the Share Exchange Warrants. As of December 31, 2025, all of the Share Exchange Warrants remained outstanding.

The following table presents the number of warrants outstanding, their exercise price, and expiration dates as of December 31, 2025 and 2024:

As of December 31, 2025		
Warrants Issued	Exercise Price	Expiration Date
27,495,396	\$ 0.001	N/A

As of December 31, 2024		
Warrants Issued	Exercise Price	Expiration Date
23,884,348	\$ 0.001	N/A

Class A Ordinary Shares Reserved for Issuance

The summary of shares reserved for issuance as of December 31, 2025 is summarized below:

	December 31, 2025
Shares issuable upon exercise of warrants to purchase Class A Ordinary Shares	27,495,396
Shares issuable upon exercise of options to purchase Class A Ordinary Shares	16,463,011
Shares available for grant under 2023 Equity Incentive Plan and ESPP	801,577
Shares issuable upon release of restricted share units	583,282
Total shares reserved for issuance	45,343,266

7. Share-Based Compensation

Equity Incentive Plan

In March 2023, JATT’s board of directors approved the Zura Bio Limited 2023 Equity Incentive Plan (the “EIP”) which allows for the grant of share options, both incentive and nonqualified share options; stock appreciation rights (“SARS”), alone or in conjunction with other awards; restricted share awards (“RSAs”) and restricted share units (“RSUs”); incentive bonuses, which may be paid in cash, shares, or a combination thereof; and other share-based awards to employees, officers, non-employee directors and other service providers. The Company has granted share options, RSUs and RSAs that generally vest over four years and expire after 10 years.

On June 1, 2023, the Board of Directors approved an increase to the number of Class A Ordinary Shares that may be issued under the EIP by an additional 5,564,315 Class A Ordinary Shares. The Class A Ordinary Shares issuable under the EIP are subject to an annual increase on January 1st of each calendar year beginning on January 1, 2024 and ending on and including January 1, 2029, equal to the

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lesser of (i) 5.0% of the aggregate number of Class A Ordinary Shares outstanding on the final day of the immediately preceding calendar year, (ii) 8,059,796 Class A Ordinary Shares or (iii) such smaller number of shares as is determined by the Board of Directors. As of January 1, 2024, the Board of Directors decided not to apply an increase to the Class A Ordinary Shares issuable under the EIP for the 2024 calendar year. The annual increase was applied for the 2025 calendar year.

Employee Stock Purchase Plan

In March 2023, JATT’s board of directors approved adopted the Zura Bio Limited 2023 Employee Stock Purchase Plan (the “ESPP”). The maximum number of Class A Ordinary Shares that may be issued under the ESPP is 4,029,898, plus an aggregate number of Class A Ordinary Shares that are automatically added under the EIP on January 1st of each calendar year, beginning on January 1, 2024 and ending on and including January 1, 2029, as discussed above. The ESPP enables eligible employees of the Company and designated affiliates to purchase Class A Ordinary Shares at a discount of 15%. As of December 31, 2025, the Company has not activated the ESPP.

As of December 31, 2025, a maximum of 16,888,988 Class A Ordinary Shares were authorized for issuance under the EIP and ESPP, collectively.

Share Options

The fair value of EIP share options is estimated on the date of grant using the Black-Scholes option pricing model. The Company lacks significant company-specific historical and implied volatility information. Therefore, it estimates its expected share volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company’s share options has been determined using the “simplified” method for awards. 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 approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following weighted-average assumptions were used to estimate the fair value of the EIP share options issued during the years ended December 31, 2025 and 2024:

	For the Year Ended December 31,	
	2025	2024
Share price	\$ 1.26	\$ 3.35
Expected volatility	102.2 %	101.1 %
Risk-free rate	4.1 %	4.2 %
Expected life	6.1 years	6.0 years
Expected dividend yield	— %	— %

The following table summarizes the Company’s share option activity for the year ended December 31, 2025:

	Number of Options	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Options outstanding as of December 31, 2024	12,217,747	\$ 2.88	8.9	\$ 8,388
Granted	5,859,490	\$ 1.26		
Exercised	(80,718)	\$ 1.35		
Forfeited	(1,533,508)	\$ 1.98		
Options outstanding as of December 31, 2025	16,463,011	\$ 2.40	8.2	\$ 48,866
Options vested and exercisable as of December 31, 2025	7,703,134	\$ 2.34	7.6	\$ 23,098

As of December 31, 2025, unrecognized compensation costs related to the unvested share options were \$13.7 million, which the Company expects to recognize over a weighted-average period of 2.8 years.

