Quince Therapeutics Provides Business Update and Reports Fiscal Year 2024 Financial Results

March 24, 2025

Phase 3 NEAT clinical trial exceeds 50% enrollment with new study site activations expected to accelerate screenings and randomization

Existing cash position of $40.8 million expected to provide operating runway through Phase 3 topline results into 2026

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 24, 2025-- Quince Therapeutics, Inc. (Nasdaq: QNCX), a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases, today provided an update on the company's development pipeline and reported financial results for the fiscal year ended December 31, 2024.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "Our Phase 3 pivotal NEAT clinical trial has exceeded 50% enrollment with 71 participants screened and 61 randomized. Recent and upcoming new site activations are expected to accelerate enrollment through our target completion date in the second quarter of 2025. Assuming target enrollment completion, topline results from the NEAT study are anticipated in the fourth quarter of 2025."

Pivotal Phase 3 NEAT Clinical Trial

- Enrolled 61 participants to date in the company's Phase 3 NEAT (**N**eurological **E**ffects of **e**DSP on Subjects with **A**-**T**; NCT06193200/IEDAT-04-2022) clinical trial to evaluate the neurological effects of eDSP (previously referred to as EryDex) in patients with Ataxia-Telangiectasia (A-T), including 54 participants in the six to nine year-old primary analysis population.
- Transitioned 24 participants to date to the NEAT open label extension study (NCT06664853/IEDAT-04-2022). Participants who complete the full treatment period, complete study assessments, and provide informed consent are eligible to transition to an open label extension study.
- Expect screening and randomization to accelerate in the coming weeks due to several new geographic regions and sites scheduled for activation.
- Quince plans to enroll approximately 86 patients with A-T ages six to nine years old (primary analysis population) and approximately 20 patients with A-T ages 10 years or older.
- Pivotal Phase 3 NEAT clinical trial is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration (FDA).
- Expect to report Phase 3 NEAT topline results in the fourth quarter of 2025 with a New Drug Application (NDA) submission to the FDA and a Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) in 2026, assuming positive study results.
- NEAT is an international, multicenter, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of the company's lead asset, eDSP (dexamethasone sodium phosphate [DSP] encapsulated in autologous red blood cells), in patients with A-T.
- Participants will be randomized (1:1) between eDSP or placebo and treatment will consist of six infusions scheduled once every 21 to 30 days. The primary efficacy endpoint will be measured by the change from baseline to last visit completion in a rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo as per the SPA agreement with the FDA.

Pipeline and Corporate Updates

- Generating Phase 2 clinical trial study designed to evaluate eDSP for the potential treatment of patients with Duchenne muscular dystrophy (DMD). Quince plans to initiate a DMD Phase 2 study in 2025, which the company expects to conduct utilizing capital efficient study approaches and with financial support from grant and/or opportunistic funding opportunities.
- Published long-term safety data from patients with A-T treated with eDSP for a minimum of 24 months in *Frontiers in Neurology* in January 2025. The online publication titled *Long-term safety of dexamethasone sodium phosphate encapsulated in autologous erythrocytes in pediatric patients with Ataxia-Telangiectasia* can be accessed here.
- Appointed Dr. William Whitehouse, Honorary Clinical Associate Professor of the School of Medicine at the University of Nottingham and recently retired Consultant Pediatric Neurologist at Nottingham Children's Hospital, Nottingham University Hospitals NHS Trust, to the company's Scientific Advisory Board (SAB).
- Strengthened Quince's growing intellectual property portfolio and long-term market position with the issuance of a Notice of Allowance from the U.S. Patent and Trademark Office's (USPTO) in February 2025. This extends the company's patent claims into 2036 in the U.S., supplementing its existing U.S. patent with coverage of patent claims related to method of treating patients with A-T using Quince's proprietary process to encapsulate DSP in autologous red blood cells.

- Held an investor webinar in February 2025 featuring key opinion leader (KOL) Dr. Mary Kay Koenig from UTHealth Houston with a discussion focused on addressing the high unmet need in A-T. During the investor webinar, Dr. Koenig 1) provided an A-T natural history overview, 2) detailed current symptomatic treatment approaches for patients with A-T, 3) discussed the competitive therapeutic A-T landscape, and 4) provided an overview of Quince's Phase 3 NEAT clinical trial of eDSP for the treatment of A-T. A replay of the A-T KOL investor webinar is available here.

