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, 2024

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)**	**98-1725736** **(I.R.S. Employer Identification No.)**
1489 W. Warm Springs Rd. #110 **Henderson, Nevada** **(Address of principal executive offices)**	**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 28, 2024 (the last business day of the Registrant's most recently completed second fiscal quarter) was $206,282,986.

As of March 21, 2025, the Registrant had 68,374,998 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 2025 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, 2024.

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FREQUENTLY USED TERMS

Unless otherwise stated in this annual report, the terms "we," "us," "our" refer to Zura Bio Limited, a Cayman Islands exempted company, or its affiliates, or, if prior to the Business Combination, to JATT Acquisition Corp, a Cayman Islands exempted company, or its affiliates.

In this document:

- "April 2023 Private Placement" means that certain private placement made to certain accredited investors, which closed in two tranches on May 1, 2023 and June 5, 2023.
- "April 2023 Private Placement Shares" means the Class A Ordinary Shares issued in connection with the April 2023 Private Placement.
- "Business Combination" means the mergers and other transactions contemplated by the Business Combination Agreement.
- "Business Combination Agreement" means that certain 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, Merger Sub, Merger Sub 2, Holdco and Legacy Zura, as may be amended or restated from time to time.
- "Cayman Islands Companies Act" means the Companies Act (Revised) of the Cayman Islands.
- "Closing" means the closing of the Business Combination.
- "Closing Date" means March 20, 2023.
- "Code" means the Internal Revenue Code of 1986, as amended.
- "Company Capital Restructuring" means the restructuring of Legacy Zura before the Closing pursuant to which all the Class A Ordinary Shares were contributed by their holders to Holdco in exchange for an equivalent number of shares of the equivalent class in Holdco.
- "Effective Time" means the time at which the Business Combination became effective.
- "EIP" means the 2023 Zura Bio Limited Equity Incentive Plan, as amended.
- "Ewon PIPE Subscription Agreement" means that certain subscription agreement, between JATT, on the one hand, and Ewon, on the other hand, dated as of June 16, 2022, as amended on November 25, 2022.
- "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- "Forward Purchase Agreements" or "FPA" means those certain Amended and Restated Forward Purchase Agreements, by and between Athanor Master Fund, LP and Athanor International Master Fund, LP and JATT, dated August 5, 2021 and as amended and restated on January 27, 2022 and further amended on March 8, 2023.
- "Founder shares" means Class B Ordinary Shares of JATT Acquisition Corp held by our Initial Shareholders (including their permitted transferees) and the Class A Ordinary Shares issued upon the conversion thereof. "FPA Shares" means the 3,000,000 JATT Class A Ordinary Shares purchased by the FPA Investors.
- "Fully Diluted Holdco Shares" means, without duplication, the aggregate number of Holdco Shares that (i) were issued and outstanding immediately prior to the Closing or (ii) would have been issuable upon the exercise of Holdco Options.
- "FPA Investors" means those two accredited investors that are parties to the Forward Purchase Agreements.
- "GAAP" means accounting principles generally accepted in the United States of America.

- "HSR Act" means Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.
- "Holdco" or "Zura Holdco" means Zura Bio Holdings Ltd, a Cayman Islands exempted company.
- "Holdco Options" means the options to purchase Holdco ordinary shares, which were exchanged for Zura Options upon Closing.
- "Holdco ordinary shares" or "Holdco shares" means ordinary shares of Holdco, par value $0.001 per share.
- "Holdco SSA" has the meaning given in "The Business Combination Agreement — Company Capital Restructuring."
- "Initial Shareholders" means the Sponsor and any other holders of Founder Shares (or their permitted transferees).
- "IPO" refers to JATT's 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.
- "IRS" means the United States Internal Revenue Service.
- "JATT" means JATT Acquisition Corp, a Cayman Islands exempted company.
- "JATT Class A Ordinary Share" means a Class A ordinary share, par value $0.0001 per share, of JATT.
- "JATT Class B Ordinary Share" means a Class B ordinary share, par value $0.0001 per share, of JATT.
- "JATT Units" means JATT's units sold in the IPO, each of which consisted of one JATT Class A Ordinary Share and one-half of one Public Warrant.
- "Legacy Zura" means Zura Bio Limited, a limited company incorporated under the laws of England and Wales.
- "Lilly" means Eli Lilly and Company.
- "Lilly Shares" means the 1,000,000 Class A Ordinary Shares being issued to Lilly pursuant to the Lilly-ZB17 License.
- "Lilly-Z33 License" means that certain License, Development and Commercialization Agreement, dated as of December 8, 2022, by and between Eli Lilly and Company and Z33 Bio Inc.
- "Lilly-ZB17 License Agreement" means that certain License, Development and Commercialization Agreement, dated as of April 26, 2023, by and between Eli Lilly and Company and ZB17 LLC.
- "MAA" means the Second Amended and Restated Memorandum and Articles of Association of Zura Bio Limited, adopted by special resolution dated March 16, 2023 and effective on March 20, 2023.
- "Merger Sub 2" means JATT Merger Sub 2, a Cayman Islands exempted company and wholly owned subsidiary of JATT.
- "Minimum Cash Condition" means Available Closing Date Cash of at least $65 million.
- "Nasdaq" means The Nasdaq Capital Market.
- "Ordinary Shares" means the JATT Class A Ordinary Shares and JATT Class B Ordinary Shares prior to the Business Combination, and the Class A Ordinary Shares of Zura Bio Limited after the Business Combination.
- "PFIC" means Passive Foreign Investment Company.

- "Pfizer Agreement" or "Pfizer License" means that certain License Agreement, effective as of March 22, 2022, by and between Zura and Pfizer Inc.
- "PIPE Financing" means the issuance and sale of Zura Class A Ordinary Shares pursuant to the PIPE Subscription Agreements.
- "PIPE Investors" means Ewon Comfortech Co., Ltd. and Eugene Investment & Securities Co., Ltd.
- "PIPE Shares" means the 2,009,950 JATT Class A Ordinary Shares purchased by the PIPE Investors in the PIPE Financing.
- "Pre-Combination MAA" means JATT's Amended and Restated Memorandum and Articles of Association, dated July 12, 2021.
- "Private Placement Warrants" means the 5,910,000 warrants sold in a private placement to the Sponsor, consummated upon JATT's initial public offering on July 13, 2021 and in the overallotment exercise on July 19, 2021. "public shareholders" means the holders of the JATT public shares.
- "Public shares" means the JATT Class A Ordinary Shares which were sold as part of the IPO, whether they were purchased in the IPO or in the aftermarket. "Public Warrants" means the redeemable warrants that were included in the JATT Units that entitle the holder thereof to purchase one-half of one JATT Class A Ordinary Share, with each whole warrant exercisable at a price of $11.50 per share.
- "SEC" means the U.S. Securities and Exchange Commission.
- "Second PIPE Subscription Agreement" means the form of Subscription Agreement entered into by the Company and certain accredited investors in connection with the April 2023 Private Placement.
- "Securities Act" means the Securities Act of 1933, as amended.
- "Selling Securityholders" means the persons listed in the tables in the section entitled "Selling Securityholders."
- "scFv" means single-chain viable region.
- "Sponsor" means JATT Ventures, L.P., a Cayman Islands exempted limited partnership.
- "Sponsor Forfeiture Agreement" means the forfeiture agreement between the Sponsor and JATT and Zura, dated as of June 16, 2022.
- "Transfer and Warrants Agent" means Continental Stock Transfer & Trust Company.
- "Trust Account" means the Trust Account of JATT at Continental Stock Transfer & Trust Company that holds the proceeds from JATT's IPO and a portion of the private placement of the Private Placement Warrants.
- "Trustee" means Continental Stock Transfer & Trust Company.
- "Units" or "JATT Units" means the units of JATT, each consisting of one JATT Class A Ordinary Share and one-half of one redeemable warrant, which separated upon the consummation of the Business Combination.
- "Warrant Agent" means Continental Stock Transfer & Trust Company.
- "Warrant Agreement" means that certain warrant agreement, dated July 16, 2021, between JATT and the Warrant Agent.

- "Z17" means ZB17 LLC, a Delaware limited liability company. "Z33" means Z33 Bio Inc., a corporation incorporated under the laws of the State of Delaware.
- "ZB-106 Equity Grant Agreement" means that agreement dated as of April 26, 2023, pursuant to which the Company agreed to issue and grant to Lilly 1,000,000 Shares (the "Lilly Shares") in a private placement transaction.
- "ZB Assets" means tibulizumab (ZB-106), torudokimab (ZB-880) and crebankitug (crebankitug).
- "Zura" means Zura Bio Limited, an exempted company incorporated under the laws of the Cayman Islands (formerly known as Jatt Acquisition Corp).
- "Zura Board" means the board of directors of Zura.
- "Zura Class A Ordinary Shares" or "Class A Ordinary Shares" means the Class A ordinary shares, par value $0.0001 per share, of Zura, following the effectiveness of the MAA in connection with the Closing.
- "Zura Options" means the options issued at Closing upon the exchange of Holdco Options.
- "Zura ordinary shares" means ordinary shares of Legacy Zura, par value £0.001 per share, prior to the Closing.
- "Zura Warrants" means the redeemable warrants that entitle the holder thereof to purchase one-half share of one Zura Class A Ordinary Share, following the effectiveness of the MAA in connection with the Closing.

Unless specified otherwise, amounts in this annual report are presented in United States ("U.S.") dollars.

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, 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 its development programs or future commercialization efforts;
- we may be unable to renew existing contracts or enter into new contracts;
- 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;
- 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 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 initiated, conducted or 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 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.
- 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 anticipated clinical trials of the ZB Assets may not be successful.
- We may find it difficult to enroll participants in our clinical trials. If we experience delays or difficulties in the enrollment of participants in clinical trials, our successful completion of clinical trials, our receipt of marketing approvals could be delayed or prevented.
- The results of preclinical testing 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 and 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 Hatch-Waxman Act and in foreign countries under similar legislation, our business may be materially harmed.

- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated 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. Of the large number of products in development, only a small percentage successfully complete regulatory approval processes and are commercialized.

- 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. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("ACA"). It is unclear how other healthcare reform measures of the current U.S. federal government administration or future administrations or other efforts, if any, to amend or challenge the ACA, will 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, including consultants, we may not be able to successfully implement our business strategy.

- 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 (including our 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.

- 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 Zura 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 the shares 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, multi-asset immunology company dedicated to developing novel dual-pathway antibodies for a range of autoimmune and inflammatory diseases with unmet needs. Leveraging the extensive experience of our team, we identify relevant diseases and develop our differentiated assets in those diseases. Our strategic focus is to harness dual-pathway biology to provide broader and deeper clinical benefits to patients with autoimmune and inflammatory diseases.

We are currently developing one clinical-stage product candidate in ongoing Phase 2 trials while actively evaluating development opportunities for our pipeline of clinical-stage assets, focusing on indications with unmet needs and commercial potential.

- Tibulizumab (ZB-106) is an immunoglobulin G (IgG)-single-chain variable fragment (scFv) bispecific dual-antagonist antibody engineered by the fusion of TALTZ® (ixekizumab) and tabalumab to neutralize interleukin-17A (IL-17A) and B-cell activating factor (BAFF). These cytokines play pivotal roles in various inflammatory and autoimmune disorders. By targeting IL-17A and BAFF, tibulizumab demonstrates potential in mitigating chronic inflammation while preserving the integrity of the immune system. Three Phase 1/1b clinical studies have been completed for tibulizumab, including studies involving participants with rheumatoid arthritis and Sjögren's syndrome.
    - In December 2024, we initiated TibuSURE, a global Phase 2 study evaluating tibulizumab in adults with systemic sclerosis (SSc). TibuSURE is a randomized, double-blind, placebo-controlled study designed to assess the safety, tolerability, and efficacy of tibulizumab in approximately 80 participants with early diffuse cutaneous systemic sclerosis (dcSSc). The study includes a 24-week efficacy period followed by a 28-week open-label extension (OLE). The primary endpoint is the modified Rodnan Skin Score (mRSS). Key efficacy endpoints include lung disease, assessed by quantitative high-resolution computed tomography (qHRCT) and forced vital capacity (FVC); physical function, measured by the Health Assessment Questionnaire-Disability Index (HAQ-DI); and the revised Combined Response Index in Systemic Sclerosis (rCRISS). Topline data are expected to be available in the fourth quarter of 2026.
    - In September 2024, we engaged a third-party CRO to oversee and conduct the Phase 2 clinical program evaluating tibulizumab in hidradenitis suppurativa (HS). We have an active Investigational New Drug ("IND") for HS and the Phase 2 study is expected to initiate in the second quarter of 2025.
- Crebankitug (ZB-168) is a fully human, high affinity monoclonal antibody that binds and neutralizes the interleukin-7 receptor (IL-7R) alpha chain. IL-7Rα sits at the nexus of two key immune pathways, IL-7 and thymic stromal lymphopoietin (TSLP), thus IL-7Rα has the potential to block activation through either of these pathways. As a result, we believe crebankitug could be therapeutically relevant in a broad set of indications where the IL-7 or TSLP pathways may be involved. Three Phase 1/1b clinical studies have been conducted to date. We are actively assessing the competitive landscape and evaluating potential therapeutic indications to guide our future development efforts for crebankitug.
- Torudokimab (ZB-880) is a fully human, high affinity monoclonal antibody that neutralizes interleukin-33 (IL-33), preventing ST2-dependent and ST2-independent (e.g., RAGE) inflammation. The IL-33/ST2 axis stands as a validated therapeutic target for conditions such as chronic obstructive pulmonary disease ("COPD") and asthma. Three Phase 1/2 clinical studies have been conducted to date. We are continuing to monitor external Phase 2 and Phase 3 IL-33/ST2 data releases from other companies related to asthma and COPD and are actively assessing the competitive landscape and evaluating potential therapeutic indications to guide our future development efforts for torudokimab.

Our Pipeline

Each of our product candidates has dual-pathway biology, merging two validated mechanisms in disease indications where each has demonstrated individual clinical activity. This innovative approach could signify a paradigm shift for patients suffering from severe and complex autoimmune conditions, whose needs remain unaddressed by conventional single-pathway strategies.

The table below provides an overview of our product candidates and their status in our development pipeline:

	TARGETS	ASSET	CLINICAL PLAN
Potential for paradigm shifting antibody treatment	IL-17 & BAFF	tibulizumab (ZB-106)	Ongoing Phase 2 clinical study in SSc Phase 2 initiation in HS expected in 2Q 2025
Integrating two validated mechanisms in disease indications, where each has demonstrated individual efficacy	IL-7R & TSLP	crebankitug (ZB-168)	CMC completion to prepare for future Phase 2
	IL-33 & RAGE	torudokimab (ZB-880)	CMC completion to prepare for future Phase 2

Table 1: Zura Development Pipeline

Our Strategy

Our mission is to enhance the well-being of all stakeholders within the healthcare community, encompassing patients, healthcare providers, caregivers, and other involved parties. Our vision is to develop transformative therapies for patients suffering from serious immune system disorders. To achieve this goal, we are committed to the following strategic objectives:

- Maximizing the potential of tibulizumab through successful execution of our initial clinical studies in SSc and HS.
- Progressing crebankitug and torudokimab in select inflammatory and autoimmune diseases.
- Leveraging our translational expertise and validating external clinical findings.
- Cultivating and retaining skilled, experienced leaders within our organization.
- Protecting our intellectual property portfolio. We aim to expand our global intellectual property portfolio to protect the ZB Assets and their uses.
- Exploring strategic collaborations to maximize the value of our product candidates. This may involve forming strategic alliances, licensing agreements, or collaborations with third parties with the aim of strengthening and aiding our research, development, and commercialization of the ZB Assets and/or the company more broadly.

Our Product Candidates

Overall Opportunity in Autoimmune and Inflammatory Diseases

Autoimmune diseases develop when the immune system inappropriately attacks the cells and/or tissues. While the mechanisms underlying the development of autoimmune diseases are not well understood, studies have demonstrated key roles for inflammatory cytokines, T cells, and B cells in driving disease pathogenesis.

Previous therapeutic approaches in autoimmunity focused initially on broad immunosuppression to block cytokine signaling and the subsequent activation of inflammatory cells. Additional therapeutic approaches focused on targeting key factors known to play a role in autoimmune conditions. Despite the growing armamentarium of therapies, autoimmune disease remains unresolved in millions of patients, further outlining the need for new therapies with improved efficacy and durability.

Tibulizumab (ZB-106)

Overview of Tibulizumab

Tibulizumab, a humanized bispecific dual antagonist antibody, has been engineered to bind to and neutralize both BAFF and IL-17A.

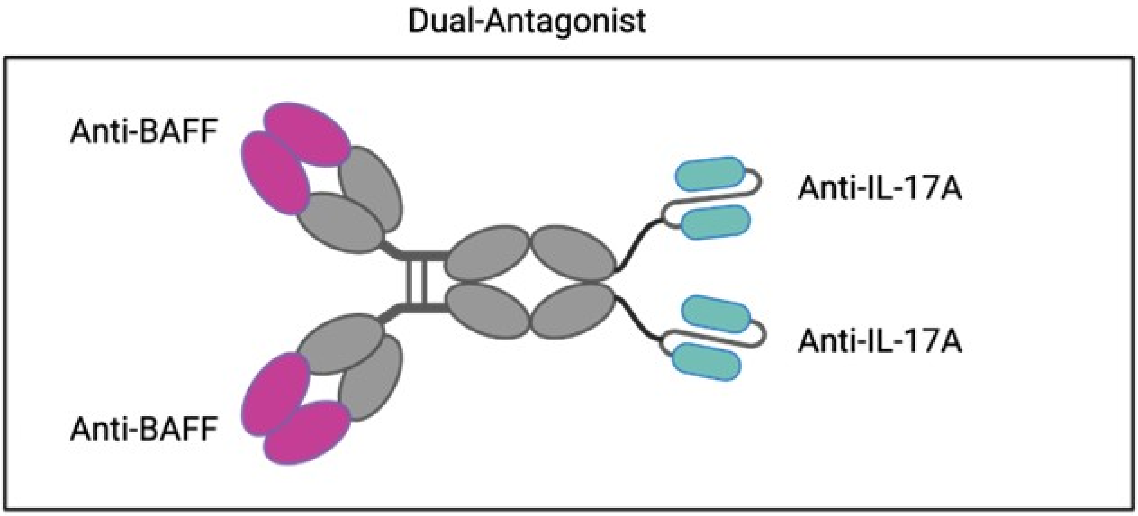

Figure 2: Tibulizumab

IL-17 is known to play a key role in the fibrotic process of various organs like lung, kidney, heart and skin. The IL-17 family of cytokines contains six structurally related isoforms with distinct abilities to form homo- or heterodimers, leading to differences in specificity and signaling potencies. These cytokines are important for the control of infections, especially by extracellular fungi. Conversely, if unrestrained, they can contribute to the pathology of autoimmune and chronic inflammatory conditions. The prototypic member of this family is IL17A, herein referred to as IL-17. T-helper cell 17 (Th17) are a subset of T cells, characterized by the production of the cytokine IL-17. In recent years, studies have established the pathogenic involvement of Th17 cells and its cytokine IL-17 in autoimmune diseases.

BAFF is involved in multiple aspects of immune system regulation but is best known for its central role in B lymphocyte development and proliferation. Initially expressed as a membrane-bound form on various cell types, BAFF is subsequently cleaved, generating a soluble protein fragment. Dysregulated BAFF expression is thought to contribute to autoimmune diseases via effects on abnormal B-lymphocyte activation, proliferation, survival, and immunoglobulin secretion. Overexpression of BAFF in mouse models induces autoimmune disease mimicking rheumatoid arthritis (RA), systemic lupus erythematosus (SLE) and primary Sjögren’s syndrome (pSS). Likewise in humans, elevated serum BAFF levels are reported in SLE, RA, pSS, IgA nephropathy, and SSc patient serum.

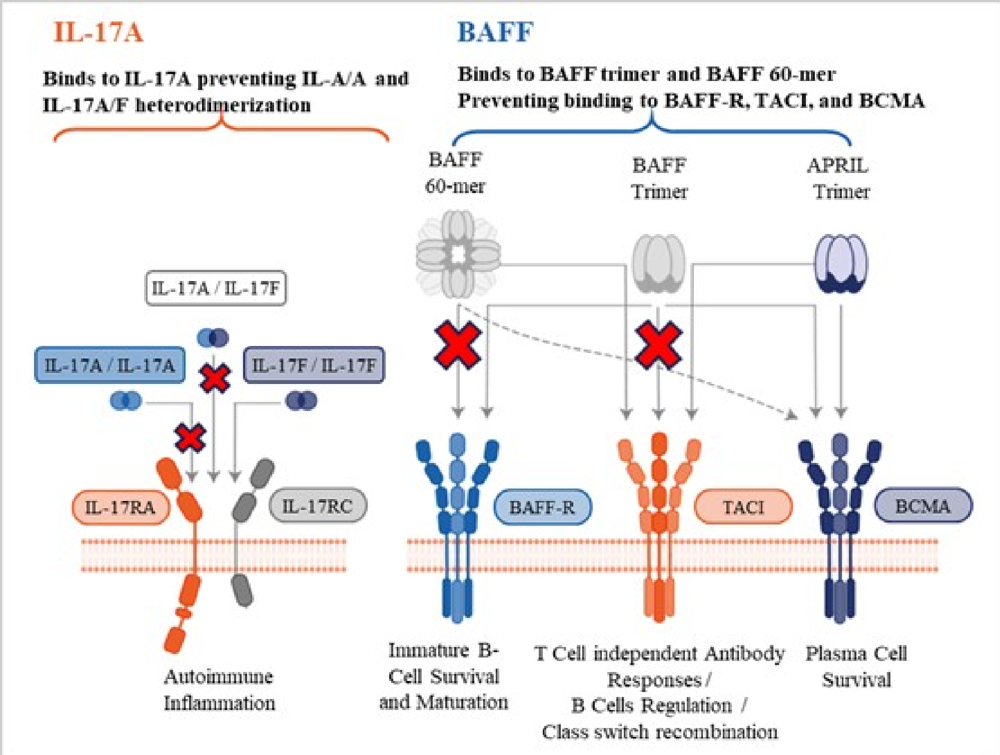

Figure 3

The BAFF cytokine is a potent B-cell activator and promotes the survival and differentiation of B cells. Similarly, IL-17A is a pro-inflammatory cytokine produced by epithelial cells and lymphocytes. In patients with SSc, levels of BAFF and IL-17A are increased, exhibiting a direct correlation with the severity of the disease. Tibulizumab has potential in immune-mediated diseases by addressing both the B- and T-cell components implicated in SSc pathology.

