Zura Bio Reports Second Quarter 2024 Financial Results and Recent Business Highlights

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- *Presented data for tibulizumab at EULAR 2024, highlighting the potential relevance of dual-inhibition of both IL-17A and BAFF in autoimmune and inflammatory diseases*
- *Expect to initiate Phase 2 studies evaluating tibulizumab for the treatment of systemic sclerosis (SSc) in 4Q 2024 and hidradenitis suppurativa (HS) in 2Q 2025*
- *Strengthened management and advisory team with appointment of Robert Lisicki as CEO & formation of Scientific Advisory Board*
- *Cash, cash equivalents and investments of $188.4 million as of June 30, 2024, including $112.5 million from private placement executed in April 2024, anticipated to support operations as currently planned through 2027*

HENDERSON, Nev.--(BUSINESS WIRE)--Aug. 13, 2024-- Zura Bio Limited (Nasdaq: ZURA) (“Zura Bio”), a clinical stage, multi-asset immunology company developing novel dual-pathway antibodies for autoimmune and inflammatory diseases, today reported its second quarter 2024 financial results, and recent business highlights.

"We have made meaningful progress on our key development programs this quarter. Highlights include selecting our CRO for the Phase 2 clinical program in SSc and advancing study start-up activities to ensure timely execution for both SSc and HS. Additionally, the tibulizumab data presented at EULAR highlighted our dual-inhibition approach and target engagement. We are eager to demonstrate the broad potential of tibulizumab as we plan to advance into Phase 2 studies for SSc this year and for HS in the first half of 2025," said Robert Lisicki, CEO of Zura Bio. "We are also excited to have established a Scientific Advisory Board, composed of leading experts in rheumatology, dermatology, and immunology. We remain committed to our mission of expanding treatment options for patients living with autoimmune disease."

RECENT BUSINESS AND FINANCIAL HIGHLIGHTS

- Completed a warrant exchange program to simplify the capital structure in August 2024.
- Presented data on the tibulizumab program at EULAR 2024, highlighting the potential relevance of dual inhibition of both IL-17A and BAFF in autoimmune and inflammatory diseases in June 2024.
    - Key findings from a randomized, double-blind, placebo-controlled Phase 1 study of tibulizumab in Sjogren’s syndrome include increased serum levels of total IL-17A and BAFF following tibulizumab administration, reflecting target engagement.
    - Key findings from a preclinical study of tibulizumab in a rheumatoid arthritis model demonstrate a reduction in inflammation through the combined inhibition of IL-17A and BAFF, compared to the control group ($p<0.05$).
- Broadened expertise with appointment of Robert Lisicki as CEO in April 2024 and formation of a Scientific Advisory Board (SAB) comprised of leading experts in rheumatology, dermatology, and immunology in June 2024.
    - Appointed Robert Lisicki as Chief Executive Officer and as a director on the Company’s Board of Directors, succeeding founding CEO Dr. Someit Sidhu, who remains on the Board of Directors.
    - The five founding members of the SAB are Johann Gudjonsson, M.D, Ph.D., Dinesh Khanna, M.D., M.Sc., Ajay Nirula, M.D., Ph.D., Michael Weinblatt, M.D. and Steven

Ziegler, Ph.D.

- Raised approximately $112.5 million in gross proceeds from a private placement in April 2024, with such proceeds expected to:
  - Support the accelerated development of tibulizumab, including the planned Phase 2 clinical study in SSc with an open-label extension, and the initiation of a Phase 2 study in HS.
  - Extend the cash runway through 2027.
- ZB-168 was assigned the International Nonproprietary Name (INN) “crebankitug.”
- Launched a new Zura Bio corporate website at www.zurabio.com in July 2024.

Cash and cash equivalents: Cash and cash equivalents were $188.4 million as of June 30, 2024, as compared to $99.8 million as of December 31, 2023. Zura Bio anticipates that its existing cash and cash equivalents and investments should be sufficient to support operations as currently planned through 2027.

Research and Development (R&D) expenses: R&D expenses were $5.5 million for the second quarter of 2024, a decrease of $22.7 million compared to $28.2 million for the same period in 2023. The decrease was primarily due to $27.2 million related to the acquisition of tibulizumab from Eli Lilly and Company (“Lilly”) during the three months ended June 30, 2023. This decrease was partially offset by an increase of $1.5 million in expenses related to compensation for personnel in R&D functions including share-based compensation and an increase of $2.3 million of costs incurred for consulting services and manufacturing of product candidates, in addition to an increase of $0.7 million for an annual milestone payment related to the 2023 Lilly License incurred during the three months ended June 30, 2024.

