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 13, 2026

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 Capital 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 13, 2026, Q32 Bio Inc. (the "Company") issued a press release titled "*Q32 Bio Announces Positive 36-Week Topline Results from Part B of the SIGNAL-AA Clinical Trial of Bempikibart in Alopecia Areata*." 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 13, 2026, the Company announced topline results from the Part B of the SIGNAL-AA Phase 2a signal finding clinical trial evaluating bempikibart (ADX-914) in patients with alopecia areata ("AA").

36-Week Topline Results from Part B of the SIGNAL-AA Program

The Part B portion of the SIGNAL-AA program is an open-label clinical trial building upon the previously completed Part A, which established proof-of-concept of bempikibart in AA. In Part B, bempikibart is being evaluated in 33 patients with severe or very severe AA (baseline Severity of Alopecia Tool ("SALT") scores of 50-100) with a maximum duration of current episode of four years. Enrollment amongst patients with prior exposure to JAK inhibitor therapy were allowed; amongst the 33 enrolled patients, 36.4% had previously been treated with oral JAK inhibitors.

Total enrollment exceeded the initial target due to patient demand. In Part B, patients are treated with bempikibart for 36 weeks, with off-drug follow-up through Week 52 before optional enrollment in the open-label extension ("OLE"). Dosing includes an initial loading regimen of 200mg of bempikibart dosed weekly for four doses, followed by continued dosing of 200mg every-other-week over a 32-week period, for a total dosing period of 36 weeks. Across both regimens, bempikibart was administered subcutaneously.

The prespecified primary efficacy analysis was evaluated on the basis of mean percentage change from baseline in SALT scores in the modified intent-to-treat ("mITT") population. Additional prespecified efficacy analyses included the proportion of patients achieving various relative and absolute SALT improvements including SALT-20 (80% of scalp hair coverage), $SALT_{30}$ (30% improvement in SALT score from baseline), and $SALT_{50}$ (50% improvement in SALT score from baseline) responses at Week 36, with follow-up through Week 52.

Key topline efficacy results from Part B of SIGNAL-AA at Week 36 include:

- Mean percent reduction in SALT score from baseline of 35.3% in the mITT analysis.
- 40.0% (10/25) of patients in the mITT analysis and 30.3% (10/33) of patients in the intent-to-treat ("ITT") analysis achieved a SALT-20 response. Achievement of a SALT-20 response was observed in patients with both severe and very severe disease.
- 44.0% (11/25) of patients in the mITT analysis and 33.3% (11/33) of patients in the ITT analysis achieved $SALT_{30}$ response.
- 44.0% (11/25) of patients in the mITT and 33.3% (11/33) of patients in the ITT analysis achieved $SALT_{50}$ response.

- Early signs of durability in the off-drug period include maintenance or deepening of response in multiple patients including one who achieved complete hair growth (SALT = 0).

Bempikibart was observed to have a generally well-tolerated safety profile in SIGNAL-AA Part B, consistent with prior studies. No new safety signals were observed. There were no serious adverse events or Grade 3 or higher adverse events related to treatment. The most common treatment-emergent adverse event was injection site reaction ("ISR") (36.3%) which were primarily singular events, with ISR incidence of 4% across all Part B dose administrations. All ISRs reported were mild and resolved with no intervention, with the majority resolving within a day.

Bempikibart demonstrated a favorable pharmacokinetic ("PK"), pharmacodynamic and anti-drug antibody ("ADA") profile in Part B. PK data from Part B support the loading dose regimen had its intended effect, achieving steady state concentrations approximately 10 weeks earlier than in Part A. Negligible ADA was observed in Part B.

The Part B off-drug follow-up period through Week 52 remains ongoing. Additionally, enrollment of eligible patients into the OLE remains ongoing. The Company intends to advance bempikibart into a registration-directed program in the first half of 2027 and plans to share full results from Part B at a future medical meeting.

