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

August 8, 2024

-- Completed enrollment in bempikibart atopic dermatitis (AD) Phase 2 clinical trial and increased trial size to 121 patients based on Part B patient demand --

-- Bempikibart Phase 2 topline results in AD and alopecia areata (AA) remain on-track for Q4'24 --

-- Enrolling patients in the Phase 2 basket trial of ADX-097 for complement mediated renal diseases; initial open-label data expected by year-end 2024 and topline results in 2H'25 --

-- Cash, cash equivalents, and short-term investments of $107.6 million as of June 30, 2024, expected to provide financial runway through four Phase 2 clinical milestones and into mid-2026 --

WALTHAM, Mass., Aug. 8, 2024 /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 June 30, 2024, and provided recent corporate updates.

"Q32 Bio made strong progress advancing both bempikibart and ADX-097 in Phase 2 clinical trials," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We completed enrollment in the Phase 2 clinical trial of bempikibart in AD, exceeding our initial enrollment target due to strong patient demand, and we look forward to sharing topline results from the Phase 2 clinical trials in AD and AA in the fourth quarter of 2024."

"Additionally, we are enrolling patients in our Phase 2 basket trial of ADX-097 for complement mediated renal diseases. We expect to share initial data from this trial by the end of this year, with topline results expected in the second half of 2025. Plans remain on-track to further expand development of ADX-097 with the initiation of a second Phase 2 clinical trial in ANCA-Associated Vasculitis in the first half of next year, with topline results expected in the second half of 2025."

Second Quarter 2024 and Recent Business Highlights

- **Completed enrollment in the ongoing SIGNAL-AD Phase 2 clinical trial of bempikibart in AD and increased the trial size to 121 patients based on patient demand, with topline results remaining on-track to be released in the fourth quarter of 2024.** Bempikibart is a fully human anti-IL-7Rα antibody that is designed to re-regulate adaptive immune function by blocking IL-7 and TSLP signaling, both of which contribute to inflammation and injury in a diversity of autoimmune disorders. SIGNAL-AD is a two-part Phase 2, randomized, double-blind, placebo-controlled, multi-center clinical trial evaluating bempikibart in adult patients with persistent, moderate-to-severe AD. Part A was conducted to evaluate safety, PK, and to enable dose selection for Part B of the clinical trial. Part A was completed, but data remains blinded. Part B is being conducted to evaluate the efficacy and safety of bempikibart as compared with placebo. In Part B, patients were enrolled 1:1 in the bempikibart 200 mg every-other-week (Q2W) subcutaneous (SC) flat dose and placebo arms for 12 weeks of treatment. The primary endpoint is the mean percent change from baseline to week 14 in the Eczema Area and Severity Index (EASI) score. Patients will be followed for an additional 12 weeks following completion of treatment. A total of 121 patients were enrolled, including 15 patients in Part A. Total enrollment exceeded the initial target of approximately 100 patients due to Part B patient enrollment demand.

- **Bempikibart Phase 2 clinical trial in AA is on track, with topline results expected in the fourth quarter of 2024.** Enrollment was completed in the first quarter of 2024 in the ongoing Phase 2 clinical trial in patients with severe AA treated over 24 weeks. Patients were randomized 3:1 in the bempikibart 200 mg Q2W SC flat dose and placebo arms. The primary endpoint is the mean percent change from baseline on the Severity of Alopecia Tool (SALT) score at week 24. Patients will be followed for an additional 12 weeks following completion of treatment.

- **Enrolling patients in the Phase 2 basket trial of ADX-097 for complement mediated renal diseases**. ADX-097 is designed to be a tissue-targeted inhibitor of complement activation while minimizing systemic complement blockade and is currently in a trial for the treatment of patients with renal diseases associated with increased complement activation. The Phase 2 open label clinical trial is evaluating the safety, pharmacodynamics, pharmacokinetics, and clinical activity of ADX-097 administered subcutaneously in participants with IgA Nephropathy (IgAN), Lupus Nephritis (LN), or C3 Glomerulopathy (C3G). The trial remains on-track, with initial open-label data expected by year-end 2024 and topline results expected in the second half of 2025. Q32 Bio also plans to evaluate ADX-097 in a Phase 2 clinical trial in ANCA-Associated Vasculitis (AAV), which is expected to commence in the first half of 2025 with topline results expected in the second half of 2025.

- **Selected for inclusion in the Russell 3000® Index.** Q32 Bio joined the Russell 3000® Index following the conclusion of the 2024 Russell Indexes annual reconstitution in June. The Russell Indexes capture the 4,000 largest U.S. stocks as of April 28, 2024, ranked by total market capitalization.

Financial Results

- Cash, cash equivalents, and short-term investments were $107.6 million as of June 30, 2024. The Company believes its cash, cash equivalents, and investments are sufficient to fund operations into mid-2026, through the following four Phase 2 clinical milestones: topline readouts from the bempikibart trials in AD and AA in Q4'24 and topline readouts from the ADX-097 renal basket and AAV trials in 2H'25.

- Research and development expenses were $13.4 million for the three months ended June 30, 2024, compared to $8.0 million for the three months ended June 30, 2023. The increase in expense of $5.4 million was primarily due to higher clinical trial and manufacturing costs associated with the Phase 2 clinical trials evaluating the use of bempikibart to treat AA and AD.