In December 2024, we initiated TibuSURE, a global Phase 2 study to evaluate tibulizumab in adults with SSc. TibuSURE is a double-blind, placebo-controlled study designed to assess the safety, tolerability, and efficacy of tibulizumab in approximately 80 participants with early dcSSc. Topline data are expected to be available in the fourth quarter of 2026.

In the fourth quarter of 2024, we submitted a request for Orphan Drug Designation for tibulizumab in SSc. We continue to correspond with the FDA regarding that request.

In addition to SSc, we plan to evaluate tibulizumab in participants with HS. The Phase 2 study is expected to initiate in the second quarter of 2025.

Systemic Sclerosis

Background on systemic sclerosis

SSc is an orphan autoimmune disease affecting a total of approximately 300,000 people in the United States, the European Union ("E.U.") and Japan. Statistics suggest that SSc is more common in women, with an average female to male ratio of 3:1. The onset of the disease typically occurs between the ages of 30 and 50, and the United States has the highest incidence and prevalence globally.

SSc is characterized by progressive fibrosis of the skin and visceral organs that can result in life-threatening complications. Although skin fibrosis is the distinguishing hallmark of SSc, the pathological changes in the lungs, gastrointestinal tract, kidney, and heart determine clinical outcomes. Its prevalence is low, but the burden of disease is substantial with the highest mortality (~75%

survival rate at 5 years) across all rheumatic diseases. Treatment has traditionally been a combination of immunosuppressants, particularly mycophenolate mofetil or cyclophosphamide, and additional therapeutics used to target organ-specific complications. These agents are used off-label in most countries. In the United States, two agents are approved to slow the decline of SSc-associated ILD but there are no licensed therapies that treat the totality of the disease.

SSc is traditionally classified by the extent of skin involvement, accompanying internal organ disease and the presence of overlapping systemic autoimmune disease.

Limited cutaneous SSc (lcSSc) involves the distal skin of the extremities and the face. Patients with lcSSc are less likely to have internal organ involvement, though they are at risk of pulmonary hypertension. *Diffuse cutaneous SSc (dcSSc)* affects large areas of skin on the proximal aspect of the extremities. Patients with dcSSc have rapid disease progression with extensive skin changes and early development of visceral organ complications. Organ damage can occur due to fibrosis or blood vessel abnormalities called vasculopathy. Severe complications of SSc include abrupt hypertension and renal failure, called renal crises, interstitial lung disease, cardiac failure, pulmonary hypertension, and digital ischemia.

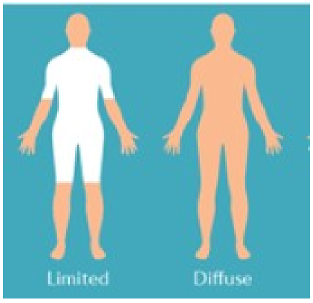

Figure 4: Systemic sclerosis subtypes

Pathogenesis of SSc and Therapeutic Targeting

Patients with SSc exhibit increased levels of BAFF which correlates with disease progression. Additional studies have demonstrated that BAFF induces collagen secretion in dermal fibroblasts, and treatment of diffuse SSc with belimumab (anti-BAFF) was associated with a decrease in B-cell signaling and fibrosis-related gene expression in patients with early diffuse SSc. Finally, belimumab treatment showed a trend towards improvement in modified Rodnan skin score (mRSS) and lung function in a small study of patients with SSc.

Expression of Th17 and IL-17 is increased in patients with SSc, which is believed to play a key role in the progression of the disease. Infiltration of IL-17-positive lymphocytes into the skin lesions has been observed. Increased IL-17 levels were associated with worse disease severity and promoted fibroblast growth and collagen production. Importantly, neutralizing IL-17 prevented collagen production and blockade of IL-17R led to significant improvements of mRSS and FVC in patients with SSc in a Phase 3 trial.

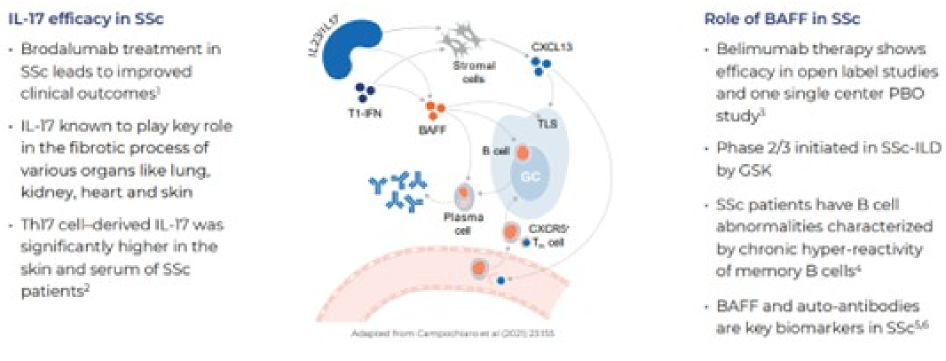

Figure 5: IL-17 and BAFF in SSc

SSc Unmet Medical Need

SSc is a progressive and debilitating disease with limited treatment options, leading to a significant demand for new and novel treatments among physicians and patients. Ten-year mortality rates in SSc range between 40% and 60%. Diagnosis for patients may take more than five years and patients can experience clinical symptoms across multiple organs with great daily impact to their lives. Patients with dcSSc have rapid disease progression with extensive skin changes and early development of visceral organ complications. An unmet need exists in dcSSc patients to slow progression of fibrosis in skin and visceral organs, slow the decline in lung disease, and decrease mortality. There are no approved therapies for dcSSc, with only off-label use of marketed products.

- Tibulizumab inhibits both IL-17 and BAFF which have separately shown clinical activity in placebo-controlled trials in SSc. Our approach with tibulizumab is to inhibit both pathways with a single agent, potentially providing clinical benefits to a broader range of patients, as well as a greater level of effect.

- Durability of treatment to antibodies may diminish over time, so dual inhibition of IL17 and BAFF could result in patients maintaining an adequate clinical benefit for a longer period of time.

- The terminal half-life of tibulizumab is 26.9 days, offering the possibility of monthly dosing. Currently, approved agents in SSc-ILD are administered as an oral drug twice per day or a subcutaneous injection on a weekly basis. Monthly dosing could offer patients more convenient dosing and result in better adherence to prescribed medication.

- Tibulizumab combines elements from two compounds, tabalumab (an anti-BAFF with demonstrated effect in clinical trials) and ixekizumab (an approved anti-IL-17 therapy with more than 140,000 patients treated in multiple indications).

Hidradenitis Suppurativa

Background on hidradenitis suppurativa

Hidradenitis suppurativa (HS), also known as acne inversa, is a chronic inflammatory, recurrent, and debilitating dermatological condition of the hair follicle with an estimated worldwide prevalence between 0.05% and 4.1%. The initial manifestations of HS typically occur in early adulthood, but delayed diagnosis is common. Patients characteristically present with painful nodules, purulent abscesses, and draining tunnels in intertriginous regions, such as axillary, groin, perineal, and inframammary areas. Together, the clinical manifestations of HS and its frequent concomitant comorbidities, including arthropathies, metabolic syndrome, increased cardiovascular disease risk, inflammatory disorders, lymphedema, squamous cell carcinoma, and depression, put the afflicted patients at risk of physical disability, suicidal ideations, stigmatization, unemployment, and profound impairment in quality of life. A multinational study reported that nearly half of patients expressed dissatisfaction with existing medical interventions, highlighting the unmet need for effective therapies that provide rapid and sustained responses.

Pathogenesis of HS and Therapeutic Targeting

Follicular occlusion is thought to be the primary event in HS, ultimately resulting in accumulation of cellular debris, cyst formation, and eventually rupture of the hair follicle. This is followed by a significant local immune response, resulting in painful inflammation, abscess formation, and in later stages, sinus tract formation and scarring.

The exact pathophysiology of HS is yet to be fully understood and continues to be investigated; however, interleukin-17 signaling is a key component of the inflammatory response and IL-17A-secreting cells can be found in lesional HS tissues. Interleukin-17A is a proinflammatory cytokine that synergizes with other proinflammatory cytokines to drive neutrophil influx into the lesions caused by inflammation, a key hallmark of HS. Ultimately, the IL-17-mediated signaling present in HS leads to an aggressive pattern of immune cell infiltration into the skin and a disruption to wound healing patterns.

Both CD20(+) B-cells and CD138(+) plasma cells are elevated within chronic HS lesions and sustain inflammation. B-cell activating factor has also been demonstrated to increase in HS lesions, with neutrophil-derived BAFF associated with increased B- and plasma cells, as well as inflammation. Reducing BAFF in HS lesions decreases B- and plasma cell gene expression, supporting the potential of this therapeutic approach.

HS Unmet Medical Need

Despite the relatively high prevalence and severe impact of HS, few treatment options are available; moreover, nearly half of patients receiving treatment report frequent disease flares. There is currently no cure for HS. Disease management is aimed at treating existing lesions to minimize pain and drainage, decrease the frequency of recurrence, and prevent disease progression. Current HS treatments include topical and oral antibiotics, biologics, surgery, laser, and light therapies. The biological therapies approved for the treatment of moderate-to-severe HS in the US are the TNFα inhibitor adalimumab, the IL-17A inhibitor secukinumab, and the IL-17A/F inhibitor bimekizumab. No therapies targeting B-cells are available for HS, but several are in development. The BTK inhibitor remibrutinib, which acts downstream of B -cell activation, has demonstrated efficacy in treating HS.

List of Completed Studies for Tibulizumab

Tibulizumab has been studied in three clinical trials to date conducted by Lilly, the clinical study reports for which show:

- *Phase 1 single ascending dose (SAD) trial.* This was a first-in-human study in healthy subjects to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and target engagement of tibulizumab in healthy volunteers and participants with rheumatoid arthritis (RA).

- *Phase 1 SAD trial in healthy Japanese and Caucasian participants.* This was a single-site, randomized, Investigator and participant blinded, placebo-controlled, SC single-dose study.

- *Phase 1b multiple ascending dose (MAD) trial in participants with Sjögren's syndrome (SS)*. This was a multicenter, parallel-group, randomized, Investigator and participant blinded, placebo-controlled, MAD study to evaluate the safety, tolerability, PK, and PD of tibulizumab administered Q4W or Q2W for 16 weeks in participants with SS.

In the phase 1 clinical trials, the pharmacokinetic profile supported subcutaneous phase 2 dosing at an interval of Q4W. The pharmacodynamic profiles confirmed impact on human biology consistent with the drug's mechanism of action, showing impact on key parameters such as CD20+ B-cells and high sensitivity-CRP in the RA patient population. The safety profiles from these studies support further development.

Phase 2 Clinical Trials, Ongoing Clinical Development for Tibulizumab

In December 2024, we initiated TibuSURE, a global Phase 2 study to evaluate tibulizumab in adults with SSc and are currently recruiting patients.

CREBANKITUG

Overview for Crebankitug

IL-7 was initially discovered by its growth and survival effects on B cells, but it has now been established that it regulates the development and homeostasis of immune cells, including B and T lymphocytes, innate lymphoid cell ("ILC") and natural killer ("NK") cells, monocytes/macrophages, dendritic cells, neutrophils and eosinophils. IL-7 is produced by stromal cells in the bone marrow, thymus and other epithelial cells in the skin, lung and intestine. IL-7-mediated signaling is important for the expression of many genes controlling apoptosis, survival, development and differentiation of immune cells. An abnormally high or upregulated IL-7/IL-7R axis can lead to high disease activity and immunopathology. Several studies have shown that IL-7R gene polymorphisms or chromosomes regions have been associated with many autoimmune diseases, including MS, pSS, RA and T1D. Crebankitug is a fully human-IgG1 monoclonal antibody targeted against the IL-7 receptor alpha (IL-7Rα), which plays a key role in the development, function and homeostasis of T cells. We believe crebankitug may be a therapeutic option for autoimmune diseases where IL-7 or TSLP signaling has been implicated.

Benefits of Crebankitug

We believe crebankitug possesses several important characteristics applicable to the treatment of autoimmune diseases:

- *Crebankitug is a high affinity antibody.* Crebankitug binds with high affinity to both purified recombinant human and cynomolgus monkey IL-7Rα proteins, with apparent Kd values of approximately 20 pM and 9 pM, respectively. Crebankitug also binds to unpurified native soluble IL-7Rα, in human serum from healthy donors, with an apparent Kd value of 21 pM, thereby confirming that crebankitug binds to a native epitope.

	UPB-101 (α-TSLPR) α-TSLPR mAb	**tezepelumab (TSLP)** TSLP mAb	**bempikibart (IL-7Rα)** IL-7Rα mAb	**ZB-168 (IL-7Rα)** IL-7Rα mAb
TSLP-Induced Signals	16.1 ng / ml / 0.1nM (CCL17)[3]	67 ng / ml / 0.44nM (CCL17)[3]	24 nM (CCL2)[4]	7.5 ng / ml / 0.05nM (CCL17)[1] 11 ng / ml / 0.07nM (CCL22)[1] 0.08 nM (CCL2)[4]
IL-7-Induced Signals	*Neg*	*Neg*	0.6 nM (IL-7 at 0.25ng/ml)[4] 2.1 nM (IL-7 at 2.5ng/ml)[4]	0.46nM (pSTAT5)[2]

Sources: [1] Zura Internal Data. [2] Herold, Kevan C., et al. JCI Insight, doi:10.1172/jci.insight.126054. [3] Numazaki, Mako, et al. Journal of Pharmacology and Experimental Therapeutics, doi:10.1124/jpet.121.000686. [4] Yamniuk, Aaron P., et al. Antibodies against Il-7r Alpha Subunit and Uses Thereof. 18 May 2021.

- *Crebankitug has already demonstrated significant clinically relevant biologic effects that may lead to a therapeutic benefit.* In phase 1b clinical testing, administration of escalating doses of crebankitug resulted in significant reductions in effector and memory T cell populations (up to 70%), while sparing regulatory T-cell populations. In addition, blocking IL-7Rα with crebankitug significantly changed the gene expression in CD4+ and CD8+ T cells with gene switches associated to T cell activation, T cell trafficking and T cell differentiation being the most relevant.

- *Crebankitug has been well tolerated to date*. In 93 subjects dosed with crebankitug to date, the majority of adverse events ("AEs") were categorized as grade 1 or grade 2. There were no deaths or permanent discontinuations due to AEs.

- *Crebankitug can be given by intravenous ("IV") infusion or subcutaneous ("SC") injection.* In clinical studies crebankitug has been dosed in healthy volunteers using an IV and SC formulation and in patients using a SC formulation. In many autoimmune diseases, patients tend to prefer treatments that they can deliver at home by a simple SC injection, however the IV route can be developed to provide a flexible alternative for physicians and patients.

List of Completed Studies for Crebankitug

Crebankitug has been studied in three clinical trials to date conducted by Pfizer:

- *Phase 1a single ascending dose ("SAD") trial.* This was a first-in-human study to evaluate ascending doses of crebankitug in adult healthy volunteers.

- *Phase 1b trial in patients with established T1D.* This was a multi-center, randomized, double-blind, sponsor-open, and placebo-controlled study to evaluate multiple ascending doses of crebankitug in adult subjects with T1D diagnosed within the preceding 2 years.

- *Phase 1b trial in patients with MS.* This was a randomized, multi-centre, double- blind, sponsor-open, placebo-controlled study to evaluate multiple ascending doses of crebankitug in adult subjects with MS. The study was terminated in April 2015 by the sponsor for reasons other than subject safety and had only 4 subjects enrolled.

Phase 1 Completed Clinical Trials for Crebankitug

In Phase 1/1b clinical studies of crebankitug, safety and pharmacokinetics were evaluated. In a Phase 1b clinical study in type 1 diabetes, crebankitug demonstrated clinically relevant biologic effects resulting in significant reductions in effector and memory T cell populations, while sparing regulatory T-cell populations (Herold KC 2019 JCI Insights). The safety profiles from these studies support further development.

Phase 2 Clinical Trials, Ongoing Clinical Development for Crebankitug

We are conducting necessary Chemistry, Manufacturing and Controls ("CMC") and regulatory activities to prepare crebankitug for Phase 2 readiness.

Torudokimab (ZB-880)

Overview of Torudokimab

Torudokimab is a human immunoglobulin (Ig) G4-variant monoclonal antibody that binds and neutralizes soluble human IL-33. IL-33 is a member of the IL-1 cytokine superfamily, and it activates several types of innate and acquired immune cells causing the production of other pro-inflammatory mediators and it is most frequently characterized as an epithelial cytokine that promotes type 2 or T-helper 2 (Th2) immune responses. We believe torudokimab may be a therapeutic option for autoimmune diseases where IL-33 signaling has been implicated.

Benefits of Torudokimab

We believe torudokimab possesses several important characteristics that may enable it to be a successful treatment for multiple autoimmune diseases:

- *Torudokimab has been well tolerated to date*. In 244 subjects dosed with torudokimab to date, the majority of adverse events ("AEs") were categorized as grade 1 or grade 2. There were no deaths to date, or any serious AEs causally related to torudokimab.

- *Torudokimab can be administered by subcutaneous ("SC") injection or intravenous ("IV") infusion.* In clinical studies, torudokimab has been dosed in healthy volunteers using an SC and IV formulation and in patients using a SC formulation.

List of Completed Studies for Torudokimab

Torudokimab has been studied in three clinical trials to date conducted by Lilly:

- *Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) trial.* This was a first-in-human study in healthy subjects to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and target engagement of torudokimab administered as single and multiple doses.

- *Phase 1 trial.* This was a safety, tolerability, and pharmacokinetic trial of different solution formulations and injection number of torudokimab using investigational injection devices in healthy subjects.

- *Phase 2 trial in patients with atopic dermatitis (AD)*. This was a multicenter, randomized, double-blind, placebo-controlled, parallel group clinical trial evaluating the efficacy and safety of torudokimab in adult subjects with moderate-to-severe AD.

Phase 1 and Phase 2 Completed Clinical Trials for Torudokimab

In Phase 1 clinical studies of torudokimab, safety and pharmacokinetics were evaluated.

The Phase 2 clinical study in adult subjects with moderate to severe atopic dermatitis was terminated early due to a lack of efficacy following the planned interim analysis. Safety findings did not contribute to the study termination, and torudokimab was well-tolerated overall with a safety profile supporting further development. The pharmacokinetics were similar to other monoclonal antibodies, with an average half-life of 20 days. There was no apparent clinical impact of anti-drug antibodies. (Laquer V 2022 Br J Dermatol)

Phase 2 Clinical Trials, Ongoing Clinical Development for Torudokimab

We plan to conduct necessary CMC and regulatory activities to prepare torudokimab for Phase 2 readiness in allergy or respiratory-related indications. Additionally, we are monitoring Phase 2 and Phase 3 external catalysts, particularly in asthma and chronic obstructive pulmonary disease.

Manufacturing

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

We have manufactured two batches of tibulizumab finished drug product through our third-party contract manufacturer in accordance with good manufacturing practice (“GMP”), which were manufactured in Italy. Manufacturing of a second batch of tibulizumab drug substance is currently underway in The Netherlands and further batches of tibulizumab are anticipated to be manufactured in Italy in the second quarter of 2025. Prior to our in-licensing of tibulizumab, it was manufactured by Lilly. Pursuant to the Lilly license, we have a license to the drug substance manufacturing process and the associated analytical testing.

Torudokimab drug substance and drug product, available for use in the next clinical studies, was moved from WuXi, People’s Republic of China (“PRC”) to the United Kingdom (“U.K.”) during 2024. 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 impact our ability to supply torudokimab to meet future demand. See our risk factors under Part I, Item 1A Risk Factors in this Annual Report.

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

We believe our outsourced manufacturing facilities are equipped to produce tibulizumab and crebankitug for both clinical development and commercial use. Before requiring torudokimab for use in clinical trials, we plan to assess the appropriate manufacturing location. We currently have no plans to establish in-house manufacturing capabilities.

Intellectual Property

Our 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); to operate without infringing valid and enforceable patents and proprietary rights of others; and to 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 (the "2023 Lilly License" and, together with the 2022 Lilly License, defined below, the "Lilly Licenses") with Lilly, for an exclusive license to develop, manufacture and commercialize a certain bispecific antibody relating to IL-17 and BAFF ("tibulizumab") in exchange for an upfront payment consisting of $5.8 million as well as 1,000,000 Class A Ordinary Shares issued at a fair value of $7.84 per Class A Ordinary Share. 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 compound licensed had not yet received regulatory approval and the in-process research and development 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.

