Q32 Bio Reports Fourth Quarter 2024 Financial Results and Provides Corporate Update

March 11, 2025

-- Presented bempikibart SIGNAL-AA Phase 2a Part A alopecia areata (AA) data demonstrating encouraging clinical activity and highlighting the potential to be a differentiated treatment as a late-breaking oral presentation at the 2025 American Academy of Dermatology (AAD) Annual Meeting --

-- Advancing bempikibart in patients with AA, with SIGNAL-AA open-label extension (OLE) and SIGNAL-AA Part B on track to dose patients in 1H'25; SIGNAL-AA Part B topline data on-track for 1H'26 --

-- Cash and cash equivalents of $78.0 million as of December 31, 2024 expected to provide financial runway into 2H'26 --

WALTHAM, Mass., March 11, 2025 /PRNewswire/ -- Q32 Bio Inc. (Nasdaq: QTTB) ("Q32 Bio"), a clinical stage biotechnology company focused on developing biologic therapeutics to restore immune homeostasis, today reported financial results for the quarter ended December 31, 2024, and provided recent corporate updates.

"We are pleased to have been selected to present our bempikibart Phase 2a Part A data at AAD as a late-breaking oral presentation, highlighting the encouraging clinical activity we have observed to date, including patients with continued responses in long-term follow-up months after completing treatment, robust pharmacologic data, and a well-tolerated safety profile. We believe this underscores the excitement amongst the dermatology community for bempikibart, recognizing its potential as a novel, differentiated approach for the treatment of AA compared to existing therapies, which are generally not associated with durable responses and carry significant safety concerns," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We look forward to building on this momentum as we advance bempikibart in the SIGNAL-AA OLE and SIGNAL-AA Part B portions of our Phase 2a clinical trial and remain on-track to dose patients in the first half of this year."

Fourth Quarter 2024 and Recent Business Highlights

- **Presented results from SIGNAL-AA Phase 2a Part A clinical trial of bempikibart in alopecia areata (AA) as a late-breaking oral presentation at the 2025 American Academy of Dermatology (AAD) Annual Meeting.** The late-breaking presentation highlighted additional results from Part A of the SIGNAL-AA Phase 2a clinical trial of bempikibart, a fully human anti-IL-7Rα antibody designed to re-regulate adaptive immune function by blocking IL-7 and TSLP signaling, beyond what was previously reported in the topline readout in December. In a difficult-to-treat severe and very severe patient population with an average duration of current episode greater than 5 years, bempikibart demonstrated clinically meaningful activity at week 24 and continued effects after dosing cessation. Despite only 24 weeks of bempikibart treatment, a deepening response, as measured by mean percent change in Severity of Alopecia Tool (SALT) compared with baseline, was observed following dosing cessation (week 24) through the post-treatment follow-up period (week 36), a paradigm believed to be associated with IL-7 on-mechanism modulation of rebalancing T effector memory cells and T regulatory function. Additional data has been collected on patients after week 36, with follow-up on multiple patients through week 55 to date, and additional long-term follow-up ongoing. Outreach was made to patients regarding the post-treatment experience and patients willing to participate were re-consented. Amongst patients responding to outreach that completed the treatment period and showed a SALT response during the trial (n=12), all achieved maintenance of response or further hair growth in the post treatment period (post 24 weeks), including after the end of the trial (post 36 weeks). All 12 were confirmed by SALT assessment by the investigator, with a median follow-up of 41 weeks to date (17 weeks post last treatment) with additional follow-up ongoing. Of these, seven patients (7/12) showed additional hair growth by SALT assessment post-treatment, with median follow-up of 44 weeks to date (20 weeks post last treatment) with additional follow-up ongoing. Across clinical trials, including SIGNAL-AA, bempikibart was observed to be safe and well-tolerated, with no grade 3 or higher related adverse events or related viral infections. Robust pharmacologic activity through desired target engagement was observed, as demonstrated by receptor occupancy, robust changes in Th2 biomarkers, and expected on-mechanism changes in T-cells, indicative of potent IL-7 and TSLP inhibition. The full AAD presentation is available on the "Presentations and Publications" page of the Q32 Bio website.
- **Bempikibart SIGNAL-AA OLE remains on track to initiate in the first half of 2025.** Based on continued emergence of bempikibart data demonstrating ongoing responses in long-term follow-up from SIGNAL-AA Part A, as well as strong re-consent rates and patient demand for continued dosing, Q32 Bio is initiating an OLE following the same bempikibart dosing regimen leveraged in Part A to enable longer-term follow up of patients, with dosing on-track for the first half of 2025.
- **SIGNAL-AA Part B on track to initiate dosing in the first half of 2025, with topline data expected in the first half of 2026.** SIGNAL-AA Part B is an open-label clinical trial, with expected bempikibart dosing for 36 weeks, with follow-up out to 52 weeks, in approximately 20 evaluable patients with severe or very severe AA. Dosing will include an initial loading regimen of 200mg of bempikibart dosed weekly over four weeks, followed by a maintenance dose of 200mg every-other-week over a 32-week period for a total of 36 weeks. Efficacy will be evaluated on the basis of mean percentage change from baseline in SALT scores as well as the proportion of subjects achieving various relative and absolute SALT improvements at week 36, with follow-up through week 52. The trial is intended to support advancement into pivotal trials upon completion, pending review of the results. Q32 Bio expects to initiate SIGNAL-AA Part B dosing in the first half of 2025 and report topline results in the first half of 2026.

