Zura Bio Reports Third Quarter 2024 Financial Results and Recent Corporate Updates

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- *Expect to initiate Phase 2 studies evaluating tibulizumab for the treatment of systemic sclerosis (SSc) in Q4 2024 and hidradenitis suppurativa (HS) in Q2 2025*
- *Cash, cash equivalents and investments totaling $188.2 million as of September 30, 2024, are anticipated to support operations, as currently planned, through 2027*

HENDERSON, Nev.--(BUSINESS WIRE)--Nov. 7, 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 financial results for the third quarter of 2024 and recent corporate updates.

"In the third quarter of 2024, we made significant progress toward initiating our first Phase 2 trial of tibulizumab in SSc. We’ve worked closely with our contract research organization (CRO) to begin trial readiness and prepare for site activation," said Robert Lisicki, CEO of Zura Bio. “Additionally, we've selected a CRO to support the anticipated Phase 2 trial initiation for tibulizumab in HS in the second quarter of 2025. We're excited to advance toward these milestones and highlight tibulizumab's potential as a best-in-class therapy for these underserved diseases."

RECENT UPDATES AND UPCOMING ANTICIPATED MILESTONES:

Tibulizumab

Systemic sclerosis

- In September 2024, the protocol for the Phase 2 clinical program in systemic sclerosis was finalized.
- The Orphan Drug Designation application was completed, and the request was submitted to the U.S. Food and Drug Administration (FDA) in Q4 2024.
- The Phase 2 clinical trial of tibulizumab for the treatment of SSc is anticipated to initiate in Q4 2024.

Hidradenitis suppurativa

- In September 2024, a third-party CRO was selected to oversee and conduct the Phase 2 clinical program in HS.
- The Pre-IND meeting request was submitted in Q4 2024 and the IND submission to the FDA for a Phase 2 trial of tibulizumab in HS is expected in Q1 2025.
- The Phase 2 trial of tibulizumab for the treatment of HS is anticipated to initiate in Q2 2025.

Crebankitug

- Ongoing monitoring of external Phase 2 data releases from other companies relating to IL-7Rα inhibitors in development for conditions such as ulcerative colitis, atopic dermatitis and alopecia areata.

Torudokimab

- Ongoing monitoring of external Phase 2 and Phase 3 IL-33/ST2 data releases from other

companies related to asthma and chronic obstructive pulmonary disease.

Corporate Highlights

- In August 2024, the company successfully completed a warrant exchange program, simplifying its capital structure.
- As of September 2024, an “at-the-market” (ATM) program is in place, providing the company with increased financial flexibility.

THIRD QUARTER 2024 FINANCIAL RESULTS:

Cash and Cash Equivalents

Cash and cash equivalents were $188.2 million as of September 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.

Operating Results

Research and development expenses were $6.0 million for the third quarter of 2024, an increase of $2.0 million compared to $4.0 million for the same period in 2023. The increase was primarily due to an increase of $1.7 million in personnel compensation for research and development functions including share-based compensation and an increase of $0.9 million for consulting services costs for preparation of clinical trials, partially offset by a decrease of $0.7 million in manufacturing costs.

General and Administrative expenses were $13.3 million for the third quarter of 2024, an increase of $7.1 million compared to $6.2 million for the same period in 2023. The increase was primarily due to $5.3 million in share-based compensation, driven by a one-time non-cash expense, as well as $1.6 million in fees related to the warrant exchange.

Net Loss

Net loss for the third quarter of 2024 was $22.9 million or $0.26 per share compared to $8.3 million or $0.18 per share for the same period in 2023.

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. 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 regulatory matters, 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: Zura Bio’s expectations regarding its product candidates and their related benefits, and Zura Bio’s beliefs regarding competing product candidates and products both in development and approved, may not be achieved; Zura Bio's vision and strategy may not be successful; the timing of key events and initiation of Zura Bio's studies, regulatory matters 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 expectations with respect to its 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 Securities and Exchange Commission (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)

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 188,221	$ 99,806
Prepaid expenses and other current assets	754	1,037
Total current assets	188,975	100,843
Property and equipment, net	44	—
Other assets	52	—
Total assets	$ 189,071	$ 100,843
Liabilities, Redeemable Noncontrolling Interest and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 18,244	$ 20,302
Total current liabilities	18,244	20,302
Private placement warrants	-	990
Total liabilities	18,244	21,292
Commitments and contingencies		
Redeemable noncontrolling interest	16,240	18,680
Shareholders' Equity:		
Preferred shares, $0.0001 par value, 1,000,000 authorized as of September 30, 2024, and December 31, 2023; -0- issued and outstanding as of September 30, 2024, and December 31, 2023	—	—
Class A Ordinary Shares, $0.0001 par value, 300,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 65,293,530 and 43,593,678 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	7	4
Additional paid-in capital	295,311	162,820
Accumulated deficit	(142,272)	(103,494)
Total Zura Bio Limited shareholders' equity	153,046	59,330
Noncontrolling interest	1,541	1,541
Total shareholders' equity	154,587	60,871
Total liabilities, redeemable noncontrolling interest and shareholders' equity	$ 189,071	$ 100,843

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

	For the Three Months Ended September 30,	
	2024	2023
Operating expenses:		
Research and development	$ 6,029	$ 3,965
General and administrative	13,290	6,222
Total operating expenses	19,319	10,187
Loss from operations	(19,319)	(10,187)
Other (income)/expense, net:		
Other (income)/expense, net	(22)	4
Interest income	(2,461)	(815)
Dividend income	—	(987)
Change in fair value of private placement warrants	3,866	(119)
Change in fair value of note payable	—	—
Total other (income)/expense, net	1,383	(1,917)
Loss before income taxes	(20,702)	(8,270)
Income tax benefit	—	—

Net loss before redeemable noncontrolling interest	(20,702)	(8,270)
Net loss attributable to redeemable noncontrolling interest	—	—
Net loss	(20,702)	(8,270)
Accretion of redeemable noncontrolling interest to redemption value	(2,240)	—
Net loss attributable to Class A Ordinary Shareholders of Zura	$ (22,942)	$ (8,270)
Net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	$ (0.26)	$ (0.18)
Weighted-average Class A Ordinary Shares used in computing net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	87,335,667	46,876,344

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Megan K. Weinshank
Head of Corporate Affairs
ir@zurabio.com

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