As a finder's fee for arranging the acquisition of the 2023 Lilly License, 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 is not exercisable until after the last patient is dosed in any single next clinical trial with tibulizumab and expires one year from the date of first indication approval for tibulizumab by the FDA or the EMA. The Company 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 represents noncontrolling interest in our consolidated subsidiary, ZB17. As of each of December 31, 2024 and 2023, the noncontrolling interest balance was $1.5 million in the consolidated balance sheets.

As additional consideration, beginning on May 1, 2023, Stone Peach receives an annual payment of $0.6 million initially, and increasing by 10% annually, so long as we maintain our license for tibulizumab, to be paid on May 1st of each year. For the years ended December 31, 2024 and 2023, we recorded $0.7 million and $0.6 million, respectively, in research and development in the consolidated statement of operations for the annual payments.

We recorded a one-time payment of $4.5 million for additional consideration due to Stone Peach upon approval from the FDA for our IND and commencement of our clinical trial for tibulizumab in research and development in the consolidated statement of operations for the years ended December 31, 2024 and in accounts payable and accrued expenses as of December 31, 2024.

As a finder's fee for arranging the acquisition of the 2023 Lilly License, we 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 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 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 and 2023.

In addition to the consideration paid and/or earned in 2024 and 2023, we are also obligated to make payments (a) to Lilly 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 tibulizumab; (b) to Lilly 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 depending on net sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of years; (c) 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; (d) to Stone Peach for a one-time milestone payment of $25 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 (e) to Stone Peach for a royalty of 2% of the aggregate net sales of any products developed from the Compound (collectively, the "2023 Lilly Contingent Payments"). As of December 31, 2024, 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 (the "2022 Lilly License") with Lilly pursuant to which Lilly granted Z33 an exclusive (even as to Lilly), royalty-bearing global license to develop, manufacture, and commercialize certain intellectual property owned by Lilly relating to its IL-33 compound.

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.

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. We have 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"). Stone Peach has the right, but not the obligation, to sell up to 50% of the 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 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 may 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 represent redeemable noncontrolling interest in our consolidated subsidiary, Z33.

In addition to the consideration paid in 2022 and shares issued in 2023, we are also obligated to make payments to Lilly for (a) $3.0 million upon the completion of a financing by Z33 with gross proceeds exceeding $100.0 million; (b) 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 (c) an annual earned royalty at a marginal royalty rate between in the mid-single to low-double digits (less than 20%), 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, 2024, 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 a compound initially developed by Pfizer, 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. 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 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 nets 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, 2024, 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.

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. We recorded $0.4 million for the Lonza License in research and development in the consolidated statements of operations for the years ended December 31, 2024 and 2023. During the year ended December 31, 2024, $0.4 million was paid for the Lonza License and the remaining $0.4 million is included in accounts payable and accrued expenses in the consolidated balance sheet as of December 31, 2024.

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 cell line license agreement (the "Cell Line License Agreement") with WuXi Biologics and its Affiliates ("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 (the "WuXi Biologics Licensed Technology") 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, 2024, there are no payments currently due under the Cell Line License Agreement.

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 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;
- 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, 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 current good manufacturing practices (“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, pharmacokinetic ("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 ("DSMB"), 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 ("PREA"), 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. A 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 a 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 European Union ("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 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 ("QPPV") who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

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 PSURs, 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 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.

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

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 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, 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 (“FCPA”) 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.

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. 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. The ACA effected the following changes of importance to our potential product candidates:

- established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price" for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 70% point-of-sale discount off of the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and

- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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 pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken.

There have been judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA"), was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and by creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare reform measures of the current U.S. federal government administration will impact the ACA.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the IRA, among other things, (i) directs the Secretary of the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years covered under Medicare Part B and Medicare Part D, and subjects drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law (the "Medicare Drug Price Negotiation Program"), and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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.

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 European Economic Area (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 new product candidates in the biopharmaceutical industry is highly competitive and is subject to technological advancements resulting in numerous assets within drug classes. The immunology market field 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 cytotherapy. 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, 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. These companies also have significantly greater research and marketing capabilities than we do.

Some of these companies also have greater financial resources, and greater research, development and marketing capabilities than we do. They may also have products that are in similar product stages of development and 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.

Tibulizumab. If tibulizumab is approved, competition may arise from approved and non-approved generic immunosuppressive agents. There may be competition from newly approved or non-approved advanced-line agents in. Currently a variety of therapies are used, including but not limited to, methotrexate, mycophenalate, OFEV® (nintedanib), ACTEMRA® (tocilizumab), brodalumab, BENLYSTA® (belimumab), UPLINZA® (inebilizumab-cdon), and RITUXAN® (rituximab).

Currently, two advanced-line drugs have been FDA-approved for the treatment of SSc-ILD: OFEV® (nintedanib) and ACTEMRA® (tocilizumab). There are multiple additional product candidates in development for SSc and/or SSc-ILD.

Currently, three biologics have been FDA-approved for the treatment of moderate to severe HS in adults: HUMIRA® (adalimumab), COSENTYX® (secukinumab) and BIMZELX® (bimekizumab-bkzx). There are multiple additional product candidates in development for HS.

Crebankitug. If crebankitug is approved, competition may arise from various companies and partnerships currently engaged in clinical studies. There are multiple assets in active clinical development targeting the IL-7 or TSLP pathways, including but not limited to: lusvertikimab, bempikibart, verekitug, SAR443765, BSI-045B, and tezepelumab.

Torudokimab. If torudokimab is approved, competition may arise from various companies and partnerships actively engaged in clinical studies targeting IL-33, including but not limited to itepekimab, tozorakimab, astegolimab, MT-2990, 9MW-1911, SSGJ-621, FB-918, QX-007-N and QX-008-N. Other potential competitors include academic institutions, government agencies, and other public and private entities that conduct research, seek patent protection, and establish collaborative arrangements for research development, manufacturing, and commercialization.

Other drugs, non-pharmaceutical therapies, and alternative approaches to indications we may pursue for our drug candidates will compete with us both in the United States and elsewhere in the world.

There are also numerous other drugs and product candidates in development for indications for which we might develop our product candidates. 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.

People and Culture

Our global team, headquartered in Henderson, Nevada, comprises highly experienced members who have actively participated in drug development, commercialization, business development, capital formation, and investor engagement across various industries. For detailed information and biographies of our management team, please refer to the "*Directors, Executive Officers, and Corporate Governance*" section.

As of December 31, 2024, we had 30 full-time employees, consisting of clinical development, general and administrative, and technical operations. None of our employees is represented by a labor union, and we believe that our relationships with them are good.

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 across all aspects of their lives, 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) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a "large accelerated filer" 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 (ii) 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 million as of the prior June 30, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our ordinary shares held by non-affiliates exceeds $700 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. On July 13, 2021, JATT completed its IPO. On March 20, 2023 (the "Closing Date"), we consummated the previously-announced transactions 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 ("Merger Sub"), JATT Merger Sub 2, a Cayman Islands exempted company and wholly owned subsidiary of JATT ("Merger Sub 2") and Zura Bio Holdings Ltd, a Cayman Islands exempted company ("Holdco"), following the approval at an extraordinary general meeting of JATT's shareholders held on March 16, 2023.

Pursuant to the Business Combination Agreement, (a) before the closing of the Business Combination, Holdco was established as our new holding company and became a party to the Business Combination Agreement; and (b) on the closing date, in sequential order: (i) Merger Sub merged with and into Holdco, with Holdco continuing as the surviving company and a wholly owned subsidiary of JATT (the "Merger"); (ii) immediately following the Merger, Holdco merged with and into Merger Sub 2, with Merger Sub 2 continuing as the surviving company and a wholly owned subsidiary of JATT (the "Subsequent Merger"); and (iii) 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 the Company and 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 initiated, conducted, or completed any clinical trials, and have not taken a product through to commercialization.

We are a clinical-stage company with limited operating history. To be cash flow positive and viable, we must develop (alone or in partnership(s)) and eventually commercialize (alone or in partnership(s)) 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 (either alone or in partnership(s)) may obtain marketing approval; satisfying any post-marketing requirements; and otherwise monetizing products, for example by licensing or selling assets or the Company.

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 conducted or 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 third-party 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 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 do not expect to 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 in the Company.

We have incurred net loss of $52.4 million for the fiscal year ended December 31, 2024. 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.

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.

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, we believe our existing cash, cash equivalents and short-term marketable securities, will be sufficient to fund our operations through 2027. 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.

Our business relies on certain rights licensed from Pfizer and Lilly that can be terminated in certain circumstances. If we breach the agreements, or if we are unable to satisfy our obligations under which we license rights to the ZB Assets, we could lose the ability to develop and commercialize one or more of the ZB Assets.

Our ability to develop and commercialize the ZB Assets is dependent on the use of certain intellectual property and regulatory rights licensed to us from Pfizer (for crebankitug) and Lilly (for torudokimab and tibulizumab). The licenses set forth certain terms and conditions for maintaining the licenses. In the event that the terms and conditions are not met or we become insolvent or bankrupt, the licenses may be terminated and we will no longer be able to develop and commercialize one or more of the ZB Assets. See "*Business — License Agreements — Lilly-Z33 License" and "Business — License Agreements — Lilly-ZB17 License*"; "*Business — License Agreements — Pfizer Agreement*". Further, a wholly owned Pfizer subsidiary is the owner of certain intellectual property licensed to us from Pfizer for crebankitug. The confirmatory three-way license agreement provides Pfizer the necessary rights to give effect to the Pfizer License. See "*Business — License Agreements — Pfizer Agreement.*"

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

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. 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 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 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. 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.

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 license from Pfizer 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 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.

In 2015, crebankitug was placed on clinical hold (an order issued by the United States FDA to the sponsor of an investigational new drug application to delay or to suspend a clinical investigation) due to concern regarding IL- 7Rα expression on certain cell types within the lung and "insufficient information to address the potential risk that RN168 treatment poses to the respiratory system in humans." The clinical hold was not the result of any adverse events or safety findings emerging from the ongoing clinical studies. Pfizer's response to the clinical hold included conducting additional non-clinical experiments, a review of IL- 7Rα expression in the lung, and proposed pulmonary monitoring plans for future clinical trials, and a detailed assessment of adverse events in the clinical trials conducted to date. The clinical hold was lifted in 2016 with the following conditions/requirements: before enrolling children in studies with crebankitug, data should be submitted supporting that the potential benefits justify the potential risks. We have subsequently received FDA written responses in September 2023, to our pre-IND application, acknowledging that the completed non-clinical studies appear reasonable to support moving forward to a phase 2 study in alopecia areata.

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 the ZB Assets, even if approved. If we are not successful in commercializing the ZB Assets, or are significantly delayed in doing so, our business will be materially harmed.

We may find it difficult to enroll patients in our clinical trials. If we experience delays or difficulties in the enrollment of patients in clinical trials, our successful completion of clinical trials, our receipt of marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for the ZB Assets if we are unable to locate and enroll a sufficient number of eligible patients to participate in trials. Patient enrollment may be affected by various factors, including if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as the ZB Assets, and patients instead enroll in such clinical trials. Our inability to enroll a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased development costs or may require us to abandon one or more clinical trials altogether.

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. 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. 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 marketing approval of their product candidates.

We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. 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 institutional review board ("IRB") approval at each clinical trial site; 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 publicly 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 risk evaluation and mitigation strategy (“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, including 54.5% of patients who developed neutralizing ADA. Although these ADAs did not appear to affect drug concentrations based on visual inspection, 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, and other third parties to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We intend to rely upon CROs and others to monitor, manage, and report data for our clinical trials, which includes biostatistical analysis and programming. Our reliance on the CROs and others will not relieve us of our regulatory responsibilities.

We, our CROs, 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 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 and others does not relieve us of our regulatory responsibilities. If we, CROs 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 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 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 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 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 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 third-party manufacturers to supply us with sufficient quantities of our product candidates, to be used, if approved, for commercialization. We do not have long-term 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 due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Our reliance on third-party 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 third-party 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 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.

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 condition 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 Lilly-Z33 License Agreement imposes upon us various diligence, payment and other obligations, as described in the section entitled "*Business — License Agreements — Lilly-Z33 License.*"

If we fail to comply with any of our obligations under the Lilly-Z33 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 Lilly-Z33 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 Lilly-Z33 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.

Our business relies on certain licensing rights from Lilly for tibulizumab 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 tibulizumab from Lilly, we could lose the ability to develop and commercialize tibulizumab.

Our ability to continue to develop and commercialize tibulizumab 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 tibulizumab.

Our license agreement with Lilly for tibulizumab imposes upon us various diligence, payment and other obligations, as described in the section entitled "*Business — License Agreements — Lilly-ZB17 License*."

If we fail to comply with any of our obligations under the Lilly-ZB17 License, Lilly may have the right to terminate the license agreement, in which event we would not be able to market any tibulizumab product.

If there is any dispute with Lilly regarding our rights under the Lilly-ZB17 License, including if we are unable to meet our milestone obligations or become insolvent or bankrupt, our ability to develop and commercialize tibulizumab may be adversely affected. Any uncured, material breach by us under the Lilly-ZB17 License could result in our loss of exclusive rights to tibulizumab and may lead to a complete termination of our product development efforts for tibulizumab.

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.

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 be block a product or technology, to minimize this risk. However, relevant patents or patent applications may be overlooked or missed, which may in turn impact our ability to commercialize the ZB Assets.

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, 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, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. 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 extension 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 Drug Price Competition and Patent Term Restoration Act of 1984, also known as 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.

It is possible that we will not obtain patent term extension for a U.S. patent covering one or more of the ZB Assets even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought.

There are requirements regarding the patents that may be submitted to the FDA for listing in the Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (also known as the “Purple Book”), an online database that contains information about biological products approved by the FDA under the PHSA. We may be unable to obtain patents covering those ZB Assets that contain one or more claims that satisfy the requirements for listing in the Purple Book. Even if we submit a patent for listing in the Purple Book, the FDA may decline to list the patent, or a manufacturer of biosimilar or interchangeable drugs may challenge the listing. If the ZB Assets are approved and patents covering the ZB Assets are not listed in the Purple Book, a manufacturer of biosimilar or interchangeable drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a biosimilar or interchangeable version of either of the ZB Assets.

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.

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, which could require us to obtain rights to patents covering such technologies.

We may be subject to claims challenging the inventorship 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. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. 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. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, arbitration or litigation 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.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and is interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on or violating third-party rights. 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. 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. 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 agreement 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., E.U. 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.

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 with current good manufacturing practices ("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. 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, if approved, 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. We have adopted a Code of Conduct applicable to all employees of the Company, but it is not always possible to 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;

- the federal Health Insurance Portability and Accountability Act of 1996 ("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 Health Information Technology for Economic and Clinical Health Act ("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 Centers for Medicare & Medicaid Services ("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 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 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 building 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 Patient Protection and ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government’s comparative effectiveness research.

There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several U.S. presidential executive orders, Congressional inquiries, proposed and enacted federal and state legislation, and other regulatory actions designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reform government program reimbursement methodologies for drug products, and otherwise reduce drug prices. For example, the Inflation Reduction Act of 2022 (“IRA”), among other things, (1) extends enhanced subsidies for individuals purchasing health insurance coverage through plan year 2025 in the Patient Protection and ACA marketplaces, (2) eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program, (3) directs HHS to negotiate the price of certain single-source drugs covered under Medicare that have been on the market for at least 7 years and (4) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We cannot predict what healthcare reform initiatives may be adopted in the future, particularly in light of the recent change in administration. We expect that these and other healthcare reform measures that may be adopted may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Reform measures that result in decreased physician reimbursement may adversely affect our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. It is unclear how other healthcare reform measures of the current U.S. federal government administration or future administrations or other efforts, if any, to amend or challenge the ACA, will impact our business.

There have been judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, on August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and by creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and healthcare reform measures of the current U.S. federal government administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, previously set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

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.

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 other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive 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 E.U. General Data Protection Regulation (“GDPR”) and similar requirements in the United Kingdom (“UK GDPR”) (hereinafter the 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 E.U. 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 will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. 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 E.U., imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training, and data audit. The GDPR provides that E.U. 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.

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.

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. 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 for the Company. While we have agreements with such third parties, we do not have the same ability to influence their time commitment to the Company 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, regulatory affairs 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 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.

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.

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.

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, 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 tibulizumab, 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 may incur substantial fees if 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 the Company 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.

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. 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 of 2002, or 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 U.S. Securities and Exchange Commission’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); as well as TSLPR inhibitors (such as Upstream Bio, Inc.), IL-33 inhibitors (such as Regeneron/Sanofi and AstraZeneca), ST2 inhibitors (such as Roche/Genentech), IL-17A inhibitors (such as MoonLake, Novartis, and Acelryin), and BAFF inhibitors (such as GSK). 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.

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 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 conflict.

Our financial position and operations may be materially and adversely affected by international conflicts, including military action (e.g., in Ukraine and Israel) 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 (WuXi, PRC) 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;
- the status and cost of our marketing commitments for the ZB Assets;
- 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 Zura Class A Ordinary Shares by us or our shareholders in the future;
- trading volume of Zura 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 Zura Class A Ordinary Shares, which could cause a decline in the value of Zura Class A Ordinary Shares. Price volatility of Zura Class A Ordinary Shares might worsen if the trading volume of Zura 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 Zura, could cause it 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 Zura 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 Zura 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 Zura Board 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 Zura 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 Zura 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 Zura Class A Ordinary Shares pursuant to this agreement and as of the date of this filing, we have $114.0 million of Zura Class A Ordinary Shares remaining available for sale under the Sales Agreement. Sales of Zura 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 Zura 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 Zura Class A Ordinary Shares or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of Zura 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 Zura Class A Ordinary Shares or the availability of Zura 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 the shares of our Class A Ordinary Shares and such holders still may receive significant proceeds.

As of the date of this Annual Report, the market price of our Class A Ordinary Shares is below $10.00 per share, which was the price per unit sold in the initial public offering of our predecessor, JATT, and the per-share price of the 2,009,950 JATT Class A Ordinary Shares it sold to certain investors in connection with our Business Combination in a private placement for an aggregate amount of $20,099,500 (the "PIPE Financing"). However, certain of our shareholders who hold shares of our Class A Ordinary Shares that were (i) 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") or (ii) originally issued by JATT in a private placement in connection with certain forward purchase agreement and backstop arrangement (the "FPA Shares") between JATT and certain investors at an effective purchase price of $6.32, may nonetheless be inclined to sell such Founder Shares or FPA Shares as they were originally purchased at an effective price significantly less than $10.00 per share. The currently outstanding 3,450,000 Founder Shares were purchased at an effective price of $0.007 per share. Holders of the FPA Shares obtained (i) an aggregate of 3,000,000 Class A Ordinary Shares at a purchase price of $10.00 per share for $30,000,000; an aggregate of 1,301,633 Class A Ordinary Shares at purchase price of $10.00 per share for $13,016,330 as public share redemptions were greater than 90% at the time of the Business Combination (backstop redemption); and (iii) an additional 2,500,000 Class A Ordinary Shares at no additional cost in consideration for the holders entering into the latest amendment to the forward purchase agreements JATT and the holders entered into on August 5, 2021, as amended and restated on January 27, 2022 and as amended on March 8, 2023, resulting in an effective purchase price for the currently outstanding 6,801,633 FPA Shares of approximately $6.32 per share. Accordingly, holders of the Founder Shares and FPA Shares could sell their securities at a per-share price that is less than $10.00 and still realize a significant profit from the sale of those securities that could not be realized by our other shareholders. The public securityholders may not experience a similar rate of return on the securities they purchase due to differences in the purchase prices and the current trading price.

The Founder Shares are currently subject to restrictions on transfer under applicable lock-up agreements; however, these restrictions are due to expire on March 20, 2025, resulting in these shares becoming eligible for public sale on March 21, 2025 pursuant to the Resale Registration Statement, if then in effect, or if they qualify for an exemption from registration under the Securities Act.

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.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse opinion regarding our share, our share price and trading volume could decline.

The trading market for Zura Class A Ordinary Shares will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. Since we became public through a merger, securities analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our ordinary shares. If no or few securities or industry analysts commence coverage of us, the trading price for our shares would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover it issues an adverse opinion regarding us, our business model, our intellectual property or our share performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require it 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. It may also issue additional equity for other purposes. These securities may have the same rights as Zura Class A Ordinary Shares or, alternatively, may have dividend, liquidation or other preferences to Zura Class A Ordinary Shares. The issuance of additional equity securities will dilute the holdings of existing shareholders and may reduce the share price of Zura Class A Ordinary Shares.

Pursuant to the EIP, which became effective the day prior to the Closing, we are authorized to grant equity awards to our employees, directors and consultants. In addition, pursuant to the 2023 Employee Stock Purchase Plan (“ESPP”), which became effective the day prior to the Closing, we are authorized to sell shares to our employees. As of December 31, 2024, a total of 9,594,213 and 4,029,898 Zura 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, 2025, the shares reserved for future issuances under each of the EIP and ESPP were increased by 3,264,877 shares. As a result of such annual increases, our shareholders may experience additional dilution, which could cause the price of Zura 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 it believes 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 Zura 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 MAA and 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 Zura Board 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 Zura 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 Zura Board, the Zura Board 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 shares of the Zura 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 Zura Board 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 Zura Board 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, it may incur additional costs associated with resolving such challenge. While we currently has 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 Zura Board, and could have an adverse effect on our business, financial condition and results of operations.