Results from SIGNAL-AA Part A OLE

Following the emergence of Part A data suggesting durability of response in the off-drug follow-up from SIGNAL-AA Part A and given patient demand for continued dosing, the Company announced the initiation of an OLE in April 2025. The Part A OLE has been completed. Eight patients enrolled in the Part A OLE, spanning responders, non-responders, and placebo patients from the Part A treatment portion. Patients were off-drug for various time periods ranging from 26 to 55 weeks prior to re-dosing. In the Part A OLE, bempikibart continued to demonstrate a generally well-tolerated safety profile with longer-term dosing and no new safety issues. Patients who maintained hair at entry to the OLE were observed to have durable or further hair growth. In totality, the Part A OLE dataset supports the importance of a maintenance dosing regimen.

Corporate Updates

On June 24, 2026, the Company paid off the remaining balance in the amount of approximately $6.8 million under the Loan and Security Agreement (the "Loan Agreement") between the Company and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("SVB"), pursuant to a Pay-Off Letter between the Company and SVB dated June 24, 2026. Accordingly, the Loan Agreement has been terminated.

Cautionary Note Regarding 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, 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 Part B of the SIGNAL-AA Phase 2a clinical trial 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, the expectations surrounding the potential, safety, efficacy, and regulatory and clinical progress of the Company's product candidates, including bempikibart, and anticipated milestones, timing of anticipated registrational trials, data readouts and timing, and the United States AA market size and potential commercial opportunities, among others 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 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 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 the Company's current beliefs and expectations for bempikibart, including with respect to the durability of clinical responses, the risk that ongoing and future clinical studies might be more costly than expected or might not yield anticipated results, that the Company may use its capital resources sooner than currently anticipated, that the Company 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 March 31, 2026 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. The Company cautions 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release issued by Q32 Bio Inc. on July 13, 2026.
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 13, 2026

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

Exhibit 99.1

Q32 Bio Announces Positive 36-Week Topline Results from Part B of the SIGNAL-AA Clinical Trial of Bempikibart in Alopecia Areata

— Clinically meaningful efficacy data on the primary endpoint was observed with a mean percent reduction in SALT score from baseline of 35.3% in the prespecified mITT analysis —

— 40.0% of patients achieved SALT-20 response at Week 36 in the mITT analysis and 30.3% of patients achieved SALT-20 response at Week 36 in the ITT analysis of all enrolled patients —

— Generally well-tolerated safety profile, consistent with prior studies, with no new safety signals —

— Bempikibart demonstrated a favorable PK, PD and ADA profile —

— Data supports further development of bempikibart in alopecia areata; Company intends to advance a registration-directed program in the first half of 2027 —

— Q32 Bio to host conference call and webcast today, July 13, 2026, at 8:00 a.m. E.T., featuring alopecia areata key opinion leader (KOL) Arash Mostaghimi, MD, MPA, MPH —

WALTHAM, Mass.— July 13, 2026 – Q32 Bio Inc. (Nasdaq: QTTB) ("Q32 Bio"), a clinical stage biotechnology company focused on developing innovative therapies for alopecia areata ("AA") and other autoimmune and inflammatory diseases, today announced positive 36-week topline results from Part B of the SIGNAL-AA Phase 2a clinical trial evaluating bempikibart in patients with severe or very severe AA. Bempikibart is a fully human anti-IL-7Rα antibody designed to re-regulate adaptive immune function by blocking IL-7 and TSLP signaling.

"Today's Part B 36-week topline results mark a significant milestone for Q32 Bio, supporting our target efficacy and safety profile and providing compelling evidence reinforcing the therapeutic potential of bempikibart in alopecia areata," said Jodie Morrison, Chief Executive Officer of Q32 Bio. "We believe these findings highlight the opportunity to deliver a differentiated, targeted treatment option for patients who remain in need of an effective, safe, and more durable alternative to JAK inhibitors. These results support advancement in alopecia areata and strengthen our conviction in bempikibart's applicability across the broader autoimmune and inflammatory landscape. We are grateful to the patients, investigators, employees, and clinical development partners who helped make today's announcement possible."

