Zura Bio Reports Third Quarter 2023 Financial Results and Recent Business Highlights

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- *Initiating Phase 2 clinical trials in 2024 to evaluate ZB-106 (tibulizumab) in systemic sclerosis and hidradenitis suppurativa, and ZB-168 in alopecia areata*
- *Experienced team building the next Immunology leader*
- *Cash position of $103.9 million in cash, cash equivalents and investments is expected to support development and operations into 2026*

HENDERSON, Nev.--(BUSINESS WIRE)--Nov. 13, 2023-- Zura Bio Limited (Nasdaq: ZURA) ("Zura Bio") a multi-asset clinical-stage biotechnology company focused on developing novel medicines for immune and inflammatory disorders, today announced its financial results for the quarter ended September 30, 2023, and recent business highlights.

"In the third quarter, Zura Bio made significant progress in its strategic planning across various key areas, including Clinical, Regulatory, CMC, and Translational Science. This progress positions Zura Bio for clinical trial readiness in 2024," stated Dr. Someit Sidhu, Chief Executive Officer of Zura Bio. "In support of the upcoming clinical trial for ZB-168, an anti-IL-7R monoclonal antibody intended for the treatment of alopecia areata, we achieved several milestones. These include the submission and feedback from a Type B meeting request to the United States Food and Drug Administration, the transfer of technology to our Contract Development and Manufacturing Organization, and the selection of a Contract Research Organization to assist with site selection and the initiation of trial activities in the coming months. Furthermore, we are excited to announce our collaboration with the Benaroya Research Institute through a sponsored research agreement. This collaboration aims to further our understanding of the pivotal role of IL-7Rα in TSLP and IL-7 signaling pathways. As we continue to strengthen our scientific rationale and gather more data, we look forward to sharing additional insights. Beyond our work on ZB-168, we are actively engaged in planning and collaboration with thought leaders and experts to advance our leading asset, ZB-106, in the treatment of systemic sclerosis and hidradenitis suppurativa. We anticipate commencing clinical activities in the second half of 2024."

THIRD QUARTER 2023 BUSINESS HIGHLIGHTS

- Progressed planning across three indications: ZB-168 is the first clinical trial to initiate in 2024 in alopecia areata, followed by ZB-106 clinical trials in 2H-2024 for systemic sclerosis and hidradenitis suppurativa.
- Entered into a sponsored research agreement with Benaroya Research Institute, focused on further characterizing the pivotal role of Interleukin-7 receptor alpha (IL-7Rα) in Thymic Stromal Lymphopoietin (TSLP) and Interleukin-7 (IL-7) signaling pathways and leveraging the expertise of Dr. Steve Ziegler, a world-renown authority in TSLP and IL-7 biology. This collaboration will further characterize the critical role of IL-7Rα in regulating these pathways (and the potential impact on immune and inflammatory disorders. Press Release, September 12, 2023)

THIRD QUARTER 2023 FINANCIAL HIGHLIGHTS

Cash and cash equivalents: Cash and cash equivalents were $103.9 million as of September 30, 2023, as compared to $1.6 million as of December 31, 2022. The increased cash balance is primarily due to the aggregate of capital raised from closing of the Business Combination Agreement in March 2023 and the private placement transaction in April 2023. Zura Bio anticipates that its cash and cash equivalents are sufficient to fund its planned operations into 2026.

Research and Development (R&D) expenses: R&D expenses were $4.0 million for the third quarter ended September 30, 2023, compared to $0.4 million for the third quarter ended September 30, 2022. The increase was primarily due to $3.1 million in expenses for manufacturing clinical trial materials and an increase of $0.5 million incurred for clinical and regulatory consulting services.

General and Administrative (G&A) expenses: G&A expenses were $6.2 million for the third quarter ended September 30, 2023, compared to $0.7 million for the third quarter ended September 30, 2022. This increase was primarily due to additional compensation for personnel in executive and administrative functions and increased legal and accounting costs to support ongoing operations as a public company.