We are an emerging growth company, and it 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 Zura Class A Ordinary Shares less attractive as a result, there may be a less active trading market for Zura Class A Ordinary Shares and our share price may be more volatile.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of the IPO, (b) in which it has total annual gross revenue of at least $1.235 billion, or (c) in which it is 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 million as of the last business day of the second fiscal quarter of such year, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. we have irrevocably elected not to avail itself 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 it is 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 (the "Dodd-Frank Act"), as well as rules and regulations adopted, and to be adopted, by the SEC and 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. We cannot predict or estimate the amount or timing of additional costs it 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 Zura Board, Zura Board committees 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.

In addition, we are implementing an enterprise resource planning ("ERP") system. The ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling it to manage operations and track performance more effectively. Any disruptions or difficulties in implementing or using the ERP system could adversely affect our controls and harm our business, financial condition and results of operations, including our ability to forecast and collect receivables. 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 Zura 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 PFIC for U.S. federal income tax purposes for the taxable year ended December 31, 2024, which could result in adverse U.S. federal income tax consequences to U.S. Holders.

If the Company is treated as a PFIC within the meaning of Section 1297 of 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 the Company remains 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, 2024. Additionally, the Company 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 the Company 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 the Company's PFIC status, or making such elections retroactively could have adverse tax consequences to you. The Company is not representing to you, and there can be no assurance, that the Company will or will not be treated as a PFIC for any past, current, or future taxable year. The Company has not sought and will not seek any rulings from 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 holder 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.

If a United States person is treated as owning at least 10% of our Class A Ordinary Shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. person is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our Class A Ordinary Shares, such U.S. person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). We generally will be classified as a controlled foreign corporation if such United States shareholders own (directly, indirectly or constructively) more than 50% of the value or voting power of our Class A Ordinary Shares. Additionally, under certain "downward attribution" rules, because our group includes U.S. subsidiaries, our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether we are treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," tested income for "global intangible low-taxed income" purposes and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. Subpart F income generally includes dividends, interest, rents, royalties, gains from the sale of securities and income from certain transactions with related parties, and "global intangible low-taxed income" generally consists of net tested income of the controlled foreign corporation, other than Subpart F income and certain other types of income, in excess of certain thresholds, subject to certain adjustments. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations from starting with respect to your U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist holders in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether such holder is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. holders of our Class A Ordinary Shares should consult their tax advisors regarding the potential application of these rules to their investment in our Class A Ordinary Shares.

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 the Company's cybersecurity threats and risks. Our IT department with the help of third-party service providers identifies and assesses the risks from cybersecurity threats 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 the Company's 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:

- Implementing data backup, recovery and restoration procedures designed to ensure business continuity, as well as through certain IT controls, policies and infrastructure.
- Monitoring network traffic and endpoints with Endpoint Detection and Response (EDR) tools, implementing a Security Operations Center (SOC) to detect & respond to cybersecurity threats, and using encryption for certain data and Multi-Factor Authentication (MFA).
- 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 contract research organizations and contract manufacturing organizations. We have a vendor management process to manage cybersecurity risks associate 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 the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, 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 the Company's cybersecurity risk management as part of its general oversight function. The board of directors' Audit Committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight and of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company 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 the Company's 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 the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response processes includes reporting to the Audit Committee of the board of directors for certain cybersecurity incidents. The Chief Legal Officer and Audit Committee oversees the IT department and receives periodic updates concerning the Company's significant cybersecurity threats and risk and the processes the Company has 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 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, 2024, there were approximately 27 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 Zura Board and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that the Zura Board 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, 2024, 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 formerly known as JATT Acquisition Corp, and its consolidated subsidiaries. References to JATT Acquisition Corp or "JATT" refers to us prior to the consummation of the Business Combination.

Overview

We are a clinical-stage, multi-asset immunology company dedicated to developing novel dual-pathway antibodies for a range of autoimmune and inflammatory diseases with unmet needs. Leveraging the extensive experience of our team, we identify relevant diseases and develop our differentiated assets in those diseases. Our strategic focus is to harness dual-pathway biology to provide broader and deeper clinical benefits to patients with autoimmune and inflammatory diseases.

We are currently developing one clinical-stage product candidate in ongoing Phase 2 trials while actively evaluating development opportunities for our pipeline of clinical-stage assets, focusing on indications with unmet needs and commercial potential.

We are currently developing tibulizumab (ZB-106), an immunoglobulin G (IgG)-single-chain variable fragment (scFv) bispecific dual-antagonist antibody engineered by the fusion of TALTZ® (ixekizumab) and tabalumab to neutralize interleukin-17A (IL-17A) and B-cell activating factor (BAFF). These cytokines play pivotal roles in various inflammatory and autoimmune disorders. By targeting IL-17A and BAFF, tibulizumab demonstrates potential in mitigating chronic inflammation while preserving the integrity of the immune system. Three Phase 1/1b clinical studies have been completed for tibulizumab, including studies involving participants with rheumatoid arthritis and Sjögren's syndrome.

In December 2024, we initiated TibuSURE, a global Phase 2 study evaluating tibulizumab in adults with systemic sclerosis (SSc). TibuSURE is a randomized, double-blind, placebo-controlled study designed to assess the safety, tolerability, and efficacy of tibulizumab in approximately 80 participants with early diffuse cutaneous systemic sclerosis (dcSSc). The study includes a 24-week efficacy period followed by a 28-week open-label extension (OLE). The primary endpoint is the modified Rodnan Skin Score (mRSS). Key efficacy endpoints include lung disease, assessed by quantitative high-resolution computed tomography (qHRCT) and forced vital capacity (FVC); physical function, measured by the Health Assessment Questionnaire-Disability Index (HAQ-DI); and the revised Combined Response Index in Systemic Sclerosis (rCRISS). Topline data are expected to be available in the fourth quarter of 2026.

In September 2024, we engaged a third-party Contract Research Organization ("CRO") to oversee and conduct the Phase 2 clinical program evaluating tibulizumab in hidradenitis suppurativa (HS). This study is expected to initiate in the second quarter of 2025.

Crebankitug (ZB-168) is a fully human, high affinity monoclonal antibody that binds and neutralizes the interleukin-7 receptor (IL-7R) alpha chain. IL-7Rα sits at the nexus of two key immune pathways, IL-7 and thymic stromal lymphopoietin (TSLP), thus IL-7Rα has the potential to block activation through either of these pathways. As a result, we believe crebankitug could be therapeutically relevant in a broad set of indications where the IL-7 or TSLP pathways may be involved. Three Phase 1/1b clinical studies have been conducted to date. We are actively assessing the competitive landscape and evaluating potential therapeutic indications for crebankitug.

Torudokimab (ZB-880) is a fully human, high affinity monoclonal antibody that neutralizes interleukin-33 (IL-33), preventing ST2-dependent and ST2-independent (e.g., RAGE) inflammation. The IL-33/ST2 axis stands as a validated therapeutic target for conditions such as chronic obstructive pulmonary disease ("COPD") and asthma. Three Phase 1/2 clinical studies have been conducted to date. We are continuing to monitor external Phase 2 and Phase 3 IL-33/ST2 data releases from other companies related to asthma and COPD and are actively assessing the competitive landscape and evaluating potential therapeutic indications to guide our future development efforts for torudokimab.

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 candidates are in the clinical testing stage; however, prior to the initiation of TibuSURE in December 2024, we have not conducted any clinical tests ourselves, nor have any been conducted during the period since our inception. 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 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 (as defined below) 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 (as defined below) 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 (as defined below) 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.

Since our inception, we have incurred significant operating losses. Our net loss for the years ended December 31, 2024 and 2023 were $52.4 million and $60.4 million, respectively. As of December 31, 2024, we had an accumulated deficit of $155.9 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 the previously-announced transactions 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 (“Merger Sub”), JATT Merger Sub 2, a Cayman Islands exempted company and wholly owned subsidiary of JATT (“Merger Sub 2”) and Zura Bio Holdings Ltd, a Cayman Islands exempted company (“Holdco”), following the approval at an extraordinary general meeting of JATT’s shareholders held on March 16, 2023.

Pursuant to the Business Combination Agreement, (a) before the closing of the Business Combination, Holdco was established as our new holding company and became a party to the Business Combination Agreement; and (b) on the closing date, in sequential order: (i) Merger Sub merged with and into Holdco, with Holdco continuing as the surviving company and a wholly owned subsidiary of JATT (the “Merger”); (ii) immediately following the Merger, Holdco merged with and into Merger Sub 2, with Merger Sub 2 continuing as the surviving company and a wholly owned subsidiary of JATT (the “Subsequent Merger”); and (iii) JATT, as the registrant changed its name to “Zura Bio Limited”.

Subject to, and in accordance with, the terms and conditions of the Business Combination Agreement, at the Closing, (i) each JATT unit was (to the extent not previously separated) automatically separated and the holder thereof was deemed to hold one JATT Class A Ordinary Share and one-half of a JATT warrant; (ii) in consideration for the Merger, JATT issued to holders of Holdco’s issued and outstanding shares immediately prior to the Effective Time (as defined in the Business Combination Agreement) an aggregate of 14,558,067 JATT Class A Ordinary Shares (including 499,993 JATT Class A Ordinary Shares underlying restricted share units granted to Amit Munshi, our Non-Executive Chairman) plus 1,941,933 options to acquire JATT Class A Ordinary Shares for which outstanding options to acquire Holdco Class A Ordinary Shares were exchanged on Closing; and (iii) pursuant to the terms and conditions of JATT’s amended and restated memorandum and articles of association, all then-outstanding Class B Ordinary Shares, par value $0.0001 per share, were automatically converted into JATT Class A Ordinary Shares on a one-for-one basis.

On the Closing Date, Ewon Comfortech Co., Ltd. (“Ewon”), an institutional accredited investor which is an indirect investor in us through its equity interest in Hana Immunotherapeutics LLC (“Hana”), purchased from JATT 2,000,000 JATT Class A Ordinary Shares and Eugene Investment & Securities Co., Ltd (“Eugene”), an unaffiliated institutional credited investor, purchased from JATT 9,950 JATT Class A Ordinary Shares (Ewon, together with Eugene, the “PIPE Investors”), for an aggregate of 2,009,950 JATT Class A Ordinary Shares (the “PIPE Shares”) at a price of $10.00 per share, for an aggregate purchase price of $20,099,500 (the “PIPE Financing”), pursuant to the subscription agreement entered into by JATT and the Ewon as of June 16, 2022, as amended on November 25, 2022 (the “Ewon PIPE Subscription Agreement”) and the subscription agreement entered into by JATT and Eugene as of March 13, 2023 (the “Eugene PIPE Subscription Agreement” and, together with the Ewon PIPE Subscription Agreement, the “PIPE Subscription Agreements”).

At the Closing of the Business Combination, Athanor Master Fund, LP and Athanor International Master Fund, LP (collectively, the “FPA Investors”), each of which is an unaffiliated institutional investor, purchased (i) an aggregate of 3,000,000 JATT Class A Ordinary Shares at $10 per share for $30,000,000; (ii) an aggregate of 1,301,633 JATT Class A Ordinary Shares at $10 per share for $13,016,330 (the “Redemption Backstop”) as public share redemptions were greater than 90% at the time of the Business Combination (the “Excess Redemptions”); and (iii) an additional 2,500,000 JATT Class A Ordinary Shares in consideration for the FPA Investors entering into the latest amendment, but for no additional monetary consideration, to the forward purchase agreements JATT and the FPA Investors entered into on August 5, 2021, as amended and restated on January 27, 2022 and as amended on March 8, 2023 (the “Forward Purchase Agreement”).

The Business Combination, together with the PIPE financing, the Forward Purchase Agreement, and the Redemption Backstop, generated approximately $56.7 million in proceeds. On March 21, 2023, our Class A Ordinary Shares and public warrants began trading on the Nasdaq under the symbols “ZURA” and “ZURAW,” respectively. On August 27, 2024, the Public Warrants (as defined below) were no longer listed on the Nasdaq in connection with the completion of the Warrant Exchange (as defined below).

Shelf Registration and ATM Program

We have 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. In the first quarter of 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.

Warrant Exchange

On July 12, 2024, we commenced an exchange offer (the "Exchange Offer") and consent solicitation (the "Consent Solicitation") relating to our outstanding warrants that we 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 to purchase 6,899,996 Class A Ordinary Shares (the "Private Placement Warrants") that were held by JATT shareholders (together with the Public Warrants, the "IPO warrants"). We 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, we also solicited consents from holders of the IPO warrants to amend that certain warrant agreement, dated as of July 16, 2021, by and between us and Continental Stock Transfer & Trust Company ("CST"), as warrant agent (the "Warrant Agreement") to permit the us 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 require 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, we completed the Exchange Offer and Consent Solicitation and issued 3,235,184 Class A ordinary shares in exchange for 10,784,008 IPO warrants and entered into an amendment to the Warrant Agreement (the "Warrant Amendment"). Pursuant to the Warrant Amendment, we had the right to mandatorily exchange our 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, we issued 547,006 Class A Ordinary Shares in exchange for the remaining 196,568 outstanding Public Warrants and 1,829,420 outstanding Private Placement Warrants. As a result, there were no outstanding IPO warrants as of December 31, 2024.

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 (the "Investors"), whereby 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 ("Insiders" and together with the Investors, the "2024 Subscribers"), whereby 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.

April 2023 Private Placement

On April 26, 2023, we entered into its second PIPE subscription agreement (the "April 2023 Private Placement") with certain accredited investors (the "Subscribers"), whereby 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. 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.

Concurrently with the April 2023 Private Placement, we 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. We 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. We and Stone Peach subsequently renegotiated the settlement terms as discussed in the "*—2022 Lilly License"* section below.

2023 Lilly License

On April 26, 2023, our consolidated subsidiary ZB17 LLC ("ZB17") entered into a license agreement (the "2023 Lilly License" and, together with the 2022 Lilly License (as defined below), the "Lilly Licenses") with Lilly, for an exclusive license to develop, manufacture and commercialize a certain bispecific antibody relating to IL-17 and BAFF ("tibulizumab") in exchange for an upfront payment consisting of $5.8 million as well as 1,000,000 Class A Ordinary Shares issued at a fair value of $7.84 per Class A Ordinary Share. 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 compound licensed had not yet received regulatory approval and the in-process research and development 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.

As a finder's fee for arranging the acquisition of the 2023 Lilly License, 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 is not exercisable until after the last patient is dosed in any single next clinical trial with tibulizumab and expires 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 represents noncontrolling interest in our consolidated subsidiary, ZB17. As of December 31, 2024 and 2023, the noncontrolling interest balance was $1.5 million in the consolidated balance sheets.

As additional consideration, beginning on May 1, 2023, Stone Peach receives an annual payment of $0.6 million initially, and increasing by 10% annually, so long as we maintain our license for tibulizumab, to be paid on May 1st of each year. For the years ended December 31, 2024 and 2023, we recorded $0.7 million and $0.6 million, respectively, in research and development in the consolidated statement of operations for the annual payments.

We recorded a one-time payment of $4.5 million for additional consideration due to Stone Peach upon approval from the FDA for our Investigational New Drug ("IND") and commencement of our clinical trial for tibulizumab in research and development in the consolidated statement of operations for the years ended December 31, 2024 and in accounts payable and accrued expenses as of December 31, 2024.

As a finder's fee for arranging the acquisition of the 2023 Lilly License, we 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 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 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 and 2023.

In addition to the consideration paid and/or earned in 2024 and 2023, we are also obligated to make payments (a) to Lilly 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 tibulizumab; (b) to Lilly 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 depending on net sales in the respective calendar year, based on a percentage of sales within varying thresholds for a certain period of years; (c) 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; (d) to Stone Peach for a one-time milestone payment of $25 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 (e) to Stone Peach for a royalty of 2% of the aggregate net sales of any products developed from the Compound (collectively, the "2023 Lilly Contingent Payments"). As of December 31, 2024, 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 (the "2022 Lilly License") with Lilly pursuant to which Lilly granted Z33 an exclusive (even as to Lilly), royalty-bearing global license to develop, manufacture, and commercialize certain intellectual property owned by Lilly relating to its IL-33 compound.

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.

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. We have 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"). Stone Peach has the right, but not the obligation to sell up to 50% of the 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 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 may 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 represent redeemable noncontrolling interest in our consolidated subsidiary, Z33.

In addition to the consideration paid in 2022 and shares issued in 2023, we are also obligated to make payments to Lilly for (a) $3.0 million upon the completion of a financing by Z33 with gross proceeds exceeding $100.0 million; (b) 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 (c) an annual earned royalty at a marginal royalty rate between in the mid-single to low-double digits (less than 20%), 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, 2024, 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 a compound initially developed by Pfizer, 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. 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 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 nets 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, 2024, 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.

Impact of Global Economic Trends

Macroeconomic conditions, including uncertainties associated with the changes to and by the U.S. federal government administration, the Israel-Hamas war, the ongoing conflict between Ukraine and Russia, international tariffs, 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. 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 supporting the processes and manufacturing in development, including consulting fees for clinical and manufacturing advisory services, 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 the related goods are delivered or the services are performed.

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 United States Generally Accepted Accounting Principles ("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:

- employee-related expenses, including salaries, bonuses, benefits, share-based compensation and other related costs for those employees involved in research and development efforts;
- external research and development expenses incurred under agreements with CROs, investigative sites and consultants to conduct our studies;
- costs related to manufacturing material for preclinical studies and clinical trials, including fees paid to contract manufacturing organizations;
- 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.

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 trials. 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, including 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, including share-based compensation.

We anticipate that our general and administrative 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, 2024 and 2023

The following table summarize our results of operations for the years ended December 31, 2024 and 2023 (in thousands):

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023	$ Change	% Change
Operating expenses:				
Research and development	$ 24,401	$ 43,999	$ (19,598)	(45)%
General and administrative	30,788	18,639	12,149	65 %
Total operating expenses	55,189	62,638	(7,449)	(12)%
Loss from operations	(55,189)	(62,638)	7,449	(12)%
Other (income)/expense, net:				
Interest income	(7,998)	(2,186)	(5,812)	266 %
Change in fair value of private placement warrants	5,240	(724)	5,964	* %
Change in fair value of note payable	—	2,244	(2,244)	(100)%
Dividend income	—	(1,392)	1,392	(100)%
Other income, net	(28)	(17)	(11)	65 %
Total other income, net	(2,786)	(2,075)	(711)	34 %
Loss before income taxes	(52,403)	(60,563)	8,160	(13)%
Income tax benefit	—	—	—	— %
Net loss before redeemable noncontrolling interest	(52,403)	(60,563)	8,160	(13)%
Net loss attributable to redeemable noncontrolling interest	—	203	(203)	(100)%
Net loss	(52,403)	(60,360)	7,957	(13)%
Adjustment of redeemable noncontrolling interest from redemption value to carrying value	7,017	—	7,017	100 %
Accretion of redeemable noncontrolling interest to redemption value	—	(7,220)	7,220	(100)%
Deemed contribution from redeemable noncontrolling interest	—	9,212	(9,212)	100 %
Deemed dividend to redeemable noncontrolling interest	—	(10,875)	10,875	(100)%
Net loss attributable to Class A Ordinary Shareholders of Zura	$ (45,386)	$ (69,243)	$ 23,857	(34)%

*Percentage change not meaningful

Operating Expenses

Research and Development Expenses

Research and development expenses decreased by $19.6 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. This was primarily due to $27.2 million related to the acquisition of an IPR&D license from Lilly during the year ended December 31, 2023, and decreases of $1.9 million related to the change in fair value of the research and development license consideration liability and $0.8 million related to share-based compensation, primarily due to award forfeitures, for the year ended December 31, 2024 as compared to the year ended December 31, 2023. This decrease was partially offset by a $4.5 million milestone payment related to the 2023 Lilly License incurred during the year ended December 31, 2024, and increases of $2.9 million in expenses related to personnel compensation for research and development functions excluding share-based compensation and $2.0 million of costs incurred for consulting services for our product candidates for the year ended December 31, 2024 as compared to the year ended December 31, 2023.

General and Administrative Expenses

General and administrative expenses increased by $12.1 million for the year ended December 31, 2024 as compared to the year ended December 31, 2023. The increase was primarily due to a $5.9 million non-cash share-based compensation expense charge for the modification of awards for the former CEO, an increase of $2.9 million in professional fees for legal and accounting costs, including $1.6 million related to the Warrant Exchange and $1.3 million related to our ongoing operations as a public company and an increase of $2.4 million in expenses related to compensation for personnel in executive and administrative functions including share-based compensation.

Other Expense (Income)

Interest income

Interest income increased by $5.8 million for the year ended December 31, 2024 as compared to the year ended December 31, 2023. This is primarily due to an increase in our cash and cash equivalents balance during year ended December 31, 2024 as compared to the year ended December 31, 2023.

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 compared to a revaluation gain of $0.7 million for the year ended December 31, 2023. 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.

Change in fair value of note payable

Revaluation loss on the note payable was $2.2 million for the year ended December 31, 2023, as the note was remeasured to its settlement value and settled at the closing of the Business Combination.

Dividend income

Dividend income decreased by $1.4 million for the year ended December 31, 2024 as compared to the year ended December 31, 2023. We held no dividend-generating cash equivalents during the year ended December 31, 2024.

Other income, net

Other income, net remained relatively consistent for the year ended December 31, 2024 and compared to the year ended December 31, 2023.

Net loss attributable to redeemable noncontrolling interest

Net loss attributable to redeemable noncontrolling interest was $0.2 million for the year ended December 31, 2023, representing the noncontrolling shareholder's interest in the net loss of our consolidated subsidiary, Z33. Z33 had an immaterial amount of net loss for the year ended December 31, 2024.