General and Administrative (G&A) expenses: G&A expenses were $6.2 million for the first quarter of 2024, an increase of $0.5 million compared to $5.7 million for the same period in 2023. The increase was primarily due to increases of $0.4 million in expenses related compensation for personnel in executive and administrative functions including share-based compensation, as well as an increase of $0.1 million in professional fees for legal and accounting costs incurred related to ongoing operations as a public company, as well as travel and office expenses.

Net loss: Net loss for the second quarter of 2024 was $12.7 million or $0.17 per share compared to $44.9 million or $1.31 per share for the same period in 2023.

RECENT AND UPCOMING ANTICIPATED MILESTONES

Tibulizumab, a humanized bispecific dual antagonist antibody that neutralizes both IL-17A and BAFF, is expected to enter Phase 2 clinical development for the treatment of SSc and HS.

- In the second quarter of 2024, Zura Bio received Type B feedback from the US FDA and expects to initiate a Phase 2 clinical study in SSc in the fourth quarter of 2024.
- In July 2024, Zura Bio entered into a start-up agreement with a third-party CRO to manage and conduct the Phase 2 clinical program in SSc.
- A second Phase 2 clinical study in patients with HS is expected to initiate in the second quarter of 2025.

Crebankitug, also known as ZB-168, is a high-affinity, fully human monoclonal antibody that neutralizes the IL-7 receptor alpha (IL-7Rα) chain, potentially blocking the immune pathways of IL-7 and thymic stromal lymphopoietin (TSLP). Zura Bio is monitoring external read-outs of other companies relating to IL-7R inhibitors in conditions such as ulcerative colitis (UC), atopic dermatitis (AD), and alopecia areata (AA). Zura Bio expects to utilize data from anticipated external readouts to help inform its initial indication selection for crebankitug by the end of 2024, with ongoing indication planning for other potential areas of unmet need.

Torudokimab is a fully human, high affinity monoclonal antibody that neutralizes IL-33, preventing ST2-dependent and ST2-independent (e.g., RAGE) inflammation. Zura Bio is actively monitoring Phase 2 and Phase 3 IL-33 external data releases from other companies related to asthma and chronic obstructive pulmonary disease.

ABOUT ZURA BIO

Zura Bio is a clinical-stage, multi-asset immunology company developing novel dual-pathway antibodies for autoimmune and inflammatory diseases. Currently, Zura Bio is developing three assets which have completed Phase 1/1b studies and are Phase 2 ready. The company is developing a portfolio of therapeutic indications for tibulizumab (ZB-106), crebankitug (ZB-168), and torudokimab (ZB-880), with a goal of demonstrating their efficacy, safety, and dosing convenience in autoimmune and inflammatory diseases, including systemic sclerosis and other novel indications with unmet needs.

FORWARD-LOOKING STATEMENTS

This communication includes “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believe,” “predict,” “potential,” “continue,” “strategy,” “future,” “opportunity,” “would,” “seem,” “seek,” “outlook,” “goal,” “mission,” and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties that could cause the actual results to differ materially from the expected results. These statements are based on various assumptions, whether or not identified in this communication. These forward-looking statements in this release include, but are not limited to, statements regarding: Zura Bio’s forecasts, including with respect to its cash resources, and Zura Bio’s expectations regarding funding, operating and working capital expenditures, business strategies and objectives; expectations with respect to data readouts and the timing thereof; Zura Bio’s product candidates, clinical trials and the design and timing thereof, statements with respect to the potential of product candidates; and expectations with respect to Zura Bio’s development program, including

clinical trials and the timing thereof, and expectations with respect to development programs, data readouts and product candidates of other parties. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, an assurance, a prediction or a definitive statement of fact or probability.

