Q32 Bio Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 8, 2025

-- First patient dosed in SIGNAL-AA Phase 2a Part B; topline data readout on-track for 1H'26 --

-- First patient dosed in SIGNAL-AA Part A open-label extension (OLE) --

-- Fast Track designation (FTD) granted to bempikibart for the treatment of alopecia areata (AA); SIGNAL-AA Part A results presented as a late-breaking oral presentation at the 2025 American Academy of Dermatology (AAD) Annual Meeting --

-- Cash and cash equivalents of $65.5 million as of March 31, 2025 expected to provide financial runway into 2H'26 --

WALTHAM, Mass., May 8, 2025 /PRNewswire/ -- Q32 Bio Inc. (Nasdaq: QTTB) ("Q32 Bio"), a clinical stage biotechnology company focused on developing innovative therapies for alopecia areata and other autoimmune and inflammatory diseases, today reported financial results for the quarter ended March 31, 2025, and provided recent corporate updates.

"This past quarter brought exciting momentum for Q32 Bio and bempikibart as we received Fast Track designation, presented results as a late-breaking oral presentation at AAD, and advanced our SIGNAL-AA Phase 2a clinical trial, dosing the first patients in both Part B and the Part A OLE. These steps reflect our ongoing progress and commitment to developing bempikibart as a potential treatment for patients with alopecia areata who need new treatment options," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We look forward to sharing topline data from Part B in the first half of next year and continuing our efforts to advance bempikibart."

First Quarter 2025 and Recent Business Highlights

- **FTD granted to bempikibart for the treatment of AA.** Fast Track is a process designed to facilitate the development and expedite the review of new drugs to treat serious diseases and fill an unmet medical need with the purpose of getting important new drugs to patients earlier. Filling an unmet medical need is defined as providing a therapy where either none exists or providing a therapy which may be potentially better than available therapies. A drug that receives FTD may be eligible for more frequent meetings and communications with the FDA to discuss development plans and ensure the collection of appropriate data needed to support approval and for a rolling review of an application for marketing approval. Drugs receiving FTD may also be eligible for Accelerated Approval and Priority Review if relevant criteria are met.
- **Dosed the first patient in Part B of the SIGNAL-AA Phase 2a clinical trial, with topline data readout on-track for the first half of 2026.** Part B of the SIGNAL-AA Phase 2a clinical trial is an open-label clinical trial evaluating bempikibart, a fully human anti-IL-7Rα antibody designed to re-regulate adaptive immune function by blocking IL-7 and TSLP signaling, in patients with severe or very severe AA. The trial will dose approximately 20 evaluable patients with severe or very severe AA with bempikibart for 36 weeks, with follow-up out to 52 weeks. Dosing includes 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 dosing period of 36 weeks. Efficacy will be evaluated on the basis of mean percentage change from baseline in Severity of Alopecia Tool (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 report topline results in the first half of 2026.
- **Dosed the first patient in Part A OLE of the SIGNAL-AA Phase 2a clinical trial.** Based on the continued emergence of bempikibart data suggesting a remittive effect and durable responses in long-term follow-up from SIGNAL-AA Part A, as well as re-consent rates and strong patient demand for continued dosing, Q32 Bio has initiated an OLE for eligible patients that completed Part A to enable longer-term follow up of patients. Patient enrollment and dosing is ongoing.
- **Presented results from SIGNAL-AA Phase 2a Part A clinical trial of bempikibart in AA as a late-breaking oral presentation at the AAD Annual Meeting.** The late-breaking presentation highlighted additional results from Part A of the SIGNAL-AA Phase 2a clinical trial of bempikibart 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 five 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 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.

Financial Results

- Cash and cash equivalents were $65.5 million as of March 31, 2025. Q32 Bio 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 $7.1 million for the three months ended March 31, 2025, compared to $9.8 million for the three months ended March 31, 2024. The decrease in expense of $2.7 million was primarily due to higher clinical development expenses for bempikibart Phase 2 clinical trials in AA and atopic dermatitis in 2024.
- General and administrative expenses were $5.1 million for the three months ended March 31, 2025, consistent with $5.0 million for the three months ended March 31, 2024.