Net loss: Net loss for the third quarter ended September 30, 2023, was $8.3 million or $(0.18) per share compared to $1.1 million or $(2.87) per share for the third quarter ended September 30, 2022.

IMPORTANT UPCOMING ANTICIPATED EVENTS FOR ZURA BIO

ZB-106 (tibulizumab): Initiate Phase 2 trials of ZB-106, an anti-IL-17 and anti-BAFF dual antagonist, for the treatment of systemic sclerosis and hidradenitis suppurativa in 2H-2024.

ZB-168: Initiate Phase 2 trial of ZB-168, an anti-IL-7Rα inhibitor, in 2024. Pending Phase 2 IL-7R external catalysts in ulcerative colitis, atopic dermatitis and additional TSLP driven catalysts.

ZB-880 (torudokimab): Conduct all necessary CMC and regulatory readiness to prepare ZB-880, an anti-IL-33 antibody, for Phase 2 in allergy or respiratory related indications. Pending Phase 2 and Phase 3 external catalysts in asthma and chronic obstructive pulmonary disease.

ABOUT ZURA BIO

Zura Bio is a multi-asset clinical-stage biotechnology company focused on developing novel medicines for immune and inflammatory disorders. 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 ZB-106 (tibulizumab), ZB-168, and ZB-880 (torudokimab) with a goal of demonstrating their efficacy, safety, and dosing convenience in immune and inflammatory disorders, including systemic sclerosis, hidradenitis suppurativa, and other novel indications with unmet needs.

ABOUT ZB-106 (tibulizumab)

ZB-106 (tibulizumab) is a potential first-in-class, anti-IL-17 and anti-BAFF dual antagonist that Zura Bio plans to develop for the treatment of systemic sclerosis and hidradenitis suppurativa. ZB-106 is an IgG-scFv bispecific dual-antagonist antibody engineered by the fusion of Taltz® (ixekizumab) and tabalumab that neutralizes IL-17A and BAFF. ZB-106 has been assessed in two Phase 1b studies completed in rheumatoid arthritis and Sjögren's syndrome. The safety profile to date appears to be acceptable, with no new findings relative to known IL-17 and BAFF inhibitors. Chronic toxicology studies have been completed with no adverse drug-related findings. Phase 2 clinical trials of ZB-106 in systemic sclerosis and hidradenitis suppurativa are planned to initiate 2H-2024.

ABOUT ZB-168

ZB-168 is a fully human, high affinity monoclonal antibody that binds and neutralizes the IL-7 receptor chain (“IL-7R”) alpha. IL-7Rα sits at the nexus of two key immune pathways (IL-7 and TSLP), thus inhibiting IL-7Rα has the potential to block activation through both of these pathways. As a result, we believe ZB-168 could be therapeutically beneficial in a broad set of indications where the IL-7 or TSLP pathways may be involved. ZB-168 has been assessed in Phase 1/1b clinical studies in Type 1 diabetes and multiple sclerosis. Safety and pharmacokinetics were evaluated and the safety profiles from these studies support further development. A Phase 2 clinical trial of ZB-168 in alopecia areata is planned to initiate in 2024.