Adjustment of Redeemable Noncontrolling Interest from Redemption Value to Carrying 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. 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 March 31, 2024. As of December 31, 2024, the redemption value was again below the initial fair value, less noncontrolling shareholder's interest in net loss of Z33, resulting in no additional adjustment of redeemable noncontrolling interest and no an accretion of the redeemable noncontrolling interest when remeasuring the Z33 Series Seed Preferred Shares to its redemption value (see below).

Accretion of redeemable noncontrolling interest to redemption value

Accretion of redeemable noncontrolling interest to redemption value was $7.2 million for the year ended December 31, 2023 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. 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.

Deemed Contribution from Redeemable Noncontrolling Interest

Deemed contribution from the redeemable noncontrolling interest was $9.2 million for the year ended December 31, 2023, due to the modification of the terms of the Z33 Series Seed Preferred Shares issued to Stone Peach in November 2023 (see *"—2022 Lilly License"* above). There were no deemed contributions from the redeemable noncontrolling interest during the year ended December 31, 2024

Deemed Dividend to Redeemable Noncontrolling Interest

Deemed dividend to the redeemable noncontrolling interest was $10.9 million for the year ended December 31, 2023, due to the modification of the terms of the Z33 Series Seed Preferred Shares issued to Stone Peach in April 2023 (see *"—2022 Lilly License"* above). There were no deemed dividends to the redeemable noncontrolling interest during the year ended December 31, 2024.

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, 2024, we had cash and cash equivalents of $176.5 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. 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 sale of approved drug products, and we do not expect to generate revenue 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 our product candidates, and we do not expect to generate revenue 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. We intend to fund these milestone payments using a portion of the proceeds from the Business Combination, the April 2023 Private Placement, the April 2024 Private Placement and sales under the ATM. 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 (less than 20%) percentage range based upon thresholds of net sales of products.

We intend to devote most of the net proceeds from the Business Combination, the April 2023 Private Placement, the April 2024 Private Placement and sales under the ATM to the preclinical and clinical development of our product candidates, our public company compliance costs and certain milestone payments. Based on our current business plans, we believe that our existing cash, cash equivalents and investments should be sufficient to fund our operating expenses and capital requirements through 2027. 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 may be 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 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 in our product candidates pipeline;
- 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 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, 2024	2023
Net cash used in operating activities	$ (28,076)	$ (15,054)
Net cash used in investing activities	(5,075)	(8,000)
Net cash provided by financing activities	109,843	121,293
Net increase in cash and cash equivalents	$ 76,692	$ 98,239

Cash flows from operating activities

Net cash used in operating activities increased by $13.0 million to $28.1 million for the year ended December 31, 2024 from $15.1 million for the year ended December 31, 2023. The increase is primarily due to an increase in our cash net loss of $10.2 million, comprised of our $8.2 million decrease in net loss before redeemable noncontrolling interest, as adjusted for the decrease in non-cash charges of $18.4 million for the year ended December 31, 2024. The decrease of $18.4 in non-cash charges was due to an expense incurred in connection with the 2023 Lilly License of $27.4 million, a change in fair value of our promissory note of $2.2 million, a share-based payment expense of $2.2 million related to the anti-dilution shares issued to Pfizer, and a change in fair value of our research and development license consideration liability of $1.9 million for the year ended December 31, 2023, partially offset by an increase in share-based compensation expense of $9.3 million, of which $5.9 million related to the modification of our former CEOs awards, and an increase in the change in fair value on the Private Placement Warrants of $6.0 million for the year ended December 31, 2024. Working capital changes increase cash used in operations by $2.8 million of cash for operating activities, resulting from higher prepaid expenses and other current assets and other assets and a decrease in cash used in paying accounts payable and accrued expenses for the year ended December 31, 2024.

Cash flows from investing activities

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 used in investing activities for the year ended December 31, 2023 was $8.0 million, which was entirely related to the cash consideration paid to acquire the 2023 Lilly License.

Cash flows from financing activities

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.

Cash provided by financing activities for the year ended December 31, 2023 was $121.3 million, which consisted of $56.7 million of net proceeds from the issuance of shares upon the closing of the Business Combination and $59.7 million of proceeds, net of transaction costs, from the issuance of Class A Ordinary Shares in connection with the April 2023 Private Placement, and $16.1 million of proceeds from the issuance of 2023 Pre-Funded Warrants in connection with the April 2023 Private Placement, partially offset by a $10.0 million repayment of our promissory note and the payment of $1.2 million of deferred transaction costs.

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 another 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 fees of $0.4 million have been recorded as research and development expense in each of the years ended December 31, 2024 and 2023. We paid the 2023 fee as of December 31, 2024 and will pay the 2024 fee in the year ended December 31, 2025.

WuXi Biologics License

In July 2023, we entered into a biologics master services agreement (the “WuXi Biologics MSA”) with 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 terminates on the completion of services under all work orders executed by the parties, unless terminated earlier. The term of each work order terminates upon completion of the services under such work order, unless terminated earlier. We can terminate the WuXi Biologics MSA or any work order at any time upon 30 days’ prior written notice and immediately upon written notice if WuXi Biologics fails to obtain or maintain required material governmental licenses or approvals. Either party may terminate a work order at any time upon three months’ prior notice with reasonable cause, provided however that if WuXi Biologics terminates a work order in such manner, no termination or cancellation fees shall be paid by us and immediately for cause upon the other party’s material breach that remains uncured for 30 days after notice of such breach.

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 (the “WuXi Biologics Licensed Technology”) 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.

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 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 group of similar companies that are publicly traded. 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 its Series Seed Preferred Shares to Stone Peach as a finder's fee for the 2022 Lilly License. As the agreement to issue the Z33 Series Seed Preferred Shares included embedded put and call features, the shares issued to Stone Peach represent redeemable noncontrolling interest that we were required to initially measure at fair value at issuance. The agreement between Z33 and Stone Peach was 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 are 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 preferred share.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements located in "Part I – Financial Information, Item 1. 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 million or (ii) our annual revenue was less than $100 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 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 our Annual Report on Form 10-K 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, Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of December 31, 2024, 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, 2024.

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, 2024.

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, 2024 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

Our Board has set May 21, 2025 as the date for its 2025 annual general meeting of shareholders (the "Annual Meeting"). In accordance with the requirements set forth in our MAA, any shareholder seeking to raise a proposal or to make a nomination for consideration at the Annual Meeting must comply with the requirements set forth in our MAA and the requirements of Rule 14a-8 of the Exchange Act, including by delivering a notice of their proposal or nomination to the Company's Secretary at 1489 W. Warm Springs Rd. #110, Henderson, NV 89014, no later than the close of business on April 4, 2025. In addition, shareholders who intend to solicit proxies in support of director nominees other than the Company's nominees must provide in their notice any additional information required by Rule 14a-19(b) under the Exchange Act.

During the quarter ended December 31, 2024, no directors or executive officers entered into, modified or terminated, contracts, instructions or written plans for the sale or purchase of the Company's 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

The information required by this item will be included in the definitive proxy statement to our 2025 Annual General Meeting of Shareholders and is incorporated herein by reference.

Our Code of Ethics (the “Code”), which applies to all directors, officers and employees, is available on our Investor Relations website, investors.zurabio.com. 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 the definitive proxy statement to our 2025 Annual General Meeting of Shareholders 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 to our 2025 Annual General Meeting of Shareholders 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 2025 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 2025 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 (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	Specimen Warrant Certificate of Zura (incorporated by reference to Exhibit 4.6 of JATT's Form S-4 (File No. 333-267005) filed with the SEC on August 19, 2022).
4.3	Form of Pre-Funded Warrant to Purchase Ordinary Shares (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 3, 2023).
4.4	Form of Pre-Funded Warrant to Purchase Ordinary Shares (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 21, 2024).
4.5	Form of Pre-Funded Warrant to purchase Ordinary Shares (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 23, 2024).
4.6*	Description of Registrant's securities.
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 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.29 of JATT's Form S-4/A (File No. 333-267005) filed with the SEC on February 2, 2023).
10.4	Form of Subscription Agreement by and among Zura Bio Limited and the other parties signatories thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on May 3, 2023).

10.5†	Severance and General Release Agreement, dated April 7, 2023, by and between Zura Bio Limited and Preston Klassen (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on April 7, 2023).
10.6	Form of Employment Agreement for Someit Sidhu (incorporated by reference to Exhibit 10.31 of JATT's Form S-4/A (File No. 333-267005) filed with the SEC on February 8, 2023).
10.7	Form of Second PIPE Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on May 2, 2023).
10.8	Share Option Award Agreement (incorporated by reference to Annex C of the Definitive Proxy Statement on Schedule 14A filed by the Issuer with the SEC on May 19, 2023).
10.9††+	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 by the Issuer with the SEC on August 25, 2023)
10.10†	Service Agreement, dated as of April 7, 2023, by and between the Company and Dr. Someit Sidhu (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on April 10, 2023).
10.11†	Service Agreement, dated as of April 7, 2023, by and between the Company and Verender Badial (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Issuer with the SEC on April 10, 2023).
10.12†	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).
10.13†††+	Service Agreement between Zura Bio Limited and Kiran Nistala (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on December 6, 2023).
10.14†	Employment Agreement between Zura Bio Limited and Robert Lisicki (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on January 8, 2023).
10.15†	Settlement Agreement by and between Zura Bio Limited and Someit Sidhu dated July 24, 2024 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on July 25, 2024).
10.16	Amendment to Warrant Agreement, by and between Zura Bio Limited and Continental Stock Transfer & Trust Company, dated August 12, 2024 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on August 12, 2024).
10.17	Share Surrender and Warrant Agreement, dated as of August 15, 2024, by and among the Company and certain investors party thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on August 21, 2024).
10.18	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on April 23, 2024).
10.19	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 by the Issuer with the SEC on September 3, 2024).
10.20	Amended and Restated Registration Rights Agreement dated March 20, 2023, by and among the Company, the Sponsor and the parties thereto (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K (File No. 001-40598) filed with the SEC on March 24, 2023).
10.21	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.13 of Zura's Current Report on Form 8-K (File No. 001-40598) filed with the SEC on March 24, 2023).
10.22†	Zura Bio Limited 2023 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.12 of the Company's Current Report on Form 8-K (File No. 001 40598), filed with the SEC on March 24, 2023).
10.23†	Share Option Award Agreement (incorporated by reference to Annex C of the Definitive Proxy Statement on Schedule 14A filed by the Issuer with the SEC on May 19, 2023).
10.24†	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).
10.25	Offer Letter Agreement with Kim Davis, dated November 22, 2022 (incorporated by reference to Exhibit 10.39 to the Form S-1/A filed by the Issuer with the SEC on August 11, 2023).
16.1	Letter dated February 23, 2024 from Marcum LLP to the Securities and Exchange Commission regarding change in Certifying Accountant of the Company (incorporated by reference to Exhibit 16.1 to the Current Report on Form 8-K filed by the Issuer with the SEC on February 23, 2024).
19.1*	Insider Trading Policy.

21.1	List of Subsidiaries of Zura Bio Limited (incorporated by reference to Exhibit 21.2 of JATT's Form S-4/A (File No. 333-267005) filed with the SEC on October 25, 2022).
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 to the Company's Annual Report on Form 10-K filed on March 28, 2024).
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (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.

	Zura Bio Limited
Date: March 25, 2025	By: /s/ Robert Lisicki
	Robert Lisicki
	Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Verender S. Badial and Kim Davis, 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, including post-effective amendments, to this registration statement, and any registration statement relating to the offering covered by this registration statement and filed pursuant to Rule 462(b) under the Securities Act of 1933, 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.

Name	Title	Date
/s/ Robert Lisicki Robert Lisicki	Chief Executive Officer and Director (Principal Executive Officer)	March 25, 2025
/s/ Verender Badial Verender Badial	Chief Financial Officer (Principal Financial and Accounting Officer)	March 25, 2025
/s/ Amit Munshi Amit Munshi	Director, Chairman of the Board	March 25, 2025
/s/ Someit Sidhu Someit Sidhu	Director	March 25, 2025
/s/ Arnout Ploos van Amstel Arnout Ploos van Amstel	Director	March 25, 2025
/s/ Steve Schoch Steve Schoch	Director	March 25, 2025
/s/ Jennifer Jarrett Jennifer Jarrett	Director	March 25, 2025
/s/ Neil Graham Neil Graham	Director	March 25, 2025
/s/ Parvinder Thiara Parvinder Thiara	Director	March 25, 2025
/s/ Sandeep Kulkarni Sandeep Kulkarni	Director	March 25, 2025

ZURA BIO LIMITED

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2024 and 2023, and the related consolidated financial statements of operations, changes in redeemable noncontrolling interest, convertible preferred shares, and shareholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on 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.

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

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
March 24, 2025

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, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 176,498	$ 99,806
Prepaid expenses and other current assets	2,246	1,037
Total current assets	178,744	100,843
Property and equipment, net	91	—
Other assets	698	—
Total assets	$ 179,533	$ 100,843
Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$ 19,514	$ 20,302
Total current liabilities	19,514	20,302
Private placement warrants	—	990
Total liabilities	19,514	21,292
Commitments and contingencies (Note 11)		
Redeemable noncontrolling interest	11,663	18,680
Shareholders' Equity		
Preferred shares, $0.0001 par value, 1,000,000 authorized as of December 31, 2024 and 2023; no shares issued and outstanding as of December 31, 2024 and 2023	—	—
Class A Ordinary Shares, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2024 and 2023; 65,297,530 and 43,593,678 shares issued and outstanding as of December 31, 2024 and 2023, respectively	7	4
Additional paid-in capital	302,705	162,820
Accumulated deficit	(155,897)	(103,494)
Total Zura Bio Limited shareholders' equity	146,815	59,330
Noncontrolling interest	1,541	1,541
Total shareholders' equity	148,356	60,871
Total liabilities, redeemable noncontrolling interest and shareholders' equity	$ 179,533	$ 100,843

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, 2024	2023
Operating expenses:		
Research and development	$ 24,401	$ 43,999
General and administrative	30,788	18,639
Total operating expenses	55,189	62,638
Loss from operations	(55,189)	(62,638)
Other (income)/expense, net		
Interest income	(7,998)	(2,186)
Change in fair value of private placement warrants	5,240	(724)
Change in fair value of note payable	—	2,244
Dividend income	—	(1,392)
Other income, net	(28)	(17)
Total other income, net	(2,786)	(2,075)
Loss before income taxes	(52,403)	(60,563)
Income tax benefit	—	—
Net loss before redeemable noncontrolling interest	(52,403)	(60,563)
Net loss attributable to redeemable noncontrolling interest	—	203
Net loss	(52,403)	(60,360)
Adjustment of redeemable noncontrolling interest from redemption value to carrying value	7,017	—
Accretion of redeemable noncontrolling interest to redemption value	—	(7,220)
Deemed contribution from redeemable noncontrolling interest	—	9,212
Deemed dividend to redeemable noncontrolling interest	—	(10,875)
Net loss attributable to Class A Ordinary Shareholders of Zura	$ (45,386)	$ (69,243)
Net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	$ (0.60)	$ (2.09)
Weighted-average Class A Ordinary Shares used in computing net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	75,070,761	33,064,036

See accompanying notes to consolidated financial statements.

Zura Bio Limited

Consolidated Statements of Changes in Redeemable Noncontrolling Interest, Convertible Preferred Shares, and Shareholders' Equity (Deficit)

(In thousands, except share data)

	Redeemable Noncontrolling Interest	Convertible Preferred Shares(1)		Class A Ordinary Shares(1)		Additional Paid-in Capital	Accumulated Deficit	Noncontrolling Interest	Total Shareholders' Equity (Deficit)
		Shares	Amount	Shares	Amount				
Balance as of December 31, 2022	**$ 10,000**	**13,510,415**	**$ 12,500**	**279,720**	**$ —**	**$ —**	**$ (32,056)**	**$ —**	**$ (32,056)**
Issuance of Series A-1 convertible preferred shares as license compensation	—	267,939	2,186	—	—	—	—	—	—
Conversion of Series A-1 convertible preferred shares to Class A Ordinary Shares in connection with Business Combination	—	(13,778,354)	(14,686)	13,778,354	2	14,684	—	—	14,686
Issuance of Class A Ordinary Shares in connection with Business Combination, including PIPE Investment, Forward Purchase Investment, and Backstop Shares, net of $4.0 million of transaction costs	—	—	—	12,444,081	1	48,350	—	—	48,351
Issuance of Class A Ordinary Shares to settle research and development license consideration liability	—	—	—	550,000	—	4,488	—	—	4,488
Reclassification of public warrant liability to equity	—	—	—	—	—	2,001	—	—	2,001
Issuance of Class A Ordinary Shares in connection with April 2023 Private Placement, net of $9.8 million of transaction costs	—	—	—	15,041,530	1	54,133	—	—	54,134
Issuance of Pre-Funded Warrants in connection with April 2023 Private Placement	—	—	—	—	—	16,070	—	—	16,070
Issuance of Class A Ordinary Shares to Lilly in connection with 2023 Lilly License	—	—	—	1,000,000	—	7,840	—	—	7,840
Issuance of restricted share awards	—	—	—	499,993	—	—	—	—	—
Share-based compensation	—	—	—	—	—	13,059	—	—	13,059
Net loss	(203)	—	—	—	—	—	(60,360)	—	(60,360)
Accretion of redeemable noncontrolling interest to redemption value	7,220	—	—	—	—	(7,017)	(203)	—	(7,220)
Stone Peach Call Right issued to noncontrolling interest	—	—	—	—	—	—	—	1,541	1,541
Deemed contribution from redeemable noncontrolling interest	(9,212)	—	—	—	—	9,212	—	—	9,212
Deemed dividend to redeemable noncontrolling interest	10,875	—	—	—	—	—	(10,875)	—	(10,875)
Balance as of December 31, 2023	**$ 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**

(1) The Company's convertible preferred shares and Class A Ordinary Shares prior to the closing of the Business Combination (as defined in Note 1) have been retroactively restated to reflect the exchange ratio of approximately 108.083 established in the Business Combination Agreement as described in Note 3.

See accompanying notes to consolidated financial statements.

Zura Bio Limited

Consolidated Statements of Cash Flows
(In thousands)

	For the Years Ended December 31,	
	2024	2023
Cash flows from operating activities		
Net loss before redeemable noncontrolling interest	$ (52,403)	$ (60,563)
Adjustments to reconcile net loss before redeemable noncontrolling interest to net cash used in operating activities		
Research and development acquired license	—	27,381
Anti-dilution share issuance compensation	—	2,186
Share-based compensation expense	16,798	7,469
Change in fair value of note payable	—	2,244
Change in fair value of research and development license consideration liability	—	1,854
Change in fair value of private placement warrants	5,240	(724)
Depreciation and amortization	9	—
Foreign exchange transaction gain	(27)	(17)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,209)	(828)
Other assets	(698)	—
Accounts payable and accrued expenses	4,214	5,944
Net cash used in operating activities	(28,076)	(15,054)
Cash flows from investing activities		
Purchase of fixed assets	(75)	—
Purchase of research and development license	(5,000)	(8,000)
Net cash used in investing activities	(5,075)	(8,000)
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	5,534	—
ATM transaction costs	(626)	—
Restricted stock units withheld to pay employee withholding taxes	(318)	—
Proceeds from issuance of Class A Ordinary Shares in connection with April 2023, Private Placement, net of $4.2 million of transaction costs	—	59,724
Proceeds from issuance of Class A Ordinary Shares upon Closing of Business Combination	—	56,683
Proceeds from issuance of Pre-Funded Warrants in connection with April 2023 Private Placement	—	16,070
Settlement of note payable	—	(10,000)
Payment of deferred transaction costs	—	(1,184)
Net cash provided by financing activities	109,843	121,293
Net increase in cash and cash equivalents	76,692	98,239
Cash and cash equivalents, beginning of period	99,806	1,567
Cash and cash equivalents, ending of period	$ 176,498	$ 99,806
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	$ —
Adjustments to redeemable noncontrolling interest from redemption value to carrying value	$ 7,017	$ —
Purchase of property and equipment included in accounts payable and accrued expenses	$ 25	$ —
Issuance of Series A-1 convertible preferred shares for license	$ —	$ —
Conversion of Series A-1 convertible preferred stock for Class A Ordinary Shares	$ —	$ 14,686
Deemed dividend to redeemable noncontrolling interest	$ —	$ 10,875
Accrued 2023 Lilly License consideration	$ —	$ 10,000
Deemed contribution from redeemable noncontrolling interest	$ —	$ 9,212
Issuance of Class A Ordinary shares for 2023 Lilly License	$ —	$ 7,840
Accretion of redeemable noncontrolling interest to redemption value	$ —	$ 7,220
Share-based equity issuance costs	$ —	$ 5,590
Settlement of research and development license consideration liability	$ —	$ 4,488
Reclassification of deferred offering costs to additional paid-in capital	$ —	$ 4,015
Assumption of public and private placement warrants in connection with Business Combination	$ —	$ 3,715
Reclassification of public warrant liability to equity	$ —	$ 2,001
Issuance of Call Right to noncontrolling interest	$ —	$ 1,541

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, multi-asset immunology company dedicated to developing novel dual-pathway antibodies for a range of autoimmune and inflammatory diseases with unmet needs. The Company's strategic focus is to harness dual-pathway biology to provide broader and deeper clinical benefits to patients with these conditions. The Company is currently developing one clinical-stage product candidate in ongoing Phase 2 trials while actively evaluating development opportunities for its pipeline of clinical-stage assets, focusing on indications with unmet needs and commercial potential.

