Quince Therapeutics Provides Business Update and Reports First Quarter 2025 Financial Results

May 13, 2025

Plan to potentially conclude enrollment early for Phase 3 NEAT clinical trial in Ataxia-Telangiectasia (A-T) to align topline results with existing cash runway

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 13, 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 first quarter ended March 31, 2025.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "In light of current cash runway and with the goal of maximizing a capital efficient development plan, Quince has made the strategic business decision to potentially conclude enrollment of our pivotal Phase 3 NEAT clinical trial early by the end of June 2025 absent additional funding to extend our cash runway beyond the first quarter of 2026. Several factors contributed to this shift in strategy, including slower than anticipated enrollment, uncertain macroeconomic environment, challenging academic site environment, and an operationally well-executed study with limited withdrawals and low rates of missing data and procedural deviations. The combination of these factors leads us to now consider concluding enrollment prior to reaching the pre-specified target of 86 patients in the primary analysis population.

"It is important to highlight that the potential to conclude enrollment at the end of June 2025 is expected to provide an approximate 80% power to determine a statistically significant difference in the primary endpoint. Additionally, this timeline would allow the company to report topline results by early 2026 while maintaining a positive cash balance. Assuming positive results from the NEAT trial, we plan to submit applications for approval in the U.S. and Europe in the second half of 2026," said Thye.

Patient Enrollment in Pivotal Phase 3 NEAT Clinical Trial

- Quince is contemplating an early conclusion of enrollment for its pivotal Phase 3 NEAT clinical trial by the end of June 2025 to align the reporting of topline results with the company's existing cash runway in early 2026.
- To date, a total of 63 participants have been enrolled, including 56 participants in the six to nine year-old primary analysis population and seven participants aged 10 years or older.
- All 19 study sites are now activated, including several additional sites opened in the U.K. and Europe. Slower than anticipated enrollment in recent months is primarily due to a challenging academic site environment.
- Quince expects an increased rate of screening and randomization activities in the near term due to the activation of new sites. Approximately seven participants are scheduled for screening over the coming week. A total of 80 NEAT participants have been screened to date and the study has a low screen failure rate of 10%.
- Quince's potential early enrollment conclusion by the end of June 2025 would result in approximately 80% power to determine a statistically significant difference in the primary endpoint. If additional funding is secured in the near term, Quince intends to continue enrollment as previously planned targeting 86 patients with A-T ages six to nine years old in the primary analysis population.
- All 30 NEAT participants to date have elected to transition 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 the OLE study.
- New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) planned in the second half of 2026, assuming positive study results.
- NEAT (**N**eurological **E**ffects of **e**DSP on Subjects with **A**-**T**; NCT06193200/IEDAT-04-2022) is an international, multicenter, randomized, double-blind, placebo-controlled clinical trial to evaluate the neurological effects of Quince's lead asset, eDSP (dexamethasone sodium phosphate [DSP] encapsulated in autologous red blood cells; previously referred to as EryDex) in patients with A-T.
- Participants are randomized (1:1) between eDSP or placebo and treatment consists of six infusions scheduled once every 21 to 30 days. The primary efficacy endpoint will be measured by the change from baseline to last efficacy visit in the

rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo.

First Quarter 2025 Financial Results

- Reported cash, cash equivalents, and short-term investments of $31.6 million for the first quarter ended March 31, 2025. Quince expects its existing cash runway to be sufficient to fund the company's capital efficient development plan through Phase 3 NEAT topline results, which are now expected by early 2026.
- Reported research and development (R&D) expenses of $8.1 million for the first quarter ended March 31, 2025. 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 $4.8 million for the first quarter ended March 31, 2025. 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 $15.0 million, or a net loss of $0.34 per basic and diluted share, for the first quarter ended March 31, 2025. Weighted average shares outstanding for the year were 43.9 million.
- Reported net cash used in operating activities of $9.6 million for the first quarter ended March 31, 2025. Cash used in operating activities was primarily due to net loss of $15.0 million for the period, adjusted for $3.4 million of non-cash items, including $1.9 million change in the fair value of contingent consideration liabilities, $1.4 million in stock-based compensation, $0.4 million change in the fair value of the European Investment Bank loan and a net decrease in operating assets of $1.1 million, offset by a net increase in accounts payable, and accrued expenses and other current liabilities of $0.9 million.

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, impact of closing enrollment, conduct, and/or complete current and additional studies; expected cash position and operating runway; ability to secure additional funding and financial support; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 24, 2025, 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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