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

May 9, 2024

-- Completed enrollment in bempikibart alopecia areata (AA) Phase 2 clinical trial, with topline results expected in Q4'24; enrollment in bempikibart atopic dermatitis (AD) Phase 2 clinical trial remains on-track, with topline results expected in Q4'24 --

-- ADX-097 continues to advance, with anticipated Phase 2 clinical trial initiations on-track: renal basket in 1H'24 and ANCA-associated vasculitis (AAV) in 1H'25, with topline results from both clinical trials expected in 2H'25 and initial renal basket data expected by end of 2024 --

-- Completed reverse merger with Homology Medicines in March 2024, including concurrent private placement of $42 million --

--Cash, cash equivalents, and short-term investments were $135.3 million as of March 31, 2024, which are expected to provide financial runway through four Phase 2 clinical milestones and into mid-2026 --

WALTHAM, Mass., May 9, 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 March 31, 2024 and provided recent corporate updates.

"The first quarter of 2024 was transformational for Q32 as we became a public company and continued to drive the advancement of our pipeline programs. Bempikibart is progressing in the ongoing Phase 2 clinical trials in AD and AA, with topline data from each expected to be released in the fourth quarter of 2024," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We are pleased with the progress we are making in both of these Phase 2 trials, including completing AA enrollment."

"Further, ADX-097, our lead novel tissue-targeted complement inhibitor product candidate, is advancing and we remain on track to initiate our renal basket clinical trial in the first half of this year, and we look forward to expanding development with the initiation of a Phase 2 clinical trial in AAV next year, with topline results from both trials in the second half of 2025. With our pipeline momentum, recent additions to our management team and board of directors and strong financial foundation following our merger close and concurrent financing, we are well positioned as a newly public company," Ms. Morrison added.

First Quarter 2024 and Recent Business Highlights

- **Enrollment was completed in the ongoing bempikibart Phase 2 clinical trial in AA, with topline results expected in the fourth quarter of 2024.** Bempikibart is a fully human anti-IL-7Rα antibody designed to re-regulate adaptive immune function by blocking signaling mediated by both IL-7 and TSLP. The Phase 2 clinical trial is ongoing in approximately 40 patients with severe AA treated over 24 weeks. Patients were randomized 3:1 in the bempikibart 200 mg every-other-week (Q2W) subcutaneous (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.

- **Enrollment remains on-track in the bempikibart Phase 2 clinical trial in AD, with topline results expected in the fourth quarter of 2024.** The Phase 2 clinical trial in AD is approximately 100 patients and consists of two parts. Part A was conducted to evaluate safety, PK, and to enable dose selection for the ongoing Part B of the clinical trial. Part A was completed, but data remains blinded. In Part B, patients are being enrolled 1:1 in the bempikibart 200 mg Q2W 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.

- **ADX-097 continues to advance, with topline results from two Phase 2 clinical trials expected in the second half of 2025.** ADX-097 is based on our novel complement inhibitor platform and is designed to enable tissue-targeted regulation of the complement system without long-term systemic blockade, a key differentiator from current complement therapeutics. A Phase 2 renal basket program is planned to commence in the first half of 2024 and a Phase 2 clinical trial in ANCA-Associated Vasculitis (AAV) is planned to commence in the first half of 2025. Topline results from both trials are expected in the second half of 2025, with initial open-label renal basket data expected by year-end 2024.

- **Lee Kalowski was appointed President and Chief Financial Officer.** Mr. Kalowski brings over 20 years of biopharmaceutical experience with a focus on strategy, raising capital, and financial operations.

- **The Board of Directors was expanded with the appointment of life sciences industry veterans Mary Thistle and Arthur Tzianabos, Ph.D.**

- **Completed the reverse merger and concurrent private placement of $42 million.** In March 2024, Q32 Bio began trading on the Nasdaq Global Market under the ticker "QTTB" following the close of a reverse merger with Homology Medicines, Inc. Concurrent with the closing of the merger, Q32 Bio completed a $42 million private placement with a syndicate of existing and new investors.

Financial Results

- Cash, cash equivalents, and short-term investments were $135.3 million as of March 31, 2024, which includes gross proceeds from the completion of the reverse merger and $42 million concurrent private placement and $7 million drawn from the SVB Loan and Security Agreement. The Company believes its cash, cash equivalents, and investments are sufficient to fund operations into mid-2026.

- Research and development expenses were $9.8 million for the three months ended March 31, 2024, compared to $7.9 million for the three months ended March 31, 2023. The increase in expense of $1.9 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 $5.0 million for the three months ended March 31, 2024, compared to $2.4 million for the three

months ended March 31, 2023. The increase in expense of $2.6 million was primarily due to costs associated with the reverse merger, including severance and retention payments to former employees of Homology Medicines, Inc., and other costs associated with the transaction that were not capitalized, as well as other public company-related costs.

- Net income was $1.0 million, or $1.03 basic net income per share and ($6.33) diluted net loss per share, for the three months ended March 31, 2024, compared to net loss of $(6.8 million), or ($19.84) basic and diluted net loss per share, for the three months ended March 31, 2023. Net income for the three months ended March 31, 2024 was a result of a gain of $15.9 million recorded on the conversion of the convertible notes upon closing the reverse merger.

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.

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 timing and data from our Phase 2 clinical trials for bempikibart in AA and AD and our planned renal basket program and AAV trial for ADX-097, our expectations regarding the sufficiency of our cash and cash equivalents, 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: 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; 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; our product candidates may cause serious adverse side effects; 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 8-K filed on March 27, 2024. 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.

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

	Three Months Ended March 31,	
	2024	2023
Collaboration arrangement revenue	$ —	$ 2,947
Operating expenses:		
Research and development	9,841	7,910
General and administrative	5,002	2,410
Total operating expenses	14,843	10,320
Loss from operations	(14,843)	(7,373)
Change in fair value of convertible notes	15,890	(43)
Other income (expense), net	158	578

Total other income (expense), net	16,048	535
Income (loss) before provision for income taxes	1,205	(6,838)
Loss from equity method investment	(176)	—
Net income (loss)	$ 1,029	$ (6,838)
Net income (loss) per share—basic	$ 1.03	$ (19.84)
Net income (loss) per share—diluted	$ (6.33)	$ (19.84)
Weighted-average common shares—basic	995,280	344,623
Weighted-average common shares—diluted	2,334,180	344,623

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

	March 31, 2024	December 31, 2023
Assets		
Cash, cash equivalents and short-term investments	$ 135,312	$ 25,617
Equity method investment	4,724	—
Right-of-use asset, operating leases	6,160	6,301
Restricted cash and restricted cash equivalents	647	5,647
Other assets	5,491	9,492
Total assets	$ 152,334	$ 47,057
Liabilities, convertible preferred stock and stockholders' deficit		
Accounts payable, accrued expenses and other current liabilities	$ 24,785	$ 13,231
CVR liability	5,080	—
Lease liability, net of current portion	6,099	6,248
Venture debt	12,488	5,459
Convertible notes	—	38,595
Other noncurrent liabilities	55,113	55,000
Convertible preferred stock	—	111,445
Stockholders' equity (deficit)	48,769	(182,921)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 152,334	$ 47,057

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