The Company is currently developing tibulizumab (ZB - 106), an immunoglobulin G (IgG)-single-chain variable fragment (scFv) bispecific dual-antagonist antibody engineered by the fusion of TALTZ® (ixekizumab) and tabalumab to neutralize interleukin-17A (IL - 17A) and B-cell activating factor (BAFF). In December 2024, the Company initiated TibuSURE, a global Phase 2 study evaluating tibulizumab in adults with systemic sclerosis (SSc). TibuSURE is a randomized, double-blind, placebo-controlled study designed to assess the safety, tolerability, and efficacy of tibulizumab in approximately 80 participants with early diffuse cutaneous systemic sclerosis (dcSSc).

Additionally, the Company is actively assessing the competitive landscape and evaluating potential therapeutic indications for crebankitug and torudokimab.

- Crebankitug (ZB-168) is a fully human, high affinity monoclonal antibody that binds and neutralizes the interleukin-7 receptor (IL - 7R) alpha chain. IL - 7Rα sits at the nexus of two key immune pathways, IL - 7 and thymic stromal lymphopoietin (TSLP), thus IL - 7Rα has the potential to block activation through either of these pathways. As a result, the Company believes crebankitug could be therapeutically relevant in a broad set of indications where the IL - 7 or TSLP pathways may be involved.

- Torudokimab (ZB - 880) is a fully human, high affinity monoclonal antibody that neutralizes interleukin-33 (IL - 33), preventing ST2 - dependent and ST2 - independent (e.g., RAGE) inflammation. The IL - 33/ST2 axis stands as a validated therapeutic target for conditions such as chronic obstructive pulmonary disease ("COPD") and asthma.

Business Combination

On March 20, 2023 (the "Closing Date"), the Company consummated the previously announced business combination (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. ("Holdco"), and Legacy Zura. Pursuant to the Business Combination Agreement, (a) before the closing of the Business Combination, Holdco was established as a new holding company of Legacy Zura and became a party to the Business Combination Agreement; and (b) on the Closing Date, in sequential order: (i) Merger Sub merged with and into Holdco, with Holdco continuing as the surviving company and a wholly owned subsidiary of JATT; (ii) immediately following the Merger, Holdco merged with and into Merger Sub 2, with Merger Sub 2 continuing as the surviving company and a wholly owned subsidiary of JATT; and (iii) JATT changed its name to "Zura Bio Limited".

The Business Combination has been accounted for as a reverse recapitalization, with Legacy Zura being the accounting acquirer and JATT as the acquired company for accounting purposes. Accordingly, all historical financial information presented in the consolidated financial statements represent the accounts of Legacy Zura. The shares and net loss per share attributable to ordinary shareholders of Legacy Zura prior to the Closing Date have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination Agreement.

Prior to the Business Combination, JATT's public shares, public warrants, and public units were listed on the New York Stock Exchange ("NYSE") under the symbols "JATT," "JATT.WS," and "JATT.U," respectively. On March 20, 2023, the Company's Class A ordinary shares ("Class A Ordinary Shares") and public warrants began trading on the Nasdaq under the symbols "ZURA" and "ZURAW," respectively. On August 27, 2024, the Public Warrants (as defined herein) were no longer listed on the Nasdaq in connection with the completion of the Warrant Exchange (as defined herein). See Note 8.

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 $155.9 and $103.5 million as of December 31, 2024 and 2023, respectively, and a net loss of $52.4 million and $60.4 million for the years ended December 31, 2024 and 2023, respectively. The Company's existing sources of liquidity as of December 31, 2024 includes $176.5 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 received $4.9 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, the fair value of share-based compensation, the fair value of redeemable noncontrolling interest, the fair value of share-based consideration transferred for acquired assets, the fair value of contingent consideration, the valuation allowance of deferred tax assets resulting from net operating losses and the fair value of the private placement warrants.

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.

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 significant expenses within net loss are separately presented in the Company's consolidated statement of operations. The CODM monitors budget versus actual results using operating loss which is a component of net loss. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets.

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 $170.7 million and $97.9 million in cash equivalents as of December 31, 2024 and 2023, 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.

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 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.

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.

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 Accounting Standards Codification ("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.

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 8.

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 instruments.

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 or the Share Exchange (as defined herein), as applicable. See Note 8.

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. See Note 6. 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.

Redeemable Noncontrolling Interest

In 2022, Z33, a consolidated subsidiary of the Company, issued 4,900,222 shares of Z33 Series Seed Preferred Shares to Stone Peach representing a redeemable noncontrolling interest. See Note 12. The Z33 Series Seed Preferred Shares issued to Stone Peach contain put features and are considered redeemable until the exercise or the expiration of the put features. The redeemable noncontrolling interests are classified outside of permanent equity in the consolidated balance sheets. The redeemable noncontrolling interest is 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.

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,	
	2024	**2023**
Shares issuable upon exercise of options to purchase Class A Ordinary Shares	10,175,633	5,791,065
Shares issuable upon exercise of Z33 Series Seed Preferred Shares Put Right	2,000,000	2,000,000
Shares issuable upon vesting of restricted share units	859,923	1,543,018
Restricted share awards	374,995	499,993
Shares issuable upon exercise of warrants to purchase Class A Ordinary Shares	—	12,809,996
Total	13,410,551	22,644,072

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting* ("ASU 2023-07"). ASU 2023-07 requires enhanced segment disclosures, including disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within the segment measure of profit or loss. The enhanced disclosures are required for all entities, including entities that have only a single reportable segment, and will be applied retrospectively. The Company adopted this standard for the year ended December 31, 2024 which resulted in additional segment disclosures (see *"—Segments"* above).

Recently Issued 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 is intended 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. ASU 2023-09 will be effective for the Company in the annual period beginning on January 1, 2025, although early adoption is permitted. The Company is currently evaluating the presentational effect that ASU 2023-09 will have on the Company's consolidated financial statements and disclosures, but the Company expects considerable changes to the Company's income tax disclosures.

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.

3. Recapitalization

As discussed in Note 1, on the Closing Date, JATT completed the acquisition of Legacy Zura and acquired 100% of Legacy Zura’s shares and Legacy Zura received proceeds of $56.7 million which includes proceeds from issuance of Class A Ordinary Shares upon the consummation of the Business Combination, including the Redemption Backstop shares (as defined below), proceeds from the PIPE investment (as defined below), and proceeds from the Forward Purchase Agreement (as defined below). The Company recorded $4.0 million of transaction costs, which consisted of legal, accounting, and other professional services directly related to the Business Combination. These costs were included in additional paid-in capital on the Company’s consolidated balance sheets. On the Closing Date, each holder of Legacy Zura’s ordinary shares received approximately 108.083 shares of the Company’s Class A Ordinary Shares, par value $0.0001 per share. See Note 7.

All equity awards of Legacy Zura were assumed by the Company and converted into comparable equity awards that are exercisable for or settled in shares of the Company’s Class A Ordinary Shares. As a result, each outstanding share option was converted into an option exercisable for the Company’s Class A Ordinary Shares based on an exchange ratio of approximately 108.083 and each outstanding restricted share unit was converted into restricted share units of the Company that, upon vesting, will be settled for the Company’s Class A Ordinary Shares based on an exchange ratio of approximately 108.083.

Each public and private placement warrant of JATT that was unexercised at the time of the Business Combination was assumed by the Company and represented the right to purchase one Class A Ordinary Share upon exercise of such warrant. See Notes 2 and 8.

The Business Combination was accounted for as a reverse recapitalization with Legacy Zura as the accounting acquirer and JATT as the acquired company for accounting purposes. Legacy Zura was determined to be the accounting acquirer since Legacy Zura’s shareholders as a group prior to the Business Combination held the majority voting interest in the combined entity, Legacy Zura’s shareholders appointed 4 out of the 7 directors of the combined Board of Directors, Legacy Zura’s management holds certain key positions in the management of the combined entity, and Legacy Zura is the largest of the combining entities based on historical operating activity and comprises all of the ongoing operations. Accordingly, all historical financial information presented in these consolidated financial statements represents the accounts of Legacy Zura. Net assets were stated at historical cost consistent with the treatment of the transaction as a reverse recapitalization of Legacy Zura. The Company’s convertible preferred shares and Class A Ordinary Shares prior to the closing of the Business Combination have been retroactively restated to reflect the exchange ratio of approximately 108.083 established in the Business Combination Agreement.

The number of Class A Ordinary Shares issued and outstanding immediately following the Business Combination on March 20, 2023 was:

	Shares	%
JATT Public shareholders	182,498	0.7 %
Zura shares issued – 2022 Lilly license	550,000	2.0 %
Redemption Backstop	1,301,633	4.8 %
Redemption Backstop Consideration	2,500,000	9.2 %
JATT Founders	3,450,000	12.8 %
PIPE Investment	2,009,950	7.4 %
Forward Purchase Agreement	3,000,000	11.1 %
Legacy Zura equity holders	14,058,074	52.0 %
Total shares outstanding	27,052,155	100.0 %

PIPE Investment

Concurrently with the execution of the Business Combination Agreement, JATT entered into subscription agreements with certain "accredited investors" (as defined by Rule 501 of Regulation D) (the "PIPE Investors") on June 16, 2022, as amended on November 25, 2022, (the "Ewon PIPE Subscription Agreement") and March 13, 2023 (the "Eugene PIPE Subscription Agreement"), pursuant to which the PIPE Investors collectively subscribed for and agreed to purchase an aggregate of 2,009,950 JATT Class A Ordinary Shares at a purchase price of $10.00 per share for $20,099,500.

Forward Purchase Agreement and Redemption Backstop

On January 27, 2022, JATT entered into an Amended Forward Purchase Agreement (the "Forward Purchase Agreement") with two institutional investors (the "FPA Investors") providing that at the Closing of the Business Combination: (i) the purchasers will purchase an aggregate of 3,000,000 Class A Ordinary Shares at $10 per share for $30,000,000; and (ii) the purchase of, in a binding redemption backstop (the "Redemption Backstop"), up to an additional $15 million of Class A Ordinary Shares in the event that public Class A Ordinary Share redemptions are greater than 90% in connection with the Business Combination (the "Excess Redemptions"). On the Closing Date, FPA Investors purchased 1,301,633 JATT Class A Ordinary Shares at $10 per share for $13,016,330. In addition, the FPA Investors were issued an additional 2,500,000 Class A Ordinary Shares ("Redemption Backstop Consideration") for no additional consideration.

4. 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, accounts payable and accrued expenses and private placement warrants. 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, 2024 and 2023, and the fair value hierarchy of the valuation techniques utilized:

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

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Cash equivalents	$ 97,913	$ —	$ —	$ 97,913
Financial liabilities:				
Private placement warrants	$ —	$ 990	$ —	$ 990

There were no transfers into or out of Level 1, Level 2, or Level 3 during the year ended December 31, 2024 and 2023.

Private Placement Warrants

In August 2024, pursuant to the Warrant Exchange, the Company exchanged all of the outstanding 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 8. 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	2023
Balance, beginning of year	$ 990	$ —
Assumption of private placement warrants	—	1,714
Change in fair value	5,240	(724)
Exchange of private placement warrants for Class A Ordinary Shares	(6,230)	—
Balance, end of year	$ —	$ 990

For the years ended December 31, 2024 and 2023, the Company recorded a loss of $5.2 million and a gain of $0.7 million, respectively, 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.

Financial Instruments Settled Upon Business Combination

The Company had two level three classified financial instruments, note payable and research and development license consideration, that were measured at fair value on a recurring basis during 2023 and settled prior to December 31, 2023. The following table provides a summary of changes in the estimated fair value of the note payable and research and development license consideration liability:

	Note Payable	Research and Development License Consideration Liability
Balance as of December 31, 2022	$ 7,756	$ 2,634
Remeasurement to settlement value upon closing of the Business Combination	2,244	1,854
Settlement of liability	(10,000)	(4,488)
Balance as of December 31, 2023	$ —	$ —

Note payable

On December 8, 2022, the Company received $7.6 million in net proceeds from the issuance of a promissory note (the “Note”) issued to Hydra, LLC (“Hydra”) with a face amount of $8.0 million. The Company elected to account for the Note at fair value. Upon the Closing Date of the Business Combination, the Note was remeasured to the settlement value and subsequently repaid for a total of $10.0 million. For the year ended December 31, 2023, the Company recorded a loss on the remeasurement of the Note of $2.2 million in change in fair value of note payable in the consolidated statement of operations. The Note was no longer outstanding as of December 31, 2024 and 2023.

Research and development license consideration

As consideration for the 2022 Lilly License (defined below), Lilly received 550,000 Class A Ordinary Shares upon the closing of the Business Combination (subject to certain lock-up provisions). See Note 6. The arrangement was liability classified and remeasured at fair value at each reporting date prior to the Business Combination (the research and development license consideration liability).

Upon the Closing Date of the Business Combination, the liability was remeasured to its settlement value and subsequently settled through the issuance of 550,000 Class A Ordinary Shares of Zura. The aggregate fair value of the Class A Ordinary Shares of Zura issued to Lilly was determined to be $4.5 million, or $8.16 per share. For the year ended December 31, 2023, the Company recorded a loss on the remeasurement of the research and development license consideration liability of $1.9 million in research and development in the consolidated statement of operations. The research and development license consideration liability was no longer outstanding as of December 31, 2024 and 2023.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses are composed of the following as of December 31, 2024 and 2023:

	December 31,	
	2024	2023
Accrued research and development costs	$ 7,100	$ 6,091
Accrued 2023 Lilly License costs	9,500	10,000
Accrued bonus	1,713	1,201
Accounts payable	733	2,749
Accrued professional fees	318	150
Other accrued expenses	150	111
Total accounts payable and accrued expenses	$ 19,514	$ 20,302

6. License Agreements

2023 Lilly License

On April 26, 2023, the Company's consolidated subsidiary ZB17 LLC ("ZB17") entered into a license agreement (the "2023 Lilly License" and, together with the 2022 Lilly License (as defined below), the "Lilly Licenses") with Lilly, for an exclusive license to develop, manufacture and commercialize a certain bispecific antibody relating to IL-17 and BAFF ("ZB-106") in exchange for an upfront payment consisting of $5.8 million as well as 1,000,000 Class A Ordinary Shares issued at a fair value of $7.84 per Class A Ordinary Share. 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 compound licensed had not yet received regulatory approval and the in-process research and development 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.

As a finder's fee for arranging the acquisition of the 2023 Lilly License, 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 is not exercisable until after the last patient is dosed in any single next clinical trial with ZB-106 and expires one year from the date of first indication approval for ZB-106 by the FDA or the European Medicines Agency ("EMA"). The Company recognized the Stone Peach Call Right at a grant-date fair value of $1.5 million in research and development in the consolidated statement of operations during the year ended December 31, 2023. The Stone Peach Call Right represents noncontrolling interest in the Company's consolidated subsidiary, ZB17. As of December 31, 2024 and 2023, the noncontrolling interest balance was $1.5 million in the consolidated balance sheets.

As additional consideration, beginning on May 1, 2023, Stone Peach receives 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 the years ended December 31, 2024 and 2023, the Company recorded $0.7 million and $0.6 million, respectively, in research and development in the consolidated statement of operations for the annual payments.

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 years ended December 31, 2024 and in accounts payable and accrued expenses as of December 31, 2024.

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 and December 31, 2023.

In addition to the consideration paid and/or earned during the years ended December 31, 2024 and 2023, the Company is obligated to make payments (a) to Lilly 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 tibulizumab; (b) to Lilly 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 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; (c) 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; (d) to Stone Peach for a one-time milestone payment of $25 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; (e) to Stone Peach for a royalty of 2% of the aggregate net sales of any products developed from the Compound (collectively, the "2023 Lilly Contingent Payments"). As of December 31, 2024, 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.

2022 Lilly License

On December 8, 2022, the Company's consolidated subsidiary, Z33, entered into a license agreement (the "2022 Lilly License") with Lilly pursuant to which Lilly granted Z33 an exclusive (even as to Lilly), royalty-bearing global license to develop, manufacture, and commercialize certain intellectual property owned by Lilly relating to its IL-33 compound. 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. See Note 4.

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"). Stone Peach has 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 may exercise its Put Option and Put Right at any time between April 24, 2024 and April 24, 2028 under the new agreement. See Note 12. 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 represent redeemable noncontrolling interest in the Company's consolidated subsidiary, Z33.

In addition to the consideration paid in 2022 and shares issued in 2023, the Company is also obligated to make payments to Lilly for (a) for $3.0 million upon the completion of a financing by Z33 with gross proceeds exceeding $100 million; (b) 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 (c) an annual earned royalty at a marginal royalty rate between in the mid-single to low-double digits (less than 20%), 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, 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, 2024, 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 a compound initially developed by Pfizer, 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 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, 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, 2024, 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.

The Pfizer Agreement also had an anti-dilution provision to allow Pfizer to maintain an 18% interest in the Company, as detailed in Note 7. 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 the Company. 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. In accordance with ASC 718, *Compensation – Stock Compensation*, the Company recorded expense related to these Class A Ordinary Shares based on their grant date fair value. See Note 9. Following the Business Combination, the anti-dilution provision is no longer in effect.

Lonza

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, 2024 and 2023. During the year ended December 31, 2024, $0.4 million was paid for the Lonza License and the remaining $0.4 million is included in accounts payable and accrued expenses in the consolidated balance sheet as of December 31, 2024.

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' know-how, cell line, and biological materials (the "WuXi Biologics Licensed Technology") 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, 2024, there are no payments currently due under the Cell Line License Agreement.

7. Convertible Preferred Shares and Shareholders' Equity

Business Combination

Immediately prior to the Closing Date of the Business Combination, 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. The shares were issued in accordance with the anti-dilution provision of the Pfizer Agreement. See Note 9.

On the Closing Date and in accordance with the terms and subject to the conditions of the Business Combination, each Ordinary Share of Legacy Zura, par value $0.001 per share, Series A-1 convertible preferred share, outstanding option (whether vested or unvested), and restricted share unit (whether vested or unvested) were canceled and converted into a comparable number of awards that consisted of either the rights to receive or acquire the Company's Class A Ordinary Shares, par value $0.0001 per share, as determined by the exchange ratio pursuant to the Business Combination Agreement. The exchange ratio was approximately 108.083.

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.

On September 18, 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. See Note 14.

Warrant Exchange

In connection with the Warrant Exchange, the Company issued 3,782,190 Class A Ordinary Shares. See Note 8.

Exchange of Class A Ordinary Shares

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").

April 2024 Private Placement

On April 18, 2024, the Company entered into subscription agreements (the "Investor Agreements") with certain institutional and other accredited investors (the "Investors"), whereby 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. See Note 8 for further information about the 2024 Pre-Funded Warrants.

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 ("Insiders" and together with the Investors, the "Subscribers"), whereby 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.

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.

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 (the "Subscribers"), whereby 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. See Note 8.

Class A Ordinary Shares Reserved for Issuance

The summary of shares reserved for issuance as of December 31, 2024 is summarized below:

	December 31, 2024
Shares issuable upon exercise of warrants to purchase Class A Ordinary Shares	23,884,348
Shares issuable upon exercise of options to purchase Class A Ordinary Shares	12,217,747
Shares available for grant under 2023 Equity Incentive Plan and ESPP	1,863,283
Shares issuable upon exercise of Z33 Put Right	2,000,000
Shares issuable upon release of restricted share units	876,923
Total shares reserved for issuance	40,842,301

Legacy Zura Ordinary Shares and Series A-1 Convertible Preferred Shares

Prior to the Business Combination, Legacy Zura was authorized to issue Ordinary Shares and Series A-1 convertible preferred shares. The outstanding Ordinary Shares and Series A-1 convertible preferred shares of Legacy Zura are presented on the consolidated statement of changes in redeemable noncontrolling interest, convertible preferred shares, and shareholders' equity (deficit) as of December 31, 2022, prior to the recapitalization (see Note 3).

As of December 31, 2024 and 2023, no Legacy Zura Ordinary Shares and no convertible preferred shares were issued and outstanding.

Series A-1 Convertible Preferred Shares Rights and Preferences

Conversion

Each Series A-1 convertible preferred share was convertible, at the option of the holder thereof, at any time after the date of issuance of such share, into such number shares of the Company's Ordinary Shares, subject to adjustment.

Each Series A-1 convertible preferred share would have automatically converted into a share of the Company's Ordinary Shares, subject to adjustment, immediately upon the occurrence of an initial public offering with a gross aggregate subscription with respect to new Ordinary Shares of greater than $50.0 million. The Ordinary Shares resulting from this conversion would have ranked pari passu with the existing Ordinary Shares at the time of conversion.

Anti-Dilution

When the Company issued equity securities, other than pursuant to a share option plan, the Company was required to issue such number of Series A-1 convertible preferred shares to Pfizer as necessary to maintain Pfizer's ownership interest of 18%, until the Company raised in excess of $30.0 million in equity, where any capital raised above this threshold is not subject to anti-dilution. Upon the closing of the Business Combination, the anti-dilution provision was no longer in effect.

Dividends

The holders of shares of Series A-1 convertible preferred shares were entitled to receive dividends, of profits available for distribution as determined by the Company's board of directors with the consent of the majority of the shareholders, payable on a pro rata, pari passu basis. No dividends have been declared by the Company's board of directors.

Liquidation

In the event of any voluntary or involuntary liquidation or return of capital (other than a conversion, redemption or purchase of shares) of the Company, the holders of the Series A-1 convertible preferred shares were entitled to receive a liquidation preference prior to any distribution to the holders of Ordinary Shares in the amount of $131 per share.

Voting Rights

The holders of the Series A-1 convertible preferred shares were entitled to one vote per share, unless the Series A-1 shares are convertible into a greater number of Ordinary Shares or the holders of Series A-1 convertible preferred shares were entitled to any anti-dilution shares, in which case the holders of Series A-1 convertible preferred shares were entitled to the number of votes that the holder would be entitled upon conversion to Ordinary Shares or after the issuance of the anti-dilution shares, respectively.

