



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

November 12, 2025

Pivotal Phase 3 NEAT clinical trial evaluating lead asset, eDSP, for the treatment of A-T remains on track with topline results expected in first quarter of 2026

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 12, 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 third quarter ended September 30, 2025.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "Quince remains on track to report topline results for our pivotal Phase 3 NEAT clinical trial evaluating our lead asset eDSP (encapsulated dexamethasone sodium phosphate) for the treatment of Ataxia-Telangiectasia (A-T) in the first quarter of 2026. The NEAT study is powered at approximately 90% to test for a statistically significant difference between eDSP and placebo, and data management metrics suggest low rates of missing data and study discontinuations. Additionally, all patients completing the NEAT study have elected to participate in the open label extension (OLE) study. We also recently received a positive outcome of a NEAT safety analysis conducted by an independent data and safety monitoring board (iDSMB), which recommended that the study continue without any modifications. All of these factors support our ongoing confidence in a successful outcome for our pivotal Phase 3 NEAT clinical trial."

Pivotal Phase 3 NEAT Clinical Trial

- Quince completed enrollment in its pivotal Phase 3 NEAT (**N**eurological **E**ffects of eDSP on Subjects with **A-T**; [NCT06193200/IEDAT-04-2022](#)) clinical trial in July 2025 with a total of 105 participants, including 83 participants in the six to nine year-old primary analysis population and 22 participants aged 10 years and older.
- Quince expects to report topline results from its Phase 3 NEAT clinical trial in the first quarter of 2026.
- Concluding the NEAT study with 83 enrolled participants in the six to nine year-old primary analysis population reflects powering of approximately 90% to determine statistical significance on the primary endpoint.
- 100% of NEAT participants to date have elected to transition to the OLE 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.
- The Phase 3 NEAT clinical trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).
- Assuming positive study results, the company plans to submit a New Drug Application (NDA) to the FDA in the second half of 2026.
- Quince was granted FDA Fast Track designation for the company's eDSP System for the treatment of patients with A-T based on the potential to address a high unmet medical need.
- NEAT 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 using the Rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo.

Pipeline and Corporate Updates

- Hosted a virtual 2025 Investor Day on October 2, 2025 showcasing Quince's latest clinical development and corporate updates, the replay of which can be accessed [here](#). Notable featured topics included a presentation of multiple synergistic mechanisms of action that support eDSP's potential efficacy and disease modifying activity while mitigating corticosteroid toxicity, and how transcriptomic profiling reveals novel insights and potential biomarkers in A-T; insights into the company's attractive commercial opportunity and launch preparedness planning for eDSP, including details of its recently announced strategic relationship with Option Care Health; a look at Quince's strong competitive positioning and significant opportunity

to quickly expand its development pipeline into additional high-value, rare disease indications; as well as a demonstration of the company's proprietary drug/device combination eDSP System, among other key topics and highlights.

- Announced the outcome of the company's pre-planned safety analysis conducted by an independent data and safety monitoring board (iDSMB) for its Phase 3 NEAT clinical trial with the iDSMB recommending that the study continue without any modifications.
- Pursuing ongoing study initiation activities to support Quince's European Union pediatric investigational plan (PIP) – named the **P**ediatric **E**ncapsulated **D**examethasone Sodium Phosphate (PeD) study – to evaluate the safety and pharmacokinetics of eDSP in smaller patients with A-T who weigh between nine and 15 kilograms.
- Advanced commercial readiness activities, including completion of qualitative payer research covering more than 200 million U.S. lives. Findings were highly encouraging with payers recognizing the significant unmet need in A-T and expressing broad support for eDSP as a potential first-to-market treatment.
- Participated at the 54th Child Neurology Society (CNS) Annual Meeting with a poster presentation of patient-reported walking capacity in children with A-T, which describes the pattern of age-related walking capacity loss in patients with A-T and compares the subjective walking scale to the two measures – International Cooperative Ataxia Rating Scale (ICARS) and Rescored modified ICARS (RmICARS) – used in Quince's Phase 3 NEAT clinical trial. Results showed that all three scales tracked age-related loss of ambulation in a similar way, suggesting suitability of RmICARS walking capacity components in assessing A-T disease progression.
- Continuing advancement of the evaluation of Duchenne muscular dystrophy (DMD) as Quince's second targeted eDSP indication, including preparing for protocol finalization, contract research organization (CRO) evaluation and selection, and site feasibility in preparation for dosing the first patient in a DMD Phase 2 clinical study in 2026.
- Published an advanced population pharmacokinetic (PK) modeling study in the scientific journal *CPT: Pharmacometrics & Systems Pharmacology* (PSP) that addresses the development of a pediatric PK model based on data from the study of healthy adults and pediatric patients with A-T administered monthly with eDSP and predicts the exposure data in the A-T patient population over a six-month period, which is accessible [here](#).
- Entered into a second amendment of Quince's European Investment Bank (EIB) debt agreement in September 2025 that reduces the company's required minimum cash balance for the period from January 1, 2026 to March 31, 2026 to €5.0 million.
- Received an update on the company's previously sold legacy small molecule protease inhibitor portfolio acquired by Lighthouse Pharmaceuticals in January 2023. Lighthouse Pharma was awarded \$49.2 million grant from the National Institute on Aging to support its Phase 2 clinical trial in patients with Alzheimer's disease. Quince retains a 7.5% ownership position in Lighthouse Pharma and is positioned to benefit from milestone and royalty commitments related to Lighthouse's ability to successfully advance the development of its compounds through regulatory approval and subsequent commercialization.

Third Quarter 2025 Financial Results

- Reported cash, cash equivalents, and short-term investments of \$26.3 million for the third quarter ended September 30, 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 into the second quarter of 2026. If warrants related to the company's recent financing are exercised in full for cash, Quince's cash runway would extend into the second half of 2026.
- Reported research and development (R&D) expenses of \$8.1 million for the third quarter ended September 30, 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 \$3.3 million for the third quarter ended September 30, 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 \$13.3 million, or a net loss of \$0.25 per basic and diluted share, for the third quarter ended September 30, 2025. Weighted average shares outstanding – basic and diluted – for the quarter were 54.0 million.
- Reported net cash used in operating activities of \$30.9 million for the nine months ended September 30, 2025. Cash used in operating activities was primarily due to net loss of \$44.5 million for the period, adjusted for \$13.2 million of non-cash items, including \$4.5 million change in the fair value of contingent consideration liabilities, \$4.2 million change in the fair value of warrants, \$3.9 million in stock-based compensation, \$1.3 million change in the fair value of the EIB loan, and a

net decrease in operating assets of \$0.3 million, offset by a net increase in accounts payable, accrued expenses, and other current liabilities of \$0.7 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 expected timing and outcome of Phase 3 NEAT topline results and submission of a related NDA; expected cash position and operating runway, including cash potentially receivable upon the exercise of warrants; 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, including the anticipated benefits of the strategic partnership with Option Care Health; planned regulatory agency submissions and clinical trials and timeline, prospects, and milestone expectations; potential benefits of eDSP and the company's market opportunity; and potential benefits from the company's investment in Lighthouse Pharmaceuticals. 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, Quarterly Report on Form 10-Q filed with the SEC on August 11, 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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