- General and administrative expenses were $4.5 million for the three months ended June 30, 2024, compared to $2.5 million for the three months ended June 30, 2023. The increase in expense of $2.0 million was primarily due to increased stock-based compensation expense as

well as increased consulting and public company-related costs.

- Net loss was $17.0 million, or $1.42 basic and diluted net loss per share, for the three months ended June 30, 2024, compared to net loss of $5.8 million, or $16.69 basic and diluted net loss per share, for the three months ended June 30, 2023.

About Q32 Bio

Q32 Bio is a clinical stage biotechnology company developing biologic therapeutics targeting potent regulators of the innate and adaptive immune systems to re-balance immunity in autoimmune and inflammatory diseases. Q32 Bio's lead programs, focused on the IL-7 / TSLP receptor pathways and complement system, address immune dysregulation to help patients take back control of their lives.

Q32 Bio's program for adaptive immunity, bempikibart (ADX-914), is a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function for the treatment of autoimmune diseases. It is being evaluated in two Phase 2 trials for the treatment of atopic dermatitis and alopecia areata. The IL-7 and TSLP pathways have been genetically and biologically implicated in driving several T cell-mediated pathological processes in numerous autoimmune diseases. Q32 Bio's program for innate immunity, ADX-097, is based on a novel platform enabling tissue-targeted regulation of the complement system without long-term systemic blockade – a key differentiator versus current complement therapeutics. Q32 Bio has completed a first-in-human, Phase 1 ascending dose clinical study of ADX-097 in healthy volunteers.

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, relating to our business, operations and financial condition, including but not limited to current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and related timing, including statements regarding expectations regarding the sufficiency of our cash, cash equivalents and short term investments to provide financial runway through clinical milestones and into mid-2026, anticipated timing of clinical data readouts, clinical milestones, among others.

Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: interim, topline and preliminary data may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data; data generated from our preclinical and clinical studies may not meet our expectations; our product candidates may not provided the intended therapeutic benefits; our product candidates may cause serious adverse side effects; the ability to integrate our business with our merger partner successfully and to achieve anticipated synergies; the possibility that other anticipated benefits of the merger will not be realized, including without limitation, anticipated revenues, expenses, earnings and other financial results, and growth and expansion of our operations, and the anticipated tax treatment of the merger; our ability to retain, attract and hire key personnel; potential adverse reactions or changes to relationships with employees, suppliers or other parties resulting from the completion of the merger; potential business uncertainty, including changes to existing business relationships that could affect our financial performance; the need for additional funding, which may not be available; failure to identify additional product candidates and develop or commercialize marketable products; the early stage of our development efforts; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process; the inability to maintain our collaborations, or the failure of these collaborations; our reliance on third parties, including for the manufacture of materials for our research programs, preclinical and clinical studies; failure to obtain U.S. or international marketing approval; ongoing regulatory obligations; effects of significant competition; unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives; product liability lawsuits; securities class action litigation; the impact of global pandemics and general economic conditions on our business and operations, including the our preclinical studies and clinical trials; the possibility of system failures or security breaches; risks relating to intellectual property; significant costs incurred as a result of operating as a public company; and such other factors as are set forth in Q32 Bio's periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in our Form 10-Q filed with the Securities and Exchange Commission on May 9, 2024 and any subsequent filings made with the Securities and Exchange Commission. Except as required by applicable law, we undertake no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts:
Investors: Brendan Burns
Media: Sarah Sutton
Argot Partners
212.600.1902
Q32Bio@argotpartners.com

Q32 BIO INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration arrangement revenue	$ —	$ 3,205	$ —	$ 6,152
Operating expenses:				
Research and development	13,411	8,017	23,252	15,927
General and administrative	4,508	2,463	9,510	4,873
Total operating expenses	17,919	10,480	32,762	20,800
Loss from operations	(17,919)	(7,275)	(32,762)	(14,648)
Change in fair value of convertible notes	—	1,303	15,890	1,260
Other income (expense), net	2,390	165	2,548	743
Total other income (expense), net	2,390	1,468	18,438	2,003
Loss before provision for income taxes	(15,529)	(5,807)	(14,324)	(12,645)
Loss from equity method investment	(1,449)	—	(1,625)	—
Net loss	$ (16,978)	$ (5,807)	$ (15,949)	$ (12,645)
Net loss per share—basic	$ (1.42)	$ (16.69)	$ (2.46)	$ (36.52)
Net loss per share—diluted	$ (1.42)	$ (16.69)	$ (4.44)	$ (36.52)
Weighted-average common shares—basic	11,964,224	347,936	6,479,752	346,288
Weighted-average common shares—diluted	11,964,224	347,936	7,149,202	346,288

Q32 BIO INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	June 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents and short-term investments	$ 107,647	$ 25,617
Equity method investment	3,275	—
Right-of-use asset, operating leases	6,016	6,301
Restricted cash and restricted cash equivalents	647	5,647

Other assets	6,622	9,492
Total assets	$ 124,207	$ 47,057
Liabilities, convertible preferred stock and stockholders' deficit		
Accounts payable, accrued expenses and other current liabilities	$ 13,504	$ 13,231
CVR liability	3,690	—
Lease liability, net of current portion	5,948	6,248
Venture debt	12,554	5,459
Convertible notes	—	38,595
Other noncurrent liabilities	55,000	55,000
Convertible preferred stock	—	111,445
Stockholders' equity (deficit)	33,511	(182,921)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 124,207	$ 47,057

SOURCE Q32 Bio