Fiscal Year 2024 Operating Highlights

- Granted Fast Track designation from the FDA for Quince's eDSP System for the treatment of patients with A-T in June 2024.
- Published efficacy and safety results from the company's Phase 3 ATTeST clinical trial evaluating eDSP for the treatment of A-T in medical journal *The Lancet Neurology*.
- Participated at notable scientific meetings, including poster presentations at the 53rd Child Neurology Society (CNS) Annual Meeting and the 2024 International Congress for Ataxia Research (ICAR), where Quince presented data from its Phase 3 ATTeST clinical trial.
- Completed an initial patient sizing project based on third-party analysis from IQVIA Medical Claims (Dx), PharmetricsPlus (P+), and IQVIA Analytics, which confirmed that the number of diagnosed patients with A-T in the U.S. is estimated to be to approximately 4,600.
- Established a SAB comprised of leading experts in biochemistry, neurology, immunology, hematology, pharmacology, and clinical practice uniquely positioned to provide Quince with deep insights and advice to support advancement of the company's drug programs.

Fiscal Year 2024 Financial Results

- Reported cash, cash equivalents, and short-term investments of $40.8 million for the fiscal year ended December 31, 2024. Quince expects its existing cash runway to be sufficient to fund the company's capital efficient development plan through Phase 3 NEAT topline results and into 2026. The company plans to be opportunistic from a financing perspective to extend its existing cash runway.
- Reported research and development (R&D) expenses of $18.6 million for the fiscal year ended December 31, 2024. R&D expenses primarily included costs related to ongoing Phase 3 NEAT clinical trial activities and related manufacturing costs.
- Reported general and administrative (G&A) expenses of $17.6 million for the fiscal year ended December 31, 2024. G&A expenses primarily included personnel-related and stock-based compensation expenses, commercial planning and new product planning expenses, and other professional administrative costs.
- Reported a net loss of $56.8 million, or a net loss of $1.31 per basic and diluted share, for the fiscal year ended December 31, 2024. Weighted average shares outstanding for the year were 43.3 million.
- Reported net cash used in operating activities of $31.9 million for the year ended December 31, 2024. Cash used in operating activities was primarily due to a net loss of $56.8 million for the period, adjusted for $25.4 million of non-cash items, including a $17.1 million goodwill impairment charge, $4.7 million in stock-based compensation, $4.0 million change in the fair value of contingent consideration liabilities, $1.7 million change in the fair value of long-term debt, and a net increase in operating assets of $2.6 million, offset by a net increase in accounts payable, and accrued expenses and other current liabilities of $ 2.1 million.
- Made a cash milestone payment of $5.0 million to EryDel shareholders in the third quarter of 2024 following the achievement of the first patient enrolled in the NEAT study in the second quarter of 2024.

About Quince Therapeutics

Quince Therapeutics, Inc. (Nasdaq: QNCX) is a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases. For more information on the company and its latest news, visit www.quincetx.com and follow Quince on social media platforms LinkedIn, Facebook, X, and YouTube.

Forward-looking Statements

Statements in this news release contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. All statements, other than statements of historical facts, may be forward-looking statements. Forward-looking statements contained in this news release may be identified by the use of words such as "believe," "may," "should," "expect," "anticipate," "plan," "believe," "estimated," "potential," "intend," "will," "can," "seek," or other similar words. Examples of forward-looking statements include, among others, statements relating to the timing, success, and reporting of results of the clinical trials and related data, including plans and the ability to enroll participants, conduct, and/or complete current and additional studies; expected cash position and operating runway; ability to secure additional funding and financial support, including from grant or opportunistic funding opportunities; current and future clinical development of eDSP, including for the potential treatment of Ataxia-Telangiectasia (A-T), Duchenne muscular dystrophy (DMD), and other potential indications; the strategic development path for eDSP; planned regulatory agency submissions and clinical trials and timeline, prospects, and milestone expectations; and the potential benefits of eDSP and the company's market opportunity. Forward-looking statements are based on Quince's current expectations and are subject to inherent uncertainties, risks, and assumptions that are difficult to predict and could cause actual results to differ materially from what the company expects. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate.

Factors that could cause actual results to differ include, but are not limited to, the risks and uncertainties described in the section titled “Risk Factors” in the company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 13, 2024, and other reports as filed with the SEC. Forward-looking statements contained in this news release are made as of this date, and Quince undertakes no duty to update such information except as required under applicable law.

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