"Alopecia areata is a complex, immune driven disease with limited therapeutic options. The robust efficacy data in a population that includes JAK inhibitor-experienced patients, combined with a differentiated safety profile, demonstrate the potential for bempikibart to be a first-line treatment for alopecia areata," said Arash Mostaghimi, MD, MPA, MPH, Associate Professor of Dermatology and Vice Chair of Clinical Trials and Innovation, Brigham and Women's Hospital, Harvard Medical School. "For patients and prescribers seeking an effective and safe alternative to JAK inhibitors, these findings are encouraging and merit further clinical advancement."

36-Week Topline Results from Part B of the SIGNAL-AA Program:

The Part B portion of the SIGNAL-AA program is an open-label clinical trial building upon the previously completed Part A, which established proof-of-concept of bempikibart in AA. In Part B, bempikibart is being evaluated in 33 patients with severe or very severe AA (baseline Severity of Alopecia Tool (SALT) scores of 50-100) with a maximum duration of current episode of four years. Enrollment amongst patients with prior exposure to JAK inhibitor therapy were allowed; amongst the 33 enrolled patients, 36.4% had previously been treated with oral JAK inhibitors.

Total enrollment exceeded the initial target due to patient demand. In Part B, patients are treated with bempikibart for 36 weeks, with off-drug follow-up through Week 52 before optional enrollment in the open-label extension (OLE). Dosing includes an initial loading regimen of 200mg of bempikibart dosed weekly for four doses, followed by continued dosing of 200mg every-other-week over a 32-week period, for a total dosing period of 36 weeks. Across both regimens, bempikibart was administered subcutaneously (SC).

The prespecified primary efficacy analysis was evaluated on the basis of mean percentage change from baseline in SALT scores in the modified intent-to-treat (mITT) population. Additional prespecified efficacy analyses included the proportion of patients achieving various relative and absolute SALT improvements including SALT-20 (80% of scalp hair coverage), $SALT_{30}$ (30% improvement in SALT score from baseline), and $SALT_{50}$ (50% improvement in SALT score from baseline) responses at Week 36, with follow-up through Week 52.

Key topline efficacy results from Part B of SIGNAL-AA at Week 36 include:

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Bempikibart demonstrated a favorable pharmacokinetic (PK), pharmacodynamic and anti-drug antibody (ADA) profile in Part B. PK data from Part B support the loading dose regimen had its intended effect, achieving steady state concentrations approximately 10 weeks earlier than in Part A. Negligible ADA was observed in Part B.

“These results provide important further evidence that our differentiated approach to targeting the biology underlying alopecia areata has the potential to translate into meaningful and durable clinical benefit for patients,” said Shelia Violette, Ph.D., Co-Founder and Chief Scientific Officer of Q32 Bio. “Despite recent advances, many patients continue to seek treatment options that combine robust efficacy with improved safety and the potential for sustained disease control. These findings strengthen our confidence in the therapeutic potential of this mechanism and its continued advancement as a differentiated treatment option for patients living with alopecia areata and other autoimmune and inflammatory diseases.”

The Part B off-drug follow-up period through Week 52 remains ongoing. Additionally, enrollment of eligible patients into the OLE remains ongoing. Q32 Bio intends to advance bempikibart into a registration-directed program in the first half of 2027 and plans to share full results from Part B at a future medical meeting.