Included in options outstanding as of December 31, 2025 and 2024 in the table above are 2,055,314 and 2,165,369, respectively, options to purchase Class A Ordinary Shares issued to certain directors, executives, and employees outside of the EIP.

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In May 2025, the Company granted 408,000 share options to purchase Class A Ordinary shares with non-market performance conditions (“PSOs”), included in the table above, that will vest upon the earlier of achieving a one-year service condition or upon the Company’s next Annual General Meeting (“AGM”).

In December 2024, the Company granted 1,053,000 PSOs, included in the table above, that will vest upon the earlier of achieving a one year service condition or upon the Company’s AGM. In February 2025, the date of the AGM was set to May 21, 2025 (the “AGM Date”). Accordingly, management determined that the performance condition was met and recorded the remaining unrecognized compensation expense of \$1.5 million ratably through the AGM Date. The 2024 PSOs vested on the AGM Date.

The weighted average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was \$1.02 and \$2.71, respectively.

Market-Based Share Options

On March 20, 2023, the Company granted 306,373 options to purchase Class A Ordinary Shares (“Market-Based Share Options”) to a member of the Board of Directors. These awards will vest only to the extent that the 20-day volume weighted average trading price (“VWAP”) of the Class A Ordinary Shares is over \$30 per Class A Ordinary Share at any time prior to the fifth anniversary of the grant date. These awards have an exercise price of \$8.16 and become exercisable when vested and the market condition is satisfied. These awards expire 10 years from the date of grant. The fair value of these Market-Based Share Options were estimated using a Monte Carlo valuation method for the year ended December 31, 2023. No Market-Based Share Options were granted during the years ended December 31, 2025 and 2024.

For the years ended December 31, 2025 and 2024, the Company recorded expense related to Market-Based Share Options of \$0.3 million and \$0.7 million, respectively. There is no unrecognized compensation costs related to the Market-Based Share Options as of December 31, 2025.

Restricted Share Units

The following table summarizes the Company’s RSU activity for the year ended December 31, 2025:

	Number of Options	Weighted Average Grant Date FV
Unvested RSUs outstanding as of December 31, 2024	874,923	\$ 5.99
Vested	(291,641)	\$ 5.99
Unvested RSUs as of December 31, 2025	<u>583,282</u>	<u>\$ 5.99</u>

As of December 31, 2025, unrecognized compensation costs related to the unvested RSUs were \$2.4 million which the Company expects to recognize over a weighted-average period of 1.2 years. For each of the years ended December 31, 2025 and 2024, the Company recorded expense related to RSUs of \$2.0 million, respectively.

Restricted Share Awards

The following table summarizes the Company’s RSA activity for the year ended December 31, 2025:

	Number of Options	Weighted Average Grant Date Fair Value
Unvested RSAs outstanding as of December 31, 2024	374,995	\$ 8.16
Vested	(124,998)	\$ 8.16
Unvested RSAs outstanding as of December 31, 2025	<u>249,997</u>	<u>\$ 8.16</u>

As of December 31, 2025, unrecognized compensation costs related to the unvested RSAs were \$1.2 million which the Company expects to recognize over a weighted-average period of 1.4 years. For each of the years ended December 31, 2025 and 2024, the Company recorded expense related to RSAs of \$1.0 million, respectively.