- Net loss was $(11.0) million, or $(0.90) basic and diluted net loss per share, for the three months ended March 31, 2025, compared to net income of $1.0 million, or $1.03 basic and ($6.33) diluted net loss per share, for the three months ended March 31, 2024.

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 and is focused on developing innovative therapies for alopecia areata and other autoimmune and inflammatory diseases. About 700,000 people in the United States live with alopecia areata[1], a disease which has a life-altering impact on patients and limited current treatment options. Q32 Bio is advancing bempikibart (ADX-914), a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function, for the treatment of alopecia areata in an ongoing 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.

[1]National Alopecia Areata Foundation

Availability of Other Information About Q32 Bio

Investors and others should note that Q32 Bio communicates with its investors and the public using its website www.Q32Bio.com, including, but not limited to, Q32 Bio's disclosures, investor presentations and FAQs, Securities and Exchange Commission (the "SEC") filings, press releases, public conference call transcripts and webcast transcripts, as well as on X (formerly Twitter) and LinkedIn. The information that Q32 Bio posts on its website or on X or LinkedIn could be deemed to be material information. As a result, Q32 Bio encourages investors, the media and others interested to review the information that it posts there on a regular basis. The contents of Q32 Bio's 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 are forward-looking statements, including, among others, Q32 Bio's beliefs, observations, expectations and assumptions regarding the data reported to date from Part A of the SIGNAL-AA Phase 2a clinical trial, the plan, purpose and timing of Part B of the SIGNAL-AA Phase 2a clinical trial and the anticipated timing of its data, the safety, tolerability, clinical activity, durability, potential efficacy and potential benefits of bempikibart, the potential benefits conferred by FTD for bempikibart, and Q32 Bio's beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, including statements regarding the sufficiency of its cash and cash equivalents to provide financial runway through clinical milestones and into second half of 2026; 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 Q32 Bio's current beliefs and expectations for bempikibart, including with respect to the durability of clinical responses, the risk that ongoing and future clinical studies, including 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, that FTD by the FDA may not actually lead to a faster development or regulatory review or approval process, that Q32 Bio may use its capital resources sooner than currently anticipated and such other risks and uncertainties identified in Q32 Bio's periodic, current and other filings with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2024 and any subsequent filings with the SEC, which are available at the SEC's website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect Q32 Bio's results of operations and its cash flows, which would, in turn, have a significant and adverse impact on Q32 Bio's stock price. Q32 Bio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Q32 Bio 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)
(Unaudited)

	March 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 65,483	$ 77,965
Equity investment	2,526	2,600
Right-of-use asset, operating leases	5,571	5,722
Restricted cash and restricted cash equivalents	647	647
Other assets	4,844	5,398
Total assets	$ 79,071	$ 92,332
Liabilities and stockholders' equity (deficit)		
Accounts payable, accrued expenses and other current liabilities	$ 7,977	$ 10,468
CVR liability	1,940	2,900
Lease liability, net of current portion	5,467	5,636

Venture debt	12,701	12,653
Other noncurrent liabilities	55,000	55,000
Stockholders' equity (deficit)	(4,014)	5,675
Total liabilities and stockholders' equity (deficit)	$ 79,071	$ 92,332

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 7,124	$ 9,841
General and administrative	5,104	5,002
Total operating expenses	12,228	14,843
Loss from operations	(12,228)	(14,843)
Change in fair value of convertible notes	—	15,890
Other income (expense), net	1,197	158
Total other income (expense), net	1,197	16,048
Income (loss) before provision for income taxes and loss from equity method investment	(11,031)	1,205
Provision for income taxes	—	—
Loss from equity method investment	—	(176)
Net income (loss)	$ (11,031)	$ 1,029
Net income (loss) per share—basic	$ (0.90)	$ 1.03
Net income (loss) per share—diluted	$ (0.90)	$ (6.33)
Weighted-average common shares—basic	12,197,615	995,280
Weighted-average common shares—diluted	12,197,615	2,334,180

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