UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 07, 2024

Q32 Bio Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38433**	**47-3468154**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
830 Winter Street Waltham, Massachusetts		**02451**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 781 999-0232

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	QTTB	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 7, 2024, Q32 Bio Inc. announced its financial results for the quarter ended September 30, 2024 and provided a corporate update. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

99.1	Press Release issued by Q32 Bio Inc. on November 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Q32 BIO INC.

Date: November 7, 2024

By: /s/ Jodie Morrison
Name: Jodie Morrison
Title: Chief Executive Officer

Exhibit 99.1

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

-- Bempikibart Phase 2 topline results in atopic dermatitis (AD) and alopecia areata (AA) remain on-track for Q4'24, with topline data from both trials expected in December --

-- Enrollment ongoing in ADX-097 Phase 2 basket trial for complement mediated renal diseases, with topline data expected in 2H'25 and initial open-label data in 1H'25 --

-- Cash and cash equivalents of $89.1 million as of September 30, 2024 expected to provide financial runway through four Phase 2 clinical milestones and into mid-2026 --

WALTHAM, Mass.—November 7, 2024 – 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 September 30, 2024, and provided recent corporate updates.

"In the third quarter of 2024, we continued to make important strides advancing our two Phase 2 clinical trials evaluating bempikibart in AD and AA, with both trials remaining on-time, even with the over-enrollment in AD, and we remain focused on releasing topline data for both clinical trials this quarter," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We believe bempikibart has the potential to bring a differentiated, disease-modifying treatment to patients with AD and AA and look forward to sharing our results. In parallel, we continue to advance our Phase 2 basket trial of ADX-097 in complement mediated renal diseases with initial open-label Phase 2 data expected in the first half of 2025 after we release bempikibart data this quarter, and we continue to expect topline results in the second half of 2025. Additionally, we are continuing our preparations to commence the ADX-097 Phase 2 trial in ANCA-Associated Vasculitis (AAV) in the first half of 2025."

Third Quarter 2024 and Recent Business Highlights

- **Bempikibart SIGNAL-AD Phase 2 clinical trial in AD remains on-track, with topline results expected to be released in December 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 SIGNAL-AA Phase 2 clinical trial in AA remains on track, with topline results expected in December 2024.** SIGNAL-AA is a Phase 2, randomized, double-blind, placebo-controlled, multi-center clinical trial evaluating bempikibart 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.

- **Enrollment is underway 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 being studied 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). Initial open-label data is expected in the first half of 2025, 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 also expected in the second half of 2025.

- **Positive Phase 1 clinical trial results from tissue-targeted complement inhibitor ADX-097 were presented at ASN Kidney Week 2024.** The poster presentation at ASN highlighted data from the first-in-human, Phase 1 ascending dose clinical trial of ADX-097 in healthy volunteers. ADX-097 demonstrated a favorable safety profile and desired PK/PD properties, supporting a Phase 2 dose that is predicted to provide tissue inhibition of complement in glomerular diseases while sparing systemic complement activity.

Financial Results

- Cash and cash equivalents were $89.1 million as of September 30, 2024. The Company believes its cash and cash equivalents 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 $14.3 million for the three months ended September 30, 2024, compared to $7.5 million for the three months ended September 30, 2023. The increase in expense of $6.8 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 and included a development milestone payment of $4.0 million to Bristol-Myers Squibb under our license agreement.

- General and administrative expenses were $4.5 million for the three months ended September 30, 2024, compared to $2.2 million for the three months ended September 30, 2023. The increase in expense of $2.3 million was primarily due to increased stock-based compensation expense as well as increased consulting and public company-related costs.

- Net loss was $17.6 million, or $1.46 basic and diluted net loss per share, for the three months ended September 30, 2024, compared to net loss of $14.0 million, or $40.52 basic and diluted net loss per share, for the three months ended September 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 our plans to report Phase 2 topline results of bempikibart in AD and AA in Q4’24 and initial open-label data from our Phase 2 basket trial of ADX-097 in complement mediated renal diseases in 1H’25 and topline data in 2H’25, our expectations regarding the sufficiency of our cash and cash equivalents to provide financial runway through clinical milestones and into mid-2026, the potential, safety, efficacy, and regulatory and clinical progress of Q32 Bio's product candidates, including bempikibart and ADX-097, and 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 including our Phase 2 clinical trials of bempikibart and ADX-097, may not meet our expectations; our product candidates may not provide the intended therapeutic benefits; our product candidates may cause serious adverse side effects; our ability to retain, attract and hire key personnel; 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 August 8, 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.

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Q32 BIO INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration arrangement revenue	$ —	$ 1,859	$ —	$ 8,011
Operating expenses:				
Research and development	14,346	7,463	37,598	23,390
General and administrative	4,468	2,194	13,978	7,067
Total operating expenses	18,814	9,657	51,576	30,457
Loss from operations	(18,814)	(7,798)	(51,576)	(22,446)
Change in fair value of convertible notes	—	(6,252)	15,890	(4,992)
Other income (expense), net	1,219	84	3,767	827
Total other income (expense), net	1,219	(6,168)	19,657	(4,165)
Loss before provision for income taxes	(17,595)	(13,966)	(31,919)	(26,611)
Provision for income taxes	—	(65)	—	(65)
Loss from equity method investment	—	—	(1,625)	—
Net loss	$ (17,595)	$ (14,031)	$ (33,544)	$ (26,676)
Net loss per share—basic	$ (1.46)	$ (40.52)	$ (4.01)	$ (76.81)
Net loss per share—diluted	$ (1.46)	$ (40.52)	$ (5.60)	$ (76.81)
Weighted-average common shares—basic	12,076,412	346,288	8,360,652	347,292
Weighted-average common shares—diluted	12,076,412	346,288	8,810,555	347,292

Q32 BIO INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 89,078	$ 25,617
Equity investment	2,600	—
Right-of-use asset, operating leases	5,869	6,301
Restricted cash and restricted cash equivalents	647	5,647
Other assets	6,348	9,492
Total assets	$ 104,542	$ 47,057
Liabilities, convertible preferred stock and stockholders' deficit		
Accounts payable, accrued expenses and other current liabilities	$ 10,170	$ 13,231
CVR liability	2,680	—
Lease liability, net of current portion	5,793	6,248
Venture debt	12,604	5,459
Convertible notes	—	38,595
Other noncurrent liabilities	55,000	55,000
Convertible preferred stock	—	111,445
Stockholders' equity (deficit)	18,295	(182,921)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 104,542	$ 47,057