Equity Award Modification

On December 11, 2025, Arnout Ploos van Amstel notified the Company of his decision to resign from the Board of Directors and as a member of the Nominating and Governance Committee of the Board of Directors. The Board of Directors approved accelerated vesting of the unvested portion of two outstanding options, previously granted to Mr. Ploos van Amstel, relating to an aggregate of 41,549 Class A Ordinary Shares, which became fully vested and exercisable on December 11, 2025. The Board of Directors also approved an extension of the post-termination exercise period of all of Mr. Ploos van Amstel's vested share options to be eighteen months from the resignation date. For the year ended December 31, 2025, the Company recognized \$0.1 million of share-based compensation expense related to this modification within general and administrative expense in the consolidated statement of operations.

On June 27, 2025, the Company and Verender Badial, the Company's former Chief Financial Officer, entered into an agreement in connection with Mr. Badial's resignation from the Company (the "Badial Settlement Agreement"). The Badial Settlement Agreement provides for accelerated vesting of the unvested portion of two outstanding options, previously granted to Mr. Badial, relating to an aggregate of 198,540 Class A Ordinary Shares, which became fully vested and exercisable on July 31, 2025. The Badial Settlement Agreement also provides for an extension of the post-termination exercise period of all of Mr. Badial's vested share options to the applicable expiration date of the applicable share option, as of July 31, 2025, subject to certain conditions therein. All other remaining unvested options to purchase Class A Ordinary Shares were forfeited and cancelled on July 31, 2025. For the year ended December 31, 2025, the Company recognized \$0.2 million of share-based compensation expense related to this modification within general and administrative expense in the consolidated statement of operations.

On April 24, 2025, the Company amended a member of the Board of Director's option agreements, causing his unvested options to purchase 32,099 Class A Ordinary Shares to become fully vested and exercisable as of the AGM Date. Additionally, the Board of Directors extended the post-termination exercise period of his vested options to purchase an aggregate of 165,149 Class A Ordinary Shares to the applicable expiration date of each of the respective option awards, upon completion of his service as a member of the Board of Directors. For the year ended December 31, 2025, the Company recognized \$0.1 million of share-based compensation expense related to this modification within general and administrative expense in the consolidated statement of operations.

On July 24, 2024, the Company entered into a settlement agreement with Someit Sidhu ("Sidhu Settlement Agreement") in connection with the Chief Executive Officer ("CEO") transition. Pursuant to the Sidhu Settlement Agreement, 1,700,000 share options became fully vested and immediately exercisable and the remaining 250,000 share options will vest annually over three years on the anniversary of the Sidhu Settlement Agreement. Accordingly, for the year ended December 31, 2024, the Company recorded \$5.9 million of share-based compensation expense, in general and administrative expense in the consolidated statement of operations, for the remaining grant date fair value of the 1,700,000 share options and the grant date fair value of the 250,000 share options is being recorded to compensation expense over the revised vesting period. The Company determined that the Sidhu Settlement Agreement did not result in any incremental expense.

On January 10, 2024, the Company and its Chief Medical Officer (the "CMO") entered into an agreement regarding the CMO's departure from the Company (the "Severance Agreement"). In connection with the Severance Agreement, 67,525 of the share options previously granted to the CMO became fully vested and exercisable and 40,515 of the RSUs previously granted to the CMO became fully vested. All remaining share options and RSUs not vested were forfeited and cancelled. During the year ended December 31, 2024, the Company recognized a reversal of approximately \$0.1 million of share-based compensation expense related to this modification in research and development expense in the consolidated statement of operations.

Share-based Compensation Expense

Share-based compensation expense for all equity arrangements for the year ended December 31, 2025 and 2024 was as follows:

	For the Year Ended December 31,	
	2025	2024
Research and development	\$ 2,014	\$ 2,223
General and administrative	10,318	14,575
Total share-based compensation expense	\$ 12,332	\$ 16,798

8. Income Taxes

The Company accounts for income taxes under the liability method; under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

The Company utilizes a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

For financial reporting purposes, Loss before income taxes, includes the following components:

	For the Year Ended December 31,	
	2025	2024
U.S. operations	\$ (69,615)	\$ (41,837)
Non-U.S. operations	965	(10,566)
Loss before income taxes	<u>\$ (68,650)</u>	<u>\$ (52,403)</u>

