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): July 09, 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** **(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 7.01 Regulation FD Disclosure.

On July 9, 2024, Q32 Bio Inc. (the "Company") issued a press release titled "Q32 Bio Announces Completion of Enrollment in the SIGNAL-AD Phase 2 Clinical Trial of Bempikibart for Atopic Dermatitis." 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 8.01 Other Events.

On July 9, 2024, the Company announced that it has completed enrollment in the SIGNAL-AD Phase 2 clinical trial of bempikibart (ADX-914) for the treatment of persistent, moderate-to-severe atopic dermatitis ("AD"). 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 (NCT05509023) 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 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.

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. Topline data from Parts A and B are expected in the fourth quarter of 2024.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, relating to the Company's business, operations and financial condition, and its expectations regarding the timing and data from its Phase 2 clinical trial for bempikibart in AD in the fourth quarter of 2024. 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 Company's ability to integrate its business with its 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 the Company's operations, and the anticipated tax treatment of the merger; the Company's 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 the Company's 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 the Company's 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; the Company's product candidates may cause serious adverse side effects; the inability to maintain the Company's collaborations, or the failure of these collaborations; the Company's reliance on third parties, including for the manufacture of materials for the Company's 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 the Company's business and operations, including the Company's 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 the Company's periodic public filings with the SEC, including but not limited to those described under the heading "Risk Factors" in the Company's Form 10-Q for the quarter ended March 31, 2024 filed on May 9, 2024. Except as required by applicable law, the

Company undertakes 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release issued by Q32 Bio Inc. on July 9, 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: July 9, 2024

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

Exhibit 99.1

Q32 Bio Announces Completion of Enrollment in the SIGNAL-AD Phase 2 Clinical Trial of Bempikibart for Atopic Dermatitis

-- Exceeded enrollment target due to patient demand; trial size increased to 121 patients --

-- Bempikibart topline results remain on track to be released in Q4'24 --

WALTHAM, Mass.—July 9, 2024 – Q32 Bio Inc. (NASDAQ: QTTB) ("Q32 Bio"), a clinical stage biotechnology company focused on developing biologic therapeutics to restore immune homeostasis, today announced that it has completed enrollment in the SIGNAL-AD Phase 2 clinical trial of bempikibart (ADX-914) for the treatment of persistent, moderate-to-severe atopic dermatitis (AD). 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.

"We are grateful to the patients and their clinical teams whose high level of interest enabled us to complete enrollment on schedule while exceeding our original target enrollment," said Jason Campagna, M.D., Ph.D., Chief Medical Officer of Q32 Bio. "We believe that this demand speaks to both the enthusiasm following completion of Part A of the trial and the unmet need for patients with AD."

"In addition to completing enrollment in SIGNAL-AD, we previously announced that enrollment in the SIGNAL-AA Phase 2 clinical trial in severe alopecia areata (AA) is also complete, marking the achievement of two critical milestones this year," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We are thrilled with our continued progress advancing bempikibart and we look forward to sharing topline data from both Phase 2 clinical trials in the fourth quarter of this year."

SIGNAL-AD (NCT05509023) 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 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.

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. Topline data from Parts A and B are expected in the fourth quarter of 2024.

AD is the most common type of eczema and affects more than 25 million people in the United States. In individuals with AD, the immune system is overactive, triggering inflammation that damages the skin barrier.

About Bempikibart
Bempikibart (ADX-914) is a fully human anti-IL-7Rα antibody that is designed to re-regulate adaptive immune function by blocking IL-7 and TSLP signaling. Q32 Bio is currently evaluating bempikibart in two ongoing Phase 2 clinical trials: SIGNAL-AD, a Phase 2 study in patients with atopic dermatitis (AD) and SIGNAL-AA, a Phase 2 study in patients with alopecia areata (AA).

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, and our expectations regarding the timing and data from our Phase 2 clinical trials for bempikibart in AA and AD in the fourth quarter of 2024.

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 10-Q for the quarter ended March 31, 2024 filed on May 9, 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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