
**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): February 10, 2025

Q32 Bio Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38433
(Commission File Number)

47-3468154
(IRS Employer
Identification No.)

830 Winter Street
Waltham, Massachusetts
(Address of Principal Executive Offices)

02451
(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 2.05 Costs Associated with Exit or Disposal Activities.

On February 10, 2025, Q32 Bio Inc. (the “Company”) notified its employees of a strategic restructuring plan adopted by the Company’s board of directors to focus its resources on the advancement of bempikibart in patients with alopecia areata (the “Restructuring Plan”). In connection with the Restructuring Plan, the Company is discontinuing its Phase 2 renal basket clinical trial of ADX-097 and is evaluating strategic options for its tissue-targeted complement inhibitor platform, inclusive of ADX-097 and early-stage assets, in combination with other cost-saving measures. The Restructuring Plan includes a reduction in force, which the Company expects to substantially complete by the end of the second quarter of 2025. As part of this Restructuring Plan, the Company expects to incur severance and severance-related charges of approximately \$1.1 million. The Company may also incur other charges or cash expenditures not currently contemplated or that cannot be currently estimated due to events that may occur as a result of, or be associated with, the Restructuring Plan.

Item 7.01 Regulation FD Disclosure.

On February 10, 2025, the Company issued a press release titled “Q32 Bio Announces Strategic Restructuring to Focus on Advancement of Bempikibart in Patients with Alopecia Areata.” A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is being 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 they be deemed incorporated by reference into any filing by the Company, 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.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Q32 Bio Inc. on February 10, 2025
104	Cover Page Interactive Data File (embedded with 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: February 10, 2025

By: /s/ Jodie Morrison

Name: Jodie Morrison

Title: Chief Executive Officer



Q32 Bio Announces Strategic Restructuring to Focus on Advancement of Bempikibart in Patients with Alopecia Areata

-- Based on continued emergence of bempikibart data from SIGNAL-AA Part A, including strong re-consent rates and patient demand for continued dosing, Company initiating open-label extension in 1H'25; SIGNAL-AA Part B remains on track for initiation of dosing in 1H'25, with topline data expected in 1H'26 --

-- Company to discontinue renal basket trial for ADX-097 to conserve resources and evaluate strategic options for its tissue-targeted complement inhibitor platform --

-- Cash runway expected to extend to 2H'26 --

WALTHAM, Mass. — February 10, 2025 – Q32 Bio Inc. (Nasdaq: QTTB) (“Q32 Bio”), a clinical stage biotechnology company focused on developing biologic therapeutics to restore immune homeostasis, today announced a corporate restructuring to focus on the advancement of its bempikibart clinical development program for the treatment of patients with alopecia areata (AA). As part of the restructuring, the Company is discontinuing the Phase 2 renal basket clinical trial of ADX-097 and is evaluating strategic options for its tissue-targeted complement inhibitor platform, inclusive of ADX-097 and early-stage assets. In combination with other cost-saving measures including a reduction in personnel and related expenses, the strategic restructuring is expected to extend cash runway to the second half of 2026.

“We have conviction that bempikibart is differentiated from existing AA therapies and has the potential to transform the treatment paradigm for this disease. This is based on the continued emergence of bempikibart data in alopecia areata patients with longer-term follow-up from Part A of the SIGNAL-AA Phase 2a clinical trial, the robust pharmacologic data, and a well-tolerated safety profile,” said Jodie Morrison, Chief Executive Officer of Q32 Bio. “Further, based on the clinical characteristics of bempikibart, we continue to believe there is potential utility across additional autoimmune conditions. Our immediate next steps will be to extend dosing of eligible patients from SIGNAL-AA Part A in an open-label extension arm and to initiate dosing of patients in the SIGNAL-AA Part B clinical trial in the first half of 2025, with Part B topline data expected in the first half of 2026.”

Morrison added, “ADX-097, our Phase 2 complement inhibitor, is a clinical asset with strong potential to treat patients with complement disorders across multiple indications through its novel tissue-targeted approach. While this restructuring is a very difficult decision, it is a necessary step in the context of the evolving complement-mediated renal disease landscape and as we prioritize our focus and capital to maximize the potential of bempikibart. Our restructuring necessitates parting with some valued colleagues, and I want to personally thank them for their dedication to our mission, commitment to patients, and their many contributions to the Company.”

Bempikibart Phase 2 Development Program

Results observed to date from Part A of the SIGNAL-AA Phase 2a clinical trial of bempikibart in patients with AA demonstrated encouraging clinical activity, including improvement from baseline on Severity of Alopecia Tool (SALT) score and meaningful achievement of SALT-20 (SALT score less than or equal to 20) response through week 36, and continued response in multiple patients through week 55, approximately 7 months post last dose. Results from this longer-term follow-up show continued mean SALT reductions, despite dosing through only 24 weeks, which may be suggestive of a remittive effect, durability of response, and a key differentiation from currently approved therapies. Across clinical trials, including SIGNAL-AA, bempikibart was observed to be well-tolerated, with robust pharmacologic activity through desired target engagement, as demonstrated by receptor occupancy, robust changes in Th2 biomarkers, and expected changes in T-cells, indicative of potent IL-7 and TSLP inhibition.

Data continues to be collected from a portion of patients who re-consented to the trial, with patient data available through 55 weeks and longer follow-up expected. Based on re-consent rates and strong patient demand for continued dosing, Q32 Bio is initiating an open-label extension (OLE) following the same bempikibart dosing regimen leveraged in Part A to enable longer-term follow-up of patients. In addition to the initiation of the OLE, Q32 Bio expects to initiate dosing in SIGNAL-AA Part B in the first half of 2025.

SIGNAL-AA Part B is an open-label clinical trial, dosing patients with bempikibart 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. The primary efficacy endpoints include the proportion of patients achieving a 30% or greater reduction in SALT score and proportion of patients achieving a SALT-20 at week 36, with follow-up through week 52. The trial is intended to enable advancement into pivotal trials upon completion, pending review of the results. Q32 Bio expects to report initial data from SIGNAL-AA Part B in the first half of 2026.

Complement Inhibitor Platform

ADX-097, a Phase 2 asset, is designed to be a tissue-targeted inhibitor of complement activation while minimizing systemic complement blockade with potential in a broad range of indications associated with C3d deposition including renal, autoimmune, vascular, and skin diseases. In preclinical studies, ADX-097 distributed to affected tissues/organs and demonstrated durable tissue pharmacokinetics (PK) and pharmacodynamics (PD). Q32 Bio has evaluated ADX-097 in a Phase 1 clinical trial in healthy volunteers where it observed circulating PK/PD consistent with preclinical studies, which established in vivo integrity of ADX-097. ADX-097 was also shown to be well-tolerated and demonstrated minimal anti-drug antibodies (ADA).

ADX-097 was discovered by Q32 Bio and is the most advanced program of its tissue-targeted complement inhibitor platform. Additional discovery and earlier development efforts include ADX-096, a C3d mAb – CR1 fusion protein which demonstrated preclinical data supportive of its use in ophthalmologic indications, as well as other C3d mAb fusions and nanobodies designed for tissue-targeted complement inhibition.

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-7R α 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 for Part B of the SIGNAL-AA Phase 2a clinical trial; 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, we may not be successful in evaluating and executing strategic options for our tissue-targeted complement inhibitor platform; 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.

Contacts:

Investors: Brendan Burns

Media: Sarah Sutton

Argot Partners

212.600.1902

Q32Bio@argotpartners.com