Provision For Income Taxes

During the year ended December 31, 2025, the Company adopted ASU 2023-09 to enhance the income tax disclosures regarding income taxes paid and the rate reconciliation disclosure. The provision for income taxes reconciles to the amount computed by applying the U.S. federal statutory rate of 21% to income (loss) before income taxes as follows (in thousands):

	December 31,			
	2025		2024	
Income tax at U.S. federal statutory rate	(14,416)	21.0 %	(11,005)	21.0 %
Change in valuation allowance	14,309	(20.8)%	9,575	(18.3)%
Nontaxable or nondeductible items	347	(0.5)%	210	(0.4)%
Other	(37)	0.1 %	(999)	1.9 %
Foreign Tax Effects:				
United Kingdom				
Change in valuation allowances	(1,474)	2.1 %	(1,503)	2.9 %
Other	181	(0.3)%	251	(0.5)%
Cayman Islands				
Rate differential	1,090	(1.6)%	3,471	(6.6)%
Total	<u>—</u>	<u>— %</u>	<u>—</u>	<u>— %</u>

The Company has not recorded any state taxes in 2025 and 2024. However, the jurisdictions that comprise the majority (greater than 50%) of the composite state rate are Florida and Virginia.

Deferred Tax Assets and Valuation Allowance

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets for federal and state income taxes are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforward	\$ 14,439	\$ 6,008
Intangible assets acquired	10,707	10,833
Capitalized research and development	10,621	5,838
Share-based compensation	2,472	1,985
Capitalized start-up costs	723	764
Accrued expenses and other	473	233
Total deferred income tax assets	39,435	25,661
Valuation allowance	(39,434)	(25,661)
Total deferred income tax assets, net	\$ 1	\$ —
Deferred tax liabilities		
Fixed assets	(1)	—
Total deferred income tax liabilities	\$ (1)	\$ —
Net deferred tax assets (liabilities)	\$ —	\$ —

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that the deferred tax assets will be realized. The ultimate realization of deferred tax assets is based on the assessment of available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit the utilization of existing deferred tax assets. The Company considered all positive and negative evidence when determining the amount of the net deferred tax assets that are more likely than not to be realized. This evidence includes, but is not limited to, historical earnings, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. A significant piece of objective negative evidence evaluated was the cumulative loss incurred since the Company's inception. Such objective evidence limits the ability to consider subjective evidence such as the Company's projections for future growth. Based on this assessment, the Company maintained a full valuation allowance against the Company's net deferred tax assets as of December 31, 2025, and 2024. If these estimates and assumptions change in the future, the Company may be required to reduce the Company's existing valuation allowance resulting in less income tax expense. The Company's overall valuation allowance increased by \$13.8 million during 2025 resulting from current year losses for which no tax benefit was provided.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance:

	December 31,	
	2025	2024
Beginning Balance	\$ (25,661)	\$ (17,893)
Change charged to income tax expense	(12,835)	(7,508)
Change charged to current translation adjustment	(938)	(260)
Ending balance	(39,434)	(25,661)

As of December 31, 2025, the Company had U.S. federal net operating loss ("NOL") carryforwards of approximately \$59.4 million which may be carried forward indefinitely but are only available to offset 80% of future taxable income. In addition, the Company had \$6.3 million of foreign net operating loss carryforwards generated in the United Kingdom which may be carried forward indefinitely. In addition, the Company also has approximately \$0.4 million in state net operating loss carryforwards (tax-effected) of which the Florida NOL of \$0.2 million can be carried forward 20 years, and the Virginia NOL of \$0.1 million and the South Carolina NOL of \$0.1 million may be carried forward indefinitely but is only available to offset 80% of future taxable income.