Financial Results

- Cash and cash equivalents were $78.0 million as of December 31, 2024. The Company believes its cash and cash equivalents are sufficient to fund operations into the second half of 2026, through the SIGNAL-AA OLE and topline results of the SIGNAL-AA Part B trial evaluating bempikibart in patients with AA.
- Research and development expenses were $10.5 million for the three months ended December 31, 2024 compared to $8.3 million for the three months ended December 31, 2023. The increase in expense of $2.2 million was primarily due to higher clinical trial and manufacturing costs associated with the Phase 2 clinical trials evaluating the use of bempikibart.
- General and administrative expenses were $4.0 million for the three months ended December 31, 2024, compared to $2.8 million for the three months ended December 31, 2023. The increase in expense of $1.2 million was primarily due to increased stock-based compensation expense as well as increased public company-related costs.
- Net loss was $14.2 million, or $1.16 basic and diluted net loss per share, for the three months ended December 31, 2024, compared to net loss of $27.1 million, or $76.39 basic and diluted net loss per share, for the three months ended December 31, 2023.

About Q32 Bio

Q32 Bio is a clinical stage biotechnology company whose science targets potent regulators of the adaptive immune system to re-balance immunity in autoimmune and inflammatory diseases.

Q32 Bio is advancing bempikibart (ADX-914), a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function for the treatment of autoimmune diseases being evaluated in a Phase 2 program. The IL-7 and TSLP pathways have been genetically and biologically implicated in driving several T cell-mediated pathological processes in numerous autoimmune diseases.

For more information, visit www.Q32Bio.com.

Availability of Other Information About Q32 Bio

Investors and others should note that we communicate with our investors and the public using our company website www.Q32Bio.com, including, but not limited to, company disclosures, investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference call transcripts and webcast transcripts, as well as on X (formerly Twitter) and LinkedIn. The information that we post on our website or on X or LinkedIn could be deemed to be material information. As a result, we encourage investors, the media and others interested to review the information that we post there on a regular basis. The contents of our website or social media shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Forward-Looking Statements

This communication contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements contained herein which do not describe historical facts, including, among others, our beliefs, observations, expectations and assumptions regarding the topline data from the SIGNAL-AA Phase 2a and the safety, tolerability, clinical activity including biomarker data, potential efficacy and potential benefits of bempikibart; plans and expectations, including timing for dosing and topline data, for Part B of the SIGNAL-AA Phase 2a clinical trial; the ability of our planned SIGNAL-AA Part B trial to support advancement into pivotal trials; and plans and expectations in connection with the evaluation and execution of strategic options for our tissue-targeted complement inhibitor platform are forward-looking statements, which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Forward-looking statements are based on management's current beliefs and assumptions, which are subject to risks and uncertainties and are not guarantees of future performance. Such risks and uncertainties include, among others, the risk that additional data, or the results of ongoing data analyses, may not support our current beliefs and expectations for bempikibart, future clinical studies, including that Part B of the SIGNAL-AA Phase 2a clinical trial, may not be completed by the first half of 2026 or at all, might be more costly than expected or might not yield anticipated results, our expectations regarding the sufficiency of our cash and cash equivalents to provide financial runway through clinical milestones and into the second half of 2026, and that we may need additional funding to complete clinical studies, which may not be available on favorable terms or at all, and such other risks and uncertainties identified in the Company's periodic, current and other filings with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and any subsequent filings with the Commission, which are available at the SEC's website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect the Company's results of operations and its cash flows, which would, in turn, have a significant and adverse impact on the Company's stock price. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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Q32 BIO INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31,	
	2024	**2023**
Assets		
Cash and cash equivalents	$ 77,965	$ 25,617
Equity investment	2,600	—
Right-of-use asset, operating leases	5,722	6,301
Restricted cash and restricted cash equivalents	647	5,647
Other assets	5,398	9,492
Total assets	$ 92,332	$ 47,057
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Accounts payable, accrued expenses and other current liabilities	$ 10,468	$ 13,231
CVR liability	2,900	—
Lease liability, net of current portion	5,636	6,248
Venture debt	12,653	5,459
Convertible notes	—	38,595
Other noncurrent liabilities	55,000	55,000
Convertible preferred stock	—	111,445
Stockholders' equity (deficit)	5,675	(182,921)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 92,332	$ 47,057

Q32 BIO INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
	(unaudited)			
Collaboration arrangement revenue	$ —	$ (14,662)	$ —	$ (6,651)
Operating expenses:				
Research and development	10,545	8,339	48,143	31,729
General and administrative	3,981	2,808	17,959	9,875
Total operating expenses	14,526	11,147	66,102	41,604
Loss from operations	(14,526)	(25,809)	(66,102)	(48,255)
Change in fair value of convertible notes	—	(1,201)	15,890	(6,193)
Other income (expense), net	358	196	4,125	1,023
Total other income (expense), net	358	(1,005)	20,015	(5,170)
Loss before provision for income taxes and loss from equity method investment	(14,168)	(26,814)	(46,087)	(53,425)
Provision for income taxes	(21)	(253)	(21)	(318)
Loss from equity method investment	—	—	(1,625)	—
Net loss	$ (14,189)	$ (27,067)	$ (47,733)	$ (53,743)
Net loss per share—basic	$ (1.16)	$ (76.39)	$ (5.12)	$ (153.96)
Net loss per share—diluted	$ (1.16)	$ (76.39)	$ (6.58)	$ (153.96)
Weighted-average common shares—basic	12,180,704	354,306	9,320,884	349,060
Weighted-average common shares—diluted	12,180,704	354,306	9,657,696	349,060

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