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” 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 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 and circumstances are difficult or impossible to predict and will differ from assumptions. You should carefully consider the risks and uncertainties described in the “Risk Factors” sections of Zura Bio’s recent filings with the SEC. These filings would identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Many of these factors are outside Zura Bio’s control and are difficult to predict. Many factors could cause actual future events to differ from the forward-looking statements in this communication, including but not limited to: (1) the outcome of any legal proceedings that may be instituted against Zura Bio; (2) volatility in the price of Zura Bio’s securities; (3) the ability of Zura Bio to successfully conduct research and development activities, grow and manage growth profitably, maintain relationships with customers and suppliers, and retain key employees; (4) the ongoing costs relating to operating as a public company; (5) changes in the applicable laws or regulations; (6) the possibility that Zura Bio may be adversely affected by other economic, business, and/or competitive factors; (7) the risk of downturns and a changing regulatory landscape in the highly competitive industry in which Zura Bio operates; (8) the potential inability of Zura Bio to raise additional capital needed to pursue its business objectives or to achieve efficiencies regarding other costs; (9) the enforceability of Zura Bio’s intellectual property, including its patents, and the potential infringement on the intellectual property rights of others, cyber security risks or potential breaches of data security; and (10) other risks and uncertainties described in the registration statement on Form S-1 filed with the SEC on June 14, 2023, and such other documents filed by Zura Bio from time to time with the SEC. These risks and uncertainties may be amplified by the COVID-19 pandemic 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, including projections, 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 publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, or should circumstances change, except as otherwise required by securities and other applicable laws.

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

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		

Cash and cash equivalents	$ 103,859	$ 1,567
Prepaid expenses and other current assets	733	209
Total current assets	104,592	1,776
Deferred offering costs	—	3,486
Total assets	$ 104,592	$ 5,262
Liabilities, Convertible Preferred Shares, Redeemable Noncontrolling Interest and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 17,012	$ 4,428
Note payable	—	7,756
Research and development license consideration liability	—	2,634
Total current liabilities	17,012	14,818
Private placement warrants	1,950	—
Total liabilities	18,962	14,818
Commitments and contingencies (Note 11)		
Convertible preferred shares		
Series A-1 convertible preferred shares, $0.001 par value, -0- and 13,510,415 shares authorized, issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	12,500
Redeemable noncontrolling interest	20,875	10,000
Shareholders' Equity (Deficit):		
Preferred Shares, $0.0001 par value, 1,000,000 and -0- authorized as of September 30, 2023 and December 31, 2022, respectively; -0- issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Class A Ordinary Shares, $0.0001 par value, 300,000,000 authorized, 43,093,685 issued and outstanding as of September 30, 2023; 1,884,649 authorized, 383,480 issued and outstanding as of December 31, 2022	4	—
Additional paid-in capital	158,231	—
Accumulated deficit	(95,021)	(32,056)
Total Zura Bio Limited shareholders' equity (deficit)	63,214	(32,056)
Noncontrolling interest	1,541	—
Total shareholders' equity (deficit)	64,755	(32,056)
Total liabilities, convertible preferred shares, redeemable noncontrolling interest and shareholders' equity (deficit)	$ 104,592	$ 5,262

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,
	2023	**2022**	**2023**
Operating expenses:			
Research and development	$ 3,965	$ 415	$ 37,079
General and administrative	6,222	653	14,732
Total operating expenses	10,187	1,068	51,811
Loss from operations	(10,187)	(1,068)	(51,811)
Other expense/(income), net:			
Other income, net	4	34	7
Interest Income	(815)	—	(816)
Dividend income	(987)		(1,392)
Change in fair value of private placement warrants	(119)	—	236
Change in fair value of note payable	—	—	2,244
Total other expense/(income), net	(1,917)	34	279
Loss before income taxes	(8,270)	(1,102)	(52,090)
Income tax benefit	—	—	—
Net loss before redeemable noncontrolling interest	(8,270)	(1,102)	(52,090)
Net loss attributable to redeemable noncontrolling interest	—	—	203
Net loss	(8,270)	(1,102)	(51,887)
Adjustment to Zura subsidiary's preferred stock to redemption	—	—	(203)

Deemed dividend to redeemable noncontrolling interest	—	—	(10,875)
Net loss attributable to Class A Ordinary Shareholders of Zura	$ (8,270)	$ (1,102)	$ (62,965)
Net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	$ (0.18)	$ (2.87)	$ (2.22)
Weighted-average Class A Ordinary Shares used in computing net loss per share attributable to Class A Ordinary Shareholders of Zura, basic and diluted	46,876,344	383,480	28,402,487

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