The net operating loss carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities. Net operating loss carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders, as defined under Section 382 of the Internal Revenue Code. This could limit the amount of NOLs that the Company could use on an annual basis to offset future taxable income or tax liabilities. As of December 31, 2025, the Company had not performed an analysis to determine whether any of the Company's net operating loss carryforwards are subject to limitation under Sections 382 of the Internal Revenue Code.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted into law. The OBBBA contains numerous business tax provisions, including business extenders made permanent such as restoration of 100% bonus depreciation, IRC Section 174 expensing for US-based research, and the EBITDA-based business interest expense limitation under Section 163(j). The enacted legislation did not have a material impact on the Company's effective tax rate for the year ended December 31, 2025.

The Company applies the applicable authoritative guidance which prescribes a comprehensive model for the manner in which a company should recognize, measure, present and disclose in its consolidated financial statements all material uncertain tax positions that the Company has taken or expects to take on a tax return. As of December 31, 2025, the Company had no uncertain tax positions. There are no uncertain tax positions for which it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within twelve months of December 31, 2025.

The Company files income tax returns in the United States, the United Kingdom and certain state jurisdictions. The U.S federal tax years open to examination by the Internal Revenue Service are 2022 to 2025. The Company's state and United Kingdom tax years that are open to tax examination are 2021 to 2025.

9. Commitments and Contingencies

Litigation

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

10. Redeemable Noncontrolling Interest

As a finder's fee for the 2022 Lilly License, Z33 issued the Z33 Series Seed Preferred Shares to Stone Peach pursuant to the Z33 Letter Agreement. Zura had the right, but not the obligation, to purchase up to 50% of the Z33 Series Seed Preferred Shares issued to Stone Peach at a price per share of \$2.448869 for a period of two years from the date of the agreement (the "Call Option"). Stone Peach had the right, but not the obligation to sell up to 50% of the Z33 Series Seed Preferred Shares issued to Stone Peach to Zura for a price per share of \$2.040724 (the "Put Option"). As it was not possible to specifically identify the shares that may be redeemed by exercising the Put Option, and the applicable unit of account is each share, the Company assessed that each share must be considered redeemable until the exercise or the expiration of the Put Option. Accordingly, the Z33 Series Seed Preferred Shares issued to Stone Peach represented redeemable noncontrolling interest.

In April 2023, the Company agreed to, within six months of April 24, 2023, exercise its Call Option on 50% of the Z33 Series Seed Preferred Shares previously issued to Stone Peach. The Company agreed to settle its Call Option by issuing 2,000,000 Class A Ordinary Shares. The amended settlement terms represented an extinguishment and reissuance of the Z33 Series Seed Preferred Shares. The \$10.9 million difference between the estimated fair value of the new instrument issued and the carrying value of the Z33 Series Seed Preferred Shares was recorded as a deemed dividend to the redeemable noncontrolling interest and as an adjustment to net loss to arrive at net loss attributable to Class A ordinary shareholders in the consolidated statement of operations.

In November 2023, the Company and Stone Peach amended the terms of the agreement, voiding the Company's obligation to exercise its Call Option, and instead reverting the Company's rights and obligations under the Call Option back to that of the original agreement. Stone Peach, in addition to the existing Put Option, was granted the right, but not the obligation to sell up to 50% of the Series Seed Preferred Shares issued to Stone Peach to Zura in exchange for 2,000,000 Class A Ordinary Shares (the "Put Right"). Stone Peach was able to exercise its Put Option and Put Right at any time between April 24, 2024 and April 24, 2028 under the new agreement. The amended settlement terms represented an extinguishment and reissuance of the Z33 Series Seed Preferred Shares. The \$9.2 million difference between the estimated fair value of the new instrument issued and the carrying value of the Z33 Series Seed Preferred Shares was recorded as a deemed contribution from the redeemable noncontrolling interest and as an adjustment to net loss to arrive at net loss attributable to Class A ordinary shareholders, in the consolidated statement of operations. On December 31, 2024, the redeemable

noncontrolling interest was remeasured from its redemption price to its initial carry amount, decreased for the noncontrolling interest's share of Z33's net loss, and the difference was recorded as an adjustment to net loss to arrive at net loss attributable to Class A ordinary shareholders for the year ended December 31, 2024 in the consolidated statement of operations. As of December 31, 2024, the redeemable noncontrolling interest balance was \$11.7 million.