Redemption Rights

The Series A-1 convertible preferred shares were not mandatorily redeemable at the option of the holder.

8. Warrants

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 to purchase 6,899,996 Class A Ordinary Shares (the "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 ("CST"), 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. 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.

Public Warrants

The Public Warrants became exercisable into Class A Ordinary Shares commencing 30 days after the Business Combination with an exercise price of $11.50 per share, subject to certain adjustments and would have expired five years from the date of the Business Combination, or earlier upon redemption or liquidation. Each warrant entitled the holder to purchase one share of the Company's Class A Ordinary Shares at a price of $11.50 per share, subject to certain adjustments.

The Public Warrants were redeemable, with 30 days written notice, for cash at a price of $0.01 per warrant if the Reference Value (as defined below) equaled or exceeded $18.00 per share, subject to certain adjustments. The warrant holders had the right to exercise their outstanding warrants prior to the scheduled redemption date at $11.50 per share, subject to certain adjustments. If the Company called the public warrants for redemption, the Company would have the option to require all holders that wished to exercise the Public Warrants to do so on a "cashless basis", as described in the warrant agreement. For purposes of the redemption, "Reference Value" shall mean the last reported sales price of the Company's Class A Ordinary Shares for any twenty trading days within the thirty trading-day period ending on the third trading day prior to the date on which notice of the redemption is given.

The Public Warrants are no longer outstanding as of December 31, 2024. See *"—Warrant Exchange"* above.

Private Placement Warrants

The Private Placement Warrants were identical to the Public Warrants, except that the Private Placement Warrants were not transferable, assignable or salable until 30 days after the completion of a Business Combination, subject to certain limited exceptions. Additionally, Private Placement Warrants held by the initial purchasers or their permitted transferees were exercisable on a cashless basis and were non-redeemable.

The Private Placement Warrants are no longer outstanding as of December 31, 2024. See *"—Warrant Exchange"* above.

Pre-Funded Warrants

On August 15, 2024, in conjunction with the Share Exchange Agreement, the Company issued the 4,000,000 Share Exchange Warrants with an exercise price of $0.001 per share and no expiration date. The Share Exchange Warrants are exercisable immediately, are exercisable until such Share Exchange Warrants are exercised in full and have substantially identical terms to the form of 2024 Pre-Funded Warrant (see below). 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. See Note 7.

In connection with the April 2023 Private Placement, the Company sold to accredited investors 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"). 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.

In connection with the April 2024 Private Placement (see Note 7), the Company sold to accredited investors the 2024 Pre-Funded Warrants to purchase up to 16,102,348 Class A Ordinary Shares. 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.

The following table presents the number of warrants outstanding, their exercise price, and expiration dates as of December 31, 2024 and 2023:

As of December 31, 2024			
Warrants Issued	**Exercise Price**		**Expiration Date**
23,884,348	$	0.001	N/A

As of December 31, 2023			
Warrants Issued	**Exercise Price**		**Expiration Date**
6,899,996	$	11.5	Mar-28
5,910,000	$	11.5	Mar-28
3,782,000	$	0.001	N/A

9. Share-Based Compensation

On March 16, 2023, JATT's board of directors approved the Zura Bio Limited 2023 Equity Incentive Plan (the "Equity Incentive Plan") which became effective on the day immediately preceding the Closing Date of the Business Combination. The Equity Incentive Plan 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 Company's board of directors approved an increase to the number of Class A Ordinary Shares that may be issued under the Equity Incentive Plan by an additional 5,564,315 Class A Ordinary Shares. See Note 14.

The Class A Ordinary Shares issuable under the Equity Incentive Plan 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 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. As of January 1, 2024, the Company's board of directors decided not to apply an increase to the Class A Ordinary Shares issuable under the Equity Incentive Plan for the 2024 calendar year.

On March 16, 2023, JATT’s board of directors approved the Zura Bio Limited 2023 Employee Stock Purchase Plan (the “ESPP”) which became effective on the day immediately preceding the Closing Date of the Business Combination. 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 Equity Incentive Plan 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, 2024, the Company has not activated the ESPP.

As of December 31, 2024, a maximum of 13,624,111 Class A Ordinary Shares were authorized for issuance under either the Equity Incentive Plan and ESPP, collectively.

Legacy Zura Option Plans Conversions

On June 8, 2022, Legacy Zura’s board of directors approved two share option plans, the UK Plan (the “UK Plan”) and the US Plan (the “US Plan”) (collectively, the “Option Plans”) which permit the granting of nonqualified share options to certain employees and directors. There were 1,501,165 Ordinary Shares available for issuance under the Option Plans, of which 383,371 Ordinary Shares were authorized for issuance under the US Plan. Upon closing of the Business Combination, all equity awards of Legacy Zura that were issued and outstanding under the Option Plans were converted into comparable equity awards that are settled or exercisable for shares of the Company’s Class A Ordinary Shares under the Equity Incentive Plan. As a result, each of Legacy Zura’s equity awards were converted into an option to purchase Class A Ordinary Shares of the Company based on an exchange ratio of approximately 108.083.

Equity Incentive Plan

Share Options

The fair value of Equity Incentive Plan 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 Equity Incentive Plan share options issued during the years ended December 31, 2024 and 2023:

	For the Year Ended December 31,	
	2024	2023
Share price	$ 3.35	$ 6.25
Expected volatility	101.1 %	97.1 %
Risk-free rate	4.2 %	3.6 %
Expected life	6.0 years	6.1 years
Expected dividend yield	— %	— %

The following table summarizes the Company's share option activity for the year ended December 31, 2024:

	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, 2023	5,791,065	$ 2.12	9.3	$ 17,752
Granted	7,164,948	$ 3.45		
Forfeited	(738,266)	$ 2.49		
Options outstanding as of December 31, 2024	12,217,747	$ 2.88	8.9	$ 8,388
Options vested and exercisable as of December 30, 2024	$ 3,672,393	$ 1.50	8.2	$ 6,080

Included in options outstanding as of December 31, 2024 and 2023 in the table above are 2,165,369 and 2,483,135, respectively, options to purchase Class A Ordinary Shares issued to certain directors, executives, and employees outside of the Equity Incentive Plan.

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 Annual General Meeting ("AGM"). The Company is recording expense over one year as the Company's management has not deemed it probable that the AGM will be earlier than one year.

The weighted average grant date fair value of options granted during the years ended December 31, 2024 and 2023 was $2.71 and $5.79, 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 certain Director of the Board. 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 year ended December 31, 2024.

The following table includes the weighted-average assumptions used at the grant date to determine the fair value of the Company's Market-Based Share Options granted during the year ended December 31, 2023.

	For the Year Ended December 31, 2023
Expected volatility	80.0 %
Risk-free rate	3.6 %
Expected life	2.2 years
Expected dividend yield	— %
Fair value per Market-Based Share Options	$ 4.66

For the years ended December 31, 2024 and 2023, the Company recorded expense related to Market-Based Share Options of $0.7 million and $0.5 million, respectively.

Restricted Share Units

The following table summarizes the Company's RSU activity for the year ended December 31, 2024:

	Number of Options	Weighted Average Grant Date FV
Unvested RSUs outstanding as of December 31, 2023	1,563,018	$ 5.93
Granted	5,000	$ 3.59
Forfeited	(297,342)	$ 5.77
Vested and issued	(393,753)	$ 5.77
Vested and unissued	(2,000)	$ 5.39
Unvested RSUs as of December 31, 2024	874,923	$ 5.99

For the years ended December 31, 2024 and 2023, the Company recorded expense related to RSUs of $2.0 million and $ 1.6 million, respectively.

Restricted Share Awards

During the year ended December 31, 2023, the Company converted RSUs granted to a certain director pursuant to the Equity Incentive Plan into RSAs. The following table summarizes the Company's RSA activity for the year ended December 31, 2024:

	Number of Options	Weighted Average Grant Date Fair Value
Unvested RSAs outstanding as of December 31, 2023	499,993	8.16
Vested	(124,998)	8.16
Unvested RSAs outstanding as of December 31, 2024	374,995	$ 8.16

For the years ended December 31, 2024 and 2023, the Company recorded expense related to RSAs of $1.0 million and $ 0.6 million, respectively.

Equity Award Modification

On July 24, 2024, the Company entered into a settlement agreement with Someit Sidhu ("Settlement Agreement") in connection with the Chief Executive Officer ("CEO") transition. Pursuant to the 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 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 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.

On April 7, 2023, the Company and its President and Chief Operating Officer (the "COO") entered into an agreement regarding the COO's departure from the Company (the "Severance Agreement"). In connection with Severance Agreement, 59,594 of the share options previously granted to the COO became fully vested and exercisable, with any shares purchased under the option subject to an 18-month lockup period. The Company recognized approximately $0.6 million of incremental share-based compensation during the year ended December 31, 2023 related to this share option modification.

Other Share-based Compensation

In accordance with the anti-dilution provisions 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. During the year ended December 31, 2023, the Company recorded expense of $2.2 million in research and development in the consolidated statement of operations, related to these Class A Ordinary Shares based on their grant-date fair value.

Share-based Compensation Expense

Share-based compensation expense for all equity arrangements for the year ended December 31, 2024 and 2023 was as follows:

	For the Year Ended December 31,	
	2024	2023
Research and development	$ 2,223	$ 2,978
General and administrative	14,575	6,677
Total share-based compensation expense	$ 16,798	$ 9,655

As of December 31, 2024, unrecognized compensation costs related to the unvested share options were $21.2 million, which the Company expects to recognize over a weighted-average period of 2.8 years. As of December 31, 2024, unrecognized compensation costs related to the unvested RSUs were $4.1 million which the Company expects to recognize over a weighted-average period of 2.2 years. As of December 31, 2024, unrecognized compensation costs related to the unvested RSAs were $2.3 million which the Company expects to recognize over a weighted-average period of 2.4 years.

10. Income Taxes

The components of loss before income taxes were as follows:

	For the Year Ended December 31,	
	2024	2023
U.S. operations	$ (41,837)	$ (36,842)
Non-U.S. operations	(10,566)	(23,721)
Loss before income taxes	$ (52,403)	$ (60,563)

Provision For Income Taxes

There is no provision for income taxes because the Company has incurred losses since its inception and maintains a full valuation allowance against its net deferred tax assets.

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	December 31,	
	2024	2023
Income tax at federal statutory rate	21.0 %	21.0 %
State income tax expense, net of federal tax effect	0.5 %	(1.7)%
Impact of non-U.S. earnings	(7.1)%	(0.3)%
Change in valuation allowance	(14.3)%	(18.9)%
Non-deductible share-based compensation	(0.3)%	(0.6)%
Permanent differences	(0.1)%	(0.6)%
Other	0.3 %	— %
Change in deferred tax rate	— %	1.1 %
	— %	— %

The difference between the United States ("U.S.") statutory federal income tax rate and the Company's effective tax rate in 2024 and 2023 is primarily attributable to no tax benefit being provided on pre-tax operating losses as the Company maintains a full valuation allowance against its deferred tax assets.

Deferred Tax Assets and Valuation Allowance

The significant components of the Company's net deferred tax assets were as follows:

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforward	$ 6,008	$ 6,947
Intangible assets acquired	10,833	9,496
Capitalized research and development	5,838	619
Share-based compensation	1,985	831
Capitalized start-up costs	764	—
Accrued expenses and other	233	—
Total deferred income tax assets	25,661	17,893
Valuation allowance	(25,661)	(17,893)
Total deferred income tax assets, net	$ —	$ —

In assessing the realizability of deferred tax assets, management 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, 2024, and 2023. 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 $7.8 million during 2024 resulting from current year losses for which no tax benefit was provided.

As of December 31, 2024, the Company had U.S. federal net operating loss ("NOL") carryforwards of approximately $12.4 million which may be carried forward indefinitely but are only available to offset 80% of future taxable income. In addition, the Company had $31.1 million of foreign net operating loss carryforwards of which $12.8 million was generated in the United Kingdom and $18.3 million was generated in the Cayman Islands. The NOLs generated in the United Kingdom can be carried forward indefinitely. The NOLs generated in the Cayman Islands have no value as the Cayman Islands do not impose any income tax on corporations. In addition, the Company also has approximately $12.2 million in state net operating loss carryforwards of which the Florida NOL of $0.4 million can be carried forward 20 years and the Virginia NOL of $11.8 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, 2024, 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.

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, 2024, 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, 2024.

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 2021 to 2024. The Company's state and United Kingdom tax years that are open to tax examination are 2020 to 2024.

11. 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.

12. Redeemable Noncontrolling Interest

As a finder's fee for the 2022 Lilly License, the Company's consolidated subsidiary Z33 issued 4,900,222 shares of Z33 Series Seed Preferred Shares to Stone Peach. Zura 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"). Stone Peach has the right, but not the obligation to sell up to 50% of the Series Seed Preferred Shares issued to Stone Peach to Zura for a price per share of $2.040724 (the "Put Option"). As it is 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 represents 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 may 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, 2023, the redeemable noncontrolling interest was accreted to its redemption value 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, 2023 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 and 2023, the redeemable noncontrolling interest balance was $11.7 million and $18.7 million, respectively.

13. 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, 2024 and 2023, the Company recorded expense of $0.3 million and $0.1 million, respectively for the defined contribution plans.

14. Subsequent Events

On January 1, 2025, the Class A Ordinary Shares reserved for future issuances under the Equity Incentive Plan and ESPP were each increased by the annual automatic increase of 5% of outstanding Class A Ordinary Shares as of December 31, 2024, or 3,264,877 Class A Ordinary Shares.

In the first quarter of 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 placement agent commissions.

In February 2025, the Company granted options to purchase 3,572,790 Class A Ordinary Shares to employees under the Equity Incentive Plan. The share options vest over four years.

Exhibit 4.6

DESCRIPTION OF THE COMPANY'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

General

We are a company incorporated in the Cayman Islands as an exempted company and our affairs are governed by our Second Amended and Restated Memorandum and Articles of Association (the "MAA"), the Cayman Islands Companies Act and the common law of the Cayman Islands. Pursuant to the MAA, our authorized share capital is $30,100 divided into 300,000,000 Class A Ordinary Shares of a par value of $0.0001 each, no Class B Ordinary Shares, and 1,000,000 Zura preference shares of a par value of $0.0001 each. The following description summarizes certain terms of our shares as set out more particularly in the MAA. Because it is only a summary, it may not contain all the information that is important to you.

Class A Ordinary Shares

Our shareholders of record are entitled to one vote for each share held on all matters to be voted on by shareholders.

The members of our Board of Directors serve until the next annual general meeting. There is no cumulative voting with respect to the appointment of directors, with the result that the holders of more than 50% of the shares eligible to vote for the appointment of directors and voting at the applicable meeting can appoint all of the directors. Subject to the rights of any holders of preference shares to appoint directors, the number of directors that shall constitute the Zura Board shall be as determined from time to time exclusively by the Zura Board.

Directors may only be removed for cause by a majority of the other directors then in office or by the affirmative vote of at least two-thirds of the total voting power of all then-outstanding shares of Zura entitled to vote thereon, voting together as a single class.

Our shareholders have no conversion, preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the ordinary shares.

Register of Members

Under Cayman Islands law, we must keep a register of members and there will be entered therein:

- the names and addresses of the members, a statement of the shares held by each member, and of the amount paid or agreed to be considered as paid, on the shares of each member and the voting rights of the shares of each member;
- whether voting rights are attached to the shares in issue;
- the date on which the name of any person was entered on the register as a member; and
- the date on which any person ceased to be a member.

Under Cayman Islands law, the register of members of our company is prima facie evidence of the matters set out therein (i.e. the register of members will raise a presumption of fact on the matters referred to above unless rebutted) and a member registered in the register of members will be deemed as a matter of Cayman Islands law to have legal title to the shares as set against its name in the register of members. However, there are certain limited circumstances where an application may be made to a Cayman Islands court for a determination on whether the register of members reflects the correct legal position. Further, the Cayman Islands court has the power to order that the register of members maintained by a company should be rectified where it considers that the register of members does not reflect the correct legal position. If an application for an order for rectification of the register of members were made in respect of our shares, then the validity of such shares may be subject to re-examination by a Cayman Islands court.

Founder Shares

Founder Shares were outstanding JATT Acquisition Corp ("JATT") Class B Ordinary Shares that automatically converted into Class A Ordinary Shares at the business combination's closing on a one-for-one basis, subject to adjustment. The Founder Shares are henceforth identical to the other Class A Ordinary Shares, and holders of Founder Shares have the same shareholder rights as public shareholders, except that (i) the Founder Shares are subject to certain transfer restrictions, as described in more detail below and (ii) the Founder Shares are entitled to registration rights.

With certain limited exceptions, the Founder Shares are not transferable, assignable or salable (except to permitted transferees, each of whom will be subject to the same transfer restrictions) until the earlier of (A) six months after the completion of the Business Combination or (B) subsequent to the Business Combination, (x) if the reported closing price of our Zura Class A Ordinary Shares equals or exceeds $12.00 per share (as adjusted for share sub-divisions, share dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the Business Combination or (y) the date, following the completion of the Business Combination, on which we complete a liquidation, merger, share exchange, reorganization or other similar transaction that results in all of our shareholders having the right to exchange their Class A Ordinary Shares for cash, securities or other property.

Preference Shares

Our MAA provide that preference shares may be issued from time to time in one or more series. Our board of directors are authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. Our board of directors are able to, without shareholder approval, issue preference shares with voting and other rights that could adversely affect the voting power and other rights of the holders of the Class A ordinary shares and could have anti-takeover effects. The ability of our board of directors to issue preference shares without shareholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management. We have no preference shares outstanding at the date hereof, and do not expect to have any preference shares outstanding immediately following consummation of the Business Combination. Although we do not currently intend to issue any preference shares, we cannot assure you that we will not do so in the future. No preference shares were issued or registered in connection with the Business Combination.

Registration Rights

March 2023 Amended & Restated Registration Rights Agreement (“A&R Registration Rights Agreement”)

On March 20, 2023, in connection with and effective upon the consummation of the Business Combination, Zura, JATT Ventures, L.P. and certain other parties entered into the A&R Registration Rights Agreement at the Closing, pursuant to which they agreed to register for resale certain Class A Ordinary Shares and other equity securities that are held by parties thereto from time to time. The A&R Registration Rights Agreement includes customary demand and piggyback registration rights.

With certain limited exceptions, certain of our Class A Ordinary Shares held by parties to the A&R Registration Rights Agreement are not transferable, assignable or salable (except to permitted transferees, each of whom will be subject to the same transfer restrictions) until the earlier of

(A) six months after the completion of the Business Combination or (B) subsequent to the Business Combination, (x) if the reported closing price of our Zura Class A Ordinary Shares equals or exceeds $12.00 per share (as adjusted for share sub-divisions, share dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the Business Combination or (y) the date, following the completion of the Business Combination, on which we complete a liquidation, merger, share exchange, reorganization or other similar transaction that results in all of our shareholders having the right to exchange their Class A Ordinary Shares for cash, securities or other property.

April 2023 Private Placement

Under the terms of the subscription agreements entered into with the investors (the “2023 Subscribers”) in the April 2023 Private Placement (the “2023 PIPE Subscription Agreements”), the Company agreed to prepare and file, within 45 days after the closing of the April 2023 Private Placement (the “2023 Filing Deadline”), one or more registration statements (each a “2023 PIPE Registration Statement”) with the SEC to register for resale the Class A Ordinary Shares (the “2023 PIPE Shares”) issued under the 2023 PIPE Subscription Agreements and the Class A Ordinary Shares issuable upon exercise of the pre-funded warrants (the “2023 Pre-Funded Warrants”) issued to purchase up to 3,782,000 Class A Ordinary Shares (the “2023 Warrant Shares”) issued pursuant to the 2023 PIPE Subscription Agreements, and to cause the applicable 2023 PIPE Registration Statement(s) to become effective within a specified period after the 2023 Filing Deadline. The Company also agreed to use its best efforts to keep such 2023 PIPE Registration Statement effective until the earlier of (i) the date all 2023 PIPE Shares and 2023 Warrant Shares held by or issuable to a 2023 Subscriber may be sold under Rule 144 (“Rule 144”) promulgated under the Securities Act without being subject to any volume or manner of sale requirements, (ii) the date on which all 2023 PIPE Shares and 2023 Warrant Shares have actually been sold pursuant to Rule 144 or pursuant to the 2023 PIPE Registration Statement and (iii) the date which is two years from the date that the initial 2023

PIPE Registration Statement is declared effective (or any Additional Effectiveness Date (as defined in the 2023 PIPE Subscription Agreements), if applicable). The Company filed the 2023 PIPE Registration Statement and it was declared effective by the SEC on September 14, 2023.