Actual events are difficult or impossible to predict and could differ materially from those expressed or implied in such forward-looking statements, as a result of these risks and uncertainties, which include, but are not limited to: the potential of Zura Bio's product candidates and their related benefits, competing product candidates and products both in development and approved; Zura Bio's vision and strategy; the timing of key events and initiation of Zura Bio's studies and release of clinical data may take longer than anticipated or may not be achieved at all; the potential general acceptability and maintenance of Zura Bio's product candidates by regulatory authorities, payors, physicians, and patients may not be achieved; Zura Bio's ability to attract and retain key personnel; Zura Bio's future operating expenses, capital requirements and needs for additional financing may not be achieved; Zura Bio has not completed any clinical trials, and has no products approved for commercial sale; Zura Bio has incurred significant losses since inception, and expects to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future; Zura Bio requires substantial additional capital to finance its operations, and if it is unable to raise such capital when needed or on acceptable terms, Zura Bio may be forced to delay, reduce, and/or eliminate one or more of its development programs or future commercialization efforts; Zura Bio may be unable to renew existing contracts or enter into new contracts; Zura Bio relies on third-party contract development manufacturing organizations for the manufacture of clinical materials; Zura Bio relies on contract research organizations, clinical trial sites, and other third parties to conduct of its preclinical studies and clinical trials; Zura Bio may be unable to obtain regulatory approval for its product candidates, and there may be related restrictions or limitations of any approved products; Zura Bio may be unable to successfully respond to general economic and geopolitical conditions; Zura Bio may be unable to effectively manage growth; Zura Bio faces competitive pressures from other companies worldwide; Zura Bio may be unable to adequately protect its intellectual property rights; and other factors set forth in documents filed, or to be filed by Zura Bio, with the SEC, including the risks and uncertainties described in the “Risk Factors” section of Zura Bio's Annual Report on Form 10-K for the year ended December 31, 2023 and other filings with the SEC. These risks and uncertainties may be amplified by health epidemics or other unanticipated global disruption events, which may continue to cause economic uncertainty. Zura Bio cautions that the foregoing list of factors is not exclusive or exhaustive and not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Zura Bio gives no assurance that it will achieve its expectations. Zura Bio does not undertake or accept any obligation to update any forward-looking statements, except as required by law.

ZURA BIO LIMITED
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	June 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 188,443	$ 99,806
Prepaid expenses and other current assets	1,032	1,037
Total current assets	189,475	100,843
Property and equipment, net	25	—
Total assets	$ 189,500	$ 100,843
Liabilities, Redeemable Noncontrolling Interest and Shareholders’ Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 15,073	$ 20,302
Total current liabilities	15,073	20,302
Private placement warrants	2,364	990
Total liabilities	17,437	21,292
Commitments and contingencies (Note 9)		
Redeemable noncontrolling interest	14,000	18,680
Shareholders’ Equity:		
Class A Ordinary shares, $0.0001 par value, 300,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 63,683,806 and 43,593,678 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	6	4
Additional paid-in capital	278,086	162,820
Accumulated deficit	(121,570)	(103,494)
Total Zura Bio Limited shareholders’ equity	156,522	59,330
Noncontrolling interest	1,541	1,541
Total shareholders’ equity	158,063	60,871
Total liabilities, redeemable noncontrolling interest and shareholders’ equity	$ 189,500	$ 100,843

ZURA BIO LIMITED
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
Unaudited

	For the Three Months Ended June 30,	
	2024	2023
Operating expenses:		
Research and development	$ 5,539	$ 28,230
General and administrative	6,220	5,675
Total operating expenses	11,759	33,905
Loss from operations	(11,759)	(33,905)
Other (income)/expense, net:		
Other (income)/expense	(2)	(7)
Interest income	(2,196)	—
Dividend income	—	(405)
Change in fair value of private placement warrants	768	532
Change in fair value of note payable	—	—
Total other (income)/expense, net	(1,430)	120
Loss before income taxes	(10,329)	(34,025)
Income tax benefit	—	—
Net loss before redeemable noncontrolling interest	(10,329)	(34,025)
Net loss attributable to redeemable noncontrolling interest	—	—
Net loss	(10,329)	(34,025)
Accretion of redeemable noncontrolling interest to redemption value	(2,337)	—
Deemed dividend to redeemable noncontrolling interest	—	(10,875)
Adjustment of redeemable noncontrolling interest from redemption value to carrying value	—	—
Net loss attributable to Class A Ordinary Shareholders of Zura	$ (12,666)	$ (44,900)
Net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	$ (0.17)	$ (1.31)
Weighted-average Class A Ordinary Shares used in computing net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	74,947,369	34,303,125

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