In July 2025, Stone Peach exercised its Put Option and Put Right. Upon exercise, the obligation to settle the Put Option in cash was recorded in accounts payable and accrued expenses extinguishing 50% of the redeemable noncontrolling interest. As it was not possible to specifically identify the shares that may be redeemed upon exercising the Put Option, and the applicable unit of account is each share, the Company assessed that the remaining 50% of the Z33 Series Seed Preferred Shares must be considered redeemable until the settlement of the Put Option or Put Right. Accordingly, the 50% of the Z33 Series Seed Preferred Shares issued to Stone Peach represented redeemable noncontrolling interest and were remeasured as of September 30, 2025.

On December 29, 2025, we terminated the Z33 Letter Agreement, and the respective call and put rights relating to Z33's Series Seed Preferred Shares recorded as redeemable noncontrolling interest and the obligation to settle the Put Option were extinguished. See Note 5.

11. Defined Contribution Plans

The Company maintains a 401(k) defined contribution retirement plan (the "401(k) Plan") for all of its U.S. employees. For the 401(k) Plan, the Company makes a matching contribution up to a maximum of 6% of an employee's annual salary. For U.K. employees, the Company contributes up to 6% of an employee's annual salary to defined contribution retirement pension plans. Contributions made by the Company vest 100% upon contribution. For the year-ended December 31, 2025 and 2024, the Company recorded expense of \$0.5 million and \$0.3 million, respectively for the defined contribution plans.

12. Subsequent Events

Resignation of Chief Executive Officer

On January 21, 2026 (the "Effective Date"), the Company and Robert Lisicki, the Company's former Chief Executive Officer, entered into a separation agreement in connection with Mr. Lisicki's resignation from the Company (the "Separation Agreement"), pursuant to which Mr. Lisicki will remain a non-executive employee of the Company through March 31, 2026 and will be eligible to receive transition compensation in an amount equal to \$72,000 (on an annualized basis) (the "Transition Compensation"). Pursuant to the terms of the Separation Agreement, Mr. Lisicki is not eligible for a bonus for fiscal years 2025 or 2026, and vesting in Mr. Lisicki's stock options ceased on the Effective Date. Under the Separation Agreement, following the Effective Date, Mr. Lisicki will also receive: (i) a lump-sum severance payment in an amount equal to twelve months of his base salary, as in effect immediately prior to the Effective Date, reduced by the amount of Transition Compensation received, and (ii) the full COBRA premium to continue his insurance in effect for himself and his dependents until the earliest of (a) nine months after the Resignation Date; (b) the expiration of his eligibility for the continuation coverage under COBRA; or (c) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment.

Additionally, the Separation Agreement provides for an extension of the post-termination exercise period for Mr. Lisicki's outstanding vested stock options to the earlier of (i) March 31, 2027 or (ii) the applicable expiration date of the applicable stock option. The Separation Agreement also provides for accelerated vesting of 25% of the shares underlying the option granted to Mr. Lisicki on February 27, 2025 as of the Effective Date, which shares were originally scheduled to vest on February 27, 2026, subject to specified lock-up restrictions. All other unvested options outstanding as of the Effective Date were immediately forfeited.

Appointment of Chief Executive Officer

On the Effective Date, the Board, upon the recommendation of the nominating and governance committee of the Board, appointed Dr. Sandeep Kulkarni, a current director on the Board, as the Company's Chief Executive Officer and principal executive officer, effective as of the Effective Date. Dr. Kulkarni will also continue serving as a director on the Board. Also on the Effective Date, Ms. Davis, who was appointed as interim Chief Executive Officer, effective October 10, 2025, stepped down as interim Chief Executive Officer and interim principal executive officer and will continue with the Company in her roles as Chief Operating Officer, Chief Legal Officer and Corporate Secretary.