April 2024 Private Placement

Under the terms of the subscription agreements entered into with the investors (the "2024 Subscribers") in the April 2024 Private Placement (the "2024 PIPE Subscription Agreements"), the Company agreed to prepare and file, within 45 days after the closing of the April 2024 Private Placement (the "2024 Filing Deadline"), one or more registration statements (each a "2024 PIPE Registration Statement") with the SEC to register for resale the Class A Ordinary Shares (the "2024 PIPE Shares") issued under the 2024 PIPE Subscription Agreements and the Class A Ordinary Shares issuable upon exercise of the pre-funded warrants (the "2024 Pre-Funded Warrants" and, together with the 2023 Pre-Funded Warrants, the "Pre- Funded Warrants") issued to purchase up to 18,732,301 Class A Ordinary Shares (the "2024 Warrant Shares") issued pursuant to the 2024 PIPE Subscription Agreements, and to cause the applicable 2024 PIPE Registration Statement(s) to become effective within a specified period after the 2024 Filing Deadline. The Company also agreed to use its best efforts to keep such 2024 PIPE Registration Statement effective until the earlier of (i) the date all 2024 PIPE Shares and 2024 Warrant Shares held by or issuable to a 2024 Subscriber may be sold under Rule 144 ("Rule 144") promulgated under the Securities Act without being subject to any volume or manner of sale requirements, (ii) the date on which all 2024 PIPE Shares and 2024 Warrant Shares have actually been sold pursuant to Rule 144 or pursuant to the 2024 PIPE Registration Statement and (iii) the date which is two years from the date that the initial 2024 PIPE Registration Statement is declared effective (or any Additional Effectiveness Date (as defined in the 2024 PIPE Subscription Agreements), if applicable). The Company filed the 2024 PIPE Registration Statement on May 24, 2024, which was subsequently declared effective by the SEC on June 3, 2024.

Dividends

We have not paid any cash dividends on our ordinary shares to date and do not expect to pay cash dividends in the foreseeable future. The payment of cash dividends in the future will be dependent upon our ability to comply with relevant legal requirements as well as our revenues and earnings, if any, capital requirements and general financial condition. The payment of any dividends will be within the discretion of the Zura Board. It is the present intention of our board of directors to retain all earnings, if any, for use in our business operations and, accordingly, our board does not anticipate declaring any dividends in the foreseeable future.

Our Transfer Agent

The transfer agent for our Class A Ordinary Shares is Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004. We have agreed to indemnify Continental Stock Transfer & Trust Company in its roles as transfer agent, its agents and each of its shareholders, directors, officers and employees against all claims and losses that may arise out of acts performed or omitted for its activities in that capacity, except for any liability due to any gross negligence, willful misconduct or bad faith of the indemnified person or entity.

Listing of Our Securities

Our Class A Ordinary Shares are listed on Nasdaq under the symbol "ZURA".

Extraordinary General Meeting of Shareholders

Our MAA provide that the directors, the chief executive officer or the chairman of the board of directors may call general meetings, and they shall on a shareholders' requisition forthwith proceed to convene an extraordinary general meeting of the Company. A shareholders' requisition is a requisition of shareholders holding at the date of deposit of the requisition not less than 10% in par value of the issued shares which as at that date carry the right to vote at general meetings of the Company.

Advance Notice Requirements for Shareholder Proposals and Director Nominations

Our MAA provide that shareholders seeking to bring business before our annual general meeting, or to nominate candidates for election as directors at our annual general meeting, must provide timely notice of their intent in writing. To be timely, a shareholder's notice will need to be delivered to our principal executive offices not less than 120 calendar days before the date of the proxy statement released to shareholders in connection with the previous year's annual general meeting or, if we did not hold an annual general meeting in the previous year, or if the date of the current year's annual general meeting has been changed by more than 30 days from the date of the previous year's annual general meeting, then the deadline shall be set by our board of directors with such deadline being a reasonable time before we begin to print and send the related proxy materials. Our MAA also specify certain requirements as to the form and content of a shareholders' meeting. These provisions may preclude our shareholders from bringing matters before our annual general meeting or from making nominations for directors at our annual general meeting.

Authorized but Unissued Shares

Our authorized but unissued Zura Class A Ordinary Shares and preference shares are available for future issuances without shareholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Zura Class A Ordinary Shares and preference shares could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

ZURA BIO LIMITED INSIDER TRADING POLICY

I. Purpose

This Insider Trading Policy (this "***Policy***") states the policy with respect to transactions in the securities of Zura Bio Limited (the "***Company***"), and the handling of confidential information about the Company and other companies with which the Company does business. The Company's Board of Directors has adopted this Policy to promote compliance with federal and state securities laws that prohibit certain persons who are aware of material nonpublic information about a company from (i) trading in securities of that company or (ii) providing material nonpublic information to other persons who may trade on the basis of that information ("tipping").

II. Persons Subject to the Policy

This Policy applies to all members of the Company's Board of Directors (collectively, "**directors**" and each, a "**director**"), officers (which means "officers" as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")) and employees of the Company and its subsidiaries, as well as other persons as determined by the Company who have access to material nonpublic information about the Company , such as contractors or consultants (collectively, the "**Covered Persons**" and each a "**Covered Person**"). This Policy also applies to any Covered Person's family members, other members of that person's household, and entities whose transactions in securities are controlled by that person, as described below under "***Transactions by Related Persons and Others***" and "***Transactions by Entities That You Direct or Control.***"

III. Transactions Subject to the Policy

This policy applies to all transactions in the Company's securities, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of the Company's shares in the public market but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of ordinary shares, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities. Transactions in mutual funds that are invested in Company Securities are not transactions subject to this Policy. This Policy similarly applies to transactions in or relating to the securities of other publicly traded companies, as described below under "***Trading in Securities of Other Companies***."

IV. Individual Responsibility

Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in Company Securities while in possession of material nonpublic information. Each individual is responsible for making sure that he or she complies with this Policy, and that any Related Persons or Controlled Entity (each as defined below) whose transactions are subject to this Policy, as discussed below, also comply with this Policy. In all cases, the responsibility for determining whether an individual is in possession of material nonpublic information rests with that individual, and any action on the part of the Company, the Administrator (as defined below) or any other officer, employee or director pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this Policy or applicable securities laws, as described below under "***Consequences of Violations.***"

V. Administration of the Policy

The "***Administrator***" of this Policy is the Company's General Counsel, or such other individual designated by the Company's Board of Directors from time to time.

VI. Principal Statement of Policy

(a) Trading in Company Securities and Disclosure of Nonpublic Information. No director, officer or other employee of the Company (or any other person designated by this Policy or by the Administrator as subject to this Policy) who is aware of material nonpublic information relating to the Company may, directly or indirectly through family members or other persons or entities:

(i) engage in any transactions in Company Securities, except as otherwise specified in this Policy under the heading "***Limited Exceptions;***"

(ii) recommend the purchase or sale of any Company Securities;

(iii) disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or to persons outside of the Company, including, but not limited to, family, friends, business associates, investors and consultants, except as required in the performance of regular corporate duties and only to the extent appropriate confidentiality protections are effective and the disclosure conforms to Company policies; or

(iv) assist anyone engaged in the above activities.

(b) Trading in Securities of Other Companies. No director, officer or other employee of the Company (or any other person designated by this Policy or by the Administrator as subject to this Policy) who, in the course of your relationship with the Company, learns of **material nonpublic information** about a publicly traded company with which the Company does or intends to do business, including a customer, supplier, service provider or collaborator of the Company, may trade in that company's securities.

(c) No Exceptions. There are no exceptions to this Policy, except as specifically noted herein. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, are not excluded from this Policy. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

VII. Definition of Material Nonpublic Information

(a) Material Information. Information is considered "material" if it would influence a reasonable investor to buy, hold or sell securities. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight.

While it is not possible to define all categories of material information, some examples of information that ordinarily would be regarded as material are:

- operating or financial results or projections, including earnings guidance;
- analyst upgrades or downgrades of the Company or one of its securities;
- corporate transactions, such as mergers, acquisitions or restructurings;
- dividend, share repurchase or recapitalization matters;
- debt or equity financing matters;
- regulatory matters;
- clinical results or trial data;
- a change in the Board of Directors or senior management;
- a change in auditors or disagreements with auditors;
- impending bankruptcy or the existence of severe liquidity problems;
- litigation or regulatory proceedings and investigations;
- the imposition of a ban on trading in Company Securities or other securities;

- intellectual property and other proprietary information; and
- significant corporate developments, including with respect to research and development activities.

(b) Nonpublic Information. Information is considered "nonpublic" if that information has not been broadly disclosed to the marketplace, such as by press release or a filing with the U.S. Securities and Exchange Commission (the "***SEC***"), and/or the investing public has not had time to fully absorb that information. Nonpublic information may include:

- information available to a select group of persons subject to confidentiality obligations to the Company;
- undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and
- information that has been entrusted to the Company on a confidential basis.

As a general rule, information should not be considered fully absorbed by the investing public until the second business day after the day on which the information is released. If, for example, the Company makes an announcement at 9 am ET on Monday, a person subject to this Policy should not trade in Company Securities until the market opens on Wednesday. If such an announcement were made at 6 pm ET on Monday, the person subject to this Policy should not trade in Company Securities until the market opens on Thursday. Depending on the particular circumstances, the Company may determine that a longer or shorter period should apply.

VIII. Transactions by Related Persons and Others

This Policy applies to your family members who reside with you, anyone else who lives in your household and any family members who do not live in your household but whose transactions in Company Securities are directed by you or are subject to your direct or control, such as parents or children who consult with you before they trade in Company Securities (collectively, "**Related Persons**"). You are responsible for the transactions of your Related Persons and therefore should make them aware of the need to confer with you before they trade in Company Securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account.

IX. Transactions by Entities That You Direct or Control

This Policy applies to any entities that you direct or control, including any corporations, partnerships or trusts (collectively, "**Controlled Entities**"), and transactions by these Controlled Entities should be treated for the purposes of this Policy and applicable securities laws as if they were for your own account.

X. Limited Exceptions

This Policy does not apply in the case of the following transactions (although these transactions may nevertheless be subject to the requirements of Section 16 of the Exchange Act, applicable to directors and executive officers):

(a) Option Exercises. This Policy does not apply generally to the exercise of an option, including a cashless exercise solely through the Company or the exercise of a tax withholding right through the Company to satisfy tax withholding requirements. However, this Policy does apply to any sale of shares received upon exercise of an option, including any deemed sale caused by an election to make a cashless exercise through a broker, or any other market sale for the purpose of generating the cash necessary to pay the option exercise price and changes to the instructions regarding the level of withholding contributions that are used to purchase shares. This Policy also applies to an employee's initial election to participate in the Company's Employee Stock Purchase Plan ("***ESPP***"), changes to an employee's election to participate in the ESPP for any enrollment period and to the subsequent sale of shares acquired pursuant to the ESPP.

(b) Sell-to-Cover Transactions. This policy does not apply to the sale of shares for the limited purpose of covering tax withholding obligations (and any associated broker or other fees) (a "***sell-to-cover transaction***"), provided that, (i) if required by the Company, prior to such sale, you irrevocably elect to sell such shares to cover tax withholding obligations in a manner approved by the Company or (ii) such sell-to-cover transaction is effected pursuant to a sell-to-cover program mandated by the Company.

(c) **Sales in a Registered Public Offering.** This policy does not apply to sales of the Company's securities as a selling stockholder in a registered public offering in accordance with applicable securities laws.

(d) **Rule 10b5-1 Plans**. Rule 10b5-1 under the Exchange Act provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company Securities that meets certain conditions specified in the Rule (a "***Rule 10b5-1 Plan***"). If the plan meets the requirements of Rule 10b5-1, Company Securities may be purchased or sold without regard to certain insider trading restrictions. To comply with this Policy, a Rule 10b5-1 Plan must be approved by the Administrator and meet the requirements of Rule 10b5-1 and the Company's "*Guidelines for Rule 10b5-1 Plans.*" In general, to ensure that a Rule 10b5-1 Plan is entered into at a time when the person entering into the plan is not aware of material nonpublic information, it must be entered into during an Open Trading Window (as defined below). Any Rule 10b5-1 Plan must be submitted for approval at least five business days prior to the entry into the Rule 10b5-1 Plan.

(e) **401(k) Plan.** This Policy does not apply to purchases of Company Securities in the Company's 401(k) plan resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election. This Policy does apply, however, to certain elections you may make under the 401(k) plan, including: (i) an election to increase or decrease the percentage of your periodic contributions that will be allocated to any Company fund; (ii) an election to make an intra-plan transfer of an existing account balance into or out of any Company fund; (iii) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of any Company fund balance; and (iv) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to any Company fund.

XI. Special and Prohibited Transactions

The Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. Therefore, it is the Company's policy that any persons covered by this Policy may not engage in any of the following transactions, or should otherwise consider the Company's preferences as described below:

(a) ***Inherently Speculative Transactions.*** No Covered Person may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to the Company's shares.

(b) ***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Covered Person to continue to own the Company's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Covered Person may no longer have the same objectives as the Company's other shareholders. Therefore, Covered Persons are prohibited from engaging in any such transactions.

(c) ***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in the Company's securities, Covered Persons are prohibited from holding the Company's securities in a margin account or otherwise pledging the Company's securities as collateral for a loan.

(d) ***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Covered Person is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on the Company's securities. If a Covered Person determines that they must use a standing order or limit order (other than under an approved Rule 10b5-1 Plan, as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Restrictions" and "***Event-Specific Trading Restriction Periods***" provisions below.

XII. Additional Procedures

The Company has established additional procedures in order to assist the Company in the administration of this Policy, to facilitate compliance with laws prohibiting insider trading while in possession of material nonpublic information, and to avoid the appearance of any impropriety. These additional procedures are applicable only to those individuals described below.

(a) **Pre-Clearance Procedures**. No director, officer or designated employees or other persons of the Company and its subsidiaries, or the Related Persons and Controlled Entities of such persons ("***Restricted Persons***"), may engage in **any transaction** in Company Securities without first obtaining pre-clearance of the transaction from the Administrator. The list of Restricted Persons is updated periodically by the Administrator. You will be notified by the Administrator if you are considered a Restricted Person for purposes of this Policy. Restricted Persons should submit **a request for pre-clearance to the Administrator at least two business days in advance of the proposed transaction.** The Administrator is under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction. If a Restricted Person seeks pre- clearance and permission to engage in the transaction is denied, then he or she should refrain from initiating any transaction in Company Securities and should not inform any other person of the restriction.

When a request for pre-clearance is made, the requestor should carefully consider whether he or she may be aware of any material nonpublic information about the Company and should describe fully those circumstances to the Administrator. The requestor should also indicate whether he or she has effected any non-exempt "opposite-way" transactions (e.g., an open market sale would be "opposite" any open market purchase, and vice versa) within the past six months, and should be prepared to report the proposed transaction on an appropriate Form 4 or Form 5. The requestor should also be prepared to comply with SEC Rule 144 and file Form 144, if necessary, at the time of any sale.

A request for pre-clearance must be made in writing, preferably by submission of a completed Request for Pre-Clearance in the form of EXHIBIT A to this Policy. Pre-cleared transactions should be effected promptly, but by no later than two business days from the date of the Request for Pre-Clearance. Requestors are required to refresh the request for pre-clearance if a pre-cleared transaction is not effected within the prescribed two business days.

Furthermore, requestors must immediately notify the Administrator following the execution of any transaction.

(b) **Quarterly Trading Restrictions**. Restricted Persons may not conduct any transactions involving the Company's Securities (other than as specified by this Policy) except during an Open Trading Window. An "***Open Trading Window***" generally begins after two full trading days have elapsed since the public dissemination of the Company's quarterly (or annual) earnings and ends 15 calendar days prior to the end of the then current quarter. The Administrator will notify Restricted Persons of the opening and closing of the trading window.

(c) **Event-Specific Trading Restriction Periods**. From time to time, an event may occur that is material to the Company and is known by only a few individuals. So long as the event remains material and nonpublic, the persons designated by the Administrator may not trade Company Securities. In addition, material developments impacting the Company may occur in a particular fiscal quarter that, in the judgment of the Administrator, make it advisable that designated persons should refrain from trading in Company Securities even during the ordinary Open Trading Window described above. In that situation, the Administrator may notify these persons that they should not trade in the Company's Securities, without disclosing the reason for the restriction. The existence of an event-specific trading restriction period or the closing of the Open Trading Window will be announced by the Administrator to persons designated by the Administrator. **Even if the Administrator has not designated you a person who should not trade due to an event-specific restriction, you may not trade while aware of material nonpublic information.**

(d) Exceptions.

(i) The quarterly trading restrictions and event-driven trading restrictions do not apply to those transactions to which this Policy does not apply, as described above under the heading "***Limited Exceptions,***" nor do they apply to an election to participate in an employer plan during an open enrollment period.

(ii) The Administrator in his or her discretion may approve other or further exceptions to these requirements on a case-by-case basis in extraordinary circumstances. Any request for an exception pursuant to this paragraph must be submitted in advance and in writing, and any approval must be in writing.

XIII. Post-Termination Transactions

This Policy continues to apply to transactions in Company Securities even after termination of service to the Company. If an individual is in possession of material nonpublic information when his or her service terminates, that individual may not trade in Company Securities until that information has become public or is no longer material. The pre-clearance procedures specified under the heading "***Additional Procedures***" above and applicable to directors and certain executives will continue to apply for a period of six months after a termination of service, in order to facilitate compliance with Section 16 of the Exchange Act.

XIV. Consequences of Violations

The purchase or sale of securities while aware of material nonpublic information, or the disclosure of material nonpublic information to others who then trade in the Company's Securities, is prohibited by federal and state laws. Insider trading violations are pursued vigorously by the SEC, the U.S. Department of Justice and state enforcement authorities. Punishment for insider trading violations is severe and could include significant fines and imprisonment. While the regulatory authorities concentrate their efforts on the individuals who trade, or who tip inside information to others who trade, the federal securities laws also impose potential liability on companies and other "controlling persons" if they fail to take reasonable steps to prevent insider trading by company personnel.

In addition, an individual's failure to comply with this Policy may subject the individual to Company-imposed sanctions, up to and including termination of employment, whether or not the employee's failure to comply results in a violation of law. Needless to say, a violation of law, or even an SEC investigation that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career.

XV. Reporting of Violations

Any person who violates this Policy or any federal or state law governing insider trading or tipping, or who knows of or reasonably suspects any such violation by another person, should report the matter immediately to his or her supervisor and/or to the Administrator identified in Section 5. Employees are obligated to report suspected and actual violations of Company policy or the law. Doing so brings the concern into the open so that it can be resolved quickly and more serious harm can be prevented. Failure to do so could result in disciplinary action up to and including termination of employment.

If you encounter a situation or are considering a course of action and its appropriateness is unclear, do not hesitate to reach out the Administrator with any questions; even the appearance of impropriety can be very damaging and should be avoided, and the Administrator may be in the best position to provide helpful information or other resources.

XVI. Certification

All persons subject to this Policy may be required to certify and re-certify, from time to time, their understanding of, and intent to comply with, this Policy.

XVII. Amendment

This Policy may be amended by the Board of Directors or any committee or designee to which the Board of Directors delegates this authority.

The Administrator has the authority to make determinations under, and interpretations of, this Policy, as specified in this Policy under the heading "***Administration of the Policy.***" In addition, the Administrator is authorized to approve amendments to this Policy that: (i) correct obvious errors (e.g., typographical or grammatical errors); (ii) are necessitated by changes in legal requirements; (iii) are necessary to clarify the meaning of this Policy; or (iv) are administrative in nature, such as the provisions of this Policy under the heading "***Additional Procedures.***"

Effective: *March 27, 2023*

Amended and Restated: March 24, 2025

Exhibit A

Request for Pre-Clearance*

For pre-clearance to transact in Company Securities.

Upon executing a transaction, Restricted Persons must immediately notify the Company.

Transaction Vehicle (check one)	**Transaction Initiated By (check one)**
☐ Open Market Transaction	☐ Employee or immediate family member directly
☐ Equity Compensation Plan	☐ Court or government decree (e.g., divorce decree)
☐ Other (specify): ____________________	☐ Broker (provide name, firm, telephone and e-mail): ____
Type of Transaction (check one)	
☐ Purchase or acquire Company Securities	
☐ Sell or dispose of Company Securities	
☐ Move Company Securities from one account to another (e.g., in or out of a trust)	
☐ Dispose of fractional shares	
☐ Pledge Company Securities for margin account, or otherwise	
☐ Exercise options without subsequent sale	
☐ Exercise options with subsequent sale (e.g., a "cashless exercise")	
Other (describe):____	
Transaction Detail (provide the following information)	
Number of securities: _________________________	
Estimated share price: _________________________	
Contemplated execution date: _____________________	
Date of your last "opposite way" transaction**:_________________	

Certification

I certify that I have fully disclosed the information requested in this form, I have read the Zura Bio Limited Insider Trading Policy, I am not in possession of material nonpublic information, and to the best of my knowledge and belief the proposed transaction will not violate the Zura Bio Limited Insider Trading Policy.

____
(Sign Above)

____
(Print Name Above)

____
(Date)

∗ *Capitalized terms used but not defined herein have the meanings ascribed to them in the Zura Bio Limited Insider Trading Policy.*

∗∗ *If a Section 16 insider buys and sells (or sells and buys) Company Securities within a six-month time frame and such transactions are not exempt under SEC rules, the two transactions can be "matched" for purposes of Section 16. The insider may be sued and will be strictly liable for any profits made,* ***regardless of whether the insider was in possession of material nonpublic information****.*

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 24, 2025, relating to the consolidated financial statements, which appear in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey
March 24, 2025

Exhibit 31.1

Certification of Principal Executive Officer

Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert Lisicki, 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the 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) 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

(c) 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 officers 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/ Robert Lisicki
Robert Lisicki
Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2025

Exhibit 31.2

Certification of Principal Financial Officer

Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Verender Badial, 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the 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) 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

(c) 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 officers 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/ Verender Badial
Verender Badial
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 25, 2025

Exhibit 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

In connection with the Annual Report of Zura Bio Limited (the “Company”) on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Robert Lisicki, 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:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the period covered by the Report.

/s/ Robert Lisicki
Robert Lisicki
Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2025

Exhibit 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

In connection with the Annual Report of Zura Bio Limited (the "Company") on Form 10-K for the year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Verender Badial, 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:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Verender Badial
Verender Badial
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 25, 2025