Results from SIGNAL-AA Part A OLE:

Following the emergence of Part A data suggesting durability of response in the off-drug follow-up from SIGNAL-AA Part A and given patient demand for continued dosing, Q32 Bio announced the initiation of an OLE in April 2025. The Part A OLE has been completed. Eight patients enrolled in the Part A OLE, spanning responders, non-responders, and placebo patients from the Part A treatment portion. Patients were off-drug for various time periods ranging from 26 to 55 weeks prior to re-dosing. In the Part A OLE, bempikibart continued to demonstrate a generally well-tolerated safety profile with longer-term dosing and no new safety issues. Patients who maintained hair at entry to the OLE were observed to have durable or further hair growth. In totality, the Part A OLE dataset supports the importance of a maintenance dosing regimen.

Conference Call

In connection with this announcement, Q32 Bio will host a conference call and webcast with accompanying slides today at 8:00 a.m. E.T. This event will feature Arash Mostaghimi, MD, MPA, MPH, Associate Professor of Dermatology and Vice Chair of Clinical Trials and Innovation, Brigham and Women’s Hospital, Harvard Medical School.

To access a live or recorded webcast of the call and accompanying slides, please visit the “Investors” section of the Q32 Bio website at www.Q32Bio.com. To access the live conference call, please dial 1-800-836-8184 from the United States or 1-646-357-8785 from other locations; to access the webcast please login to https://app.webinar.net/m5ZoPmkRXdL.

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 and is focused on developing innovative therapies for alopecia areata and other autoimmune and inflammatory diseases. About 700,000 people in the United States live with alopecia areata[1], a disease which has a life-altering impact on patients and limited current treatment options. Q32 Bio is advancing bempikibart (ADX-914), a fully human anti-IL-7Rα antibody that re-regulates adaptive immune function, for the treatment of alopecia areata in an ongoing 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.

[1] National Alopecia Areata Foundation

Availability of Other Information About Q32 Bio

Investors and others should note that Q32 Bio communicates with its investors and the public using its website www.Q32Bio.com, including, but not limited to, Q32 Bio's disclosures, investor presentations and FAQs, Securities and Exchange Commission (the "SEC") filings, press releases, public conference call transcripts and webcast transcripts, as well as on X (formerly Twitter) and LinkedIn. The information that Q32 Bio posts on its website or on X or LinkedIn could be deemed to be material information. As a result, Q32 Bio encourages investors, the media and others interested to review the information that it posts there on a regular basis. The contents of Q32 Bio's website or social media shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Certain information in this press release constitutes forward-looking statements and forward-looking information (collectively, "forward-looking information") within the meaning of applicable securities laws. In some cases, but not necessarily in all cases, forward-looking information can be identified by the use of forward-looking terminology such as "plans", "excited to", "targets", "expects" or "does not expect", "is expected", "an opportunity exists", "is positioned", "estimates", "intends", "assumes", "anticipates" or "does not anticipate" or "believes", or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might", "will" or "will be taken", "occur" or "be achieved". In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Specifically,

this press release contains forward-looking information relating to the beliefs, observations, expectations and assumptions regarding the topline data from Part B of the SIGNAL-AA Phase 2a clinical trial 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, the expectations surrounding the potential, safety, efficacy, and regulatory and clinical progress of Q32 Bio's product candidates, including bempikibart, and anticipated milestones, timing of anticipated registrational trials, data readouts and timing, among others. Statements containing forward-looking information are not historical facts but instead represent management's current expectations, estimates and projections regarding the future of our business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by Q32 Bio as of the date of this press release, are subject to known and unknown risks, uncertainties and assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information. Such risks and uncertainties include, but are not limited to, the risk that additional data, or the results of ongoing data analyses, may not support Q32 Bio's current beliefs and expectations for bempikibart, including with respect to the durability of clinical responses, the risk that ongoing and future clinical studies might be more costly than expected or might not yield anticipated results, that Q32 Bio may use its capital resources sooner than currently anticipated, that Q32 Bio 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 "Risk Factors" section of Q32 Bio's most recently Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC, and subsequent quarterly reports. Except as required by applicable securities laws, Q32 Bio undertakes no obligation to publicly update any forward-looking information, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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