In connection with the appointment of Dr. Kulkarni as Chief Executive Officer, the Company entered into an offer letter with Dr. Kulkarni on the Effective Date (the "Offer Letter"). The Offer Letter provides for Dr. Kulkarni's at-will employment as the Company's Chief Executive Officer. Pursuant to the Offer Letter, Dr. Kulkarni will receive an annual base salary of \$655,000 per year. Dr. Kulkarni will also be eligible to receive a discretionary annual cash bonus with a target amount equal to 55% of his base salary and to participate in the Company's employee benefit plans and programs in accordance with the terms and conditions of the applicable plans and programs.

Pursuant to the Offer Letter, the Board also granted to Dr. Kulkarni the following equity awards, each effective as of the Effective Date with an exercise price equal to the closing price per share of the Company's Class A ordinary shares on the Effective Date. The equity awards were granted pursuant to and subject to the terms and conditions of the Company's 2023 Equity Incentive Plan:

- an option to purchase 2,934,107 Class A ordinary shares (the "New-Hire Option Award"). The New-Hire Option Award will vest over four years, with 25% of the shares vesting on the first anniversary of the Effective Date and the remainder vesting in equal quarterly installments over the following three years, subject to Dr. Kulkarni's continued service through each vesting date; and
- an option to purchase 505,881 Class A ordinary shares of the Company (the "Performance Option Award"). The Performance Option Award will vest in full on the first date upon which both of the following performance goals are achieved, subject to Dr. Kulkarni's continued service through such date: (a) the Company's completion of an equity raise above a specified amount prior to a specified date, and (b) the volume-weighted average price of a Class A ordinary share of the Company equals or exceeds a specified price over a period of 30 consecutive trading days, prior to December 31, 2030.

February 2026 Equity Offering

On February 24, 2026, the Company entered into an underwriting agreement with Leerink Partners LLC, Piper Sandler & Co. and Cantor Fitzgerald & Co., as representatives of the several underwriters listed therein, pursuant to which the Company agreed to issue and sell 21,200,000 Class A ordinary shares (the "Shares"), par value \$0.0001 per share, at a price to the public of \$6.25 per share, which included 3,000,000 additional Class A ordinary shares sold upon exercise in full by the underwriters of their option to purchase additional shares of stock in the offering, along with pre-funded warrants (the "Pre-Funded Warrants") to purchase 1,800,000 Ordinary Shares at a price to the public of \$6.249 per Pre-Funded Warrant, which represents the per share public offering price for the Shares less the \$0.001 exercise price of each Pre-Funded Warrant (the "Offering"). The net proceeds from the Offering were approximately \$135.1 million after deducting underwriting discounts and commissions and estimated offering expenses. The Offering closed on February 26, 2026.

List of Subsidiaries

JATT Merger Sub 2, a Cayman Islands exempted company

Zura Bio Limited, a limited company incorporated under the laws of England and Wales

Zura Bio Inc., a Delaware corporation

Z33 Bio Inc., a Delaware corporation

ZB17, LLC, a Delaware limited liability company

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 No. 333-272842, and Form S-3 Nos. 333-281905, 333-272628, and 333-279719 of Zura Bio Limited of our report dated March 19, 2026, relating to the consolidated financial statements, which appear in this Annual Report on Form 10-K, for the years ended December 31, 2025 and 2024.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
March 19, 2026

Certification of Principal Executive Officer

Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Sandeep Kulkarni, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zura Bio Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Sandeep Kulkarni

Sandeep Kulkarni
Chief Executive Officer
(Principal Executive Officer)

Date: March 19, 2026

Certification of Principal Financial Officer

Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Eric Hyllengren, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zura Bio Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Eric Hyllengren

Eric Hyllengren
Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: March 19, 2026

Certification of Chief Executive Officer
Pursuant to 18 U.S.C. Section 1350,
As adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Zura Bio Limited (the "Company") on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sandeep Kulkarni, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

/s/ Sandeep Kulkarni

Sandeep Kulkarni
Chief Executive Officer
(Principal Executive Officer)

Date: March 19, 2026

Certification of Chief Financial Officer
Pursuant to 18 U.S.C. Section 1350,
As adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Zura Bio Limited (the "Company") on Form 10-K for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eric Hyllengren, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Eric Hyllengren

Eric Hyllengren

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: March 19, 2026
