Quince Therapeutics Provides Business Update and Reports Third Quarter 2024 Financial Results

November 13, 2024

Phase 3 NEAT clinical trial on track with 32 patients enrolled to date with majority of U.S. and European study sites now enrolling patients

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 13, 2024-- 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, 2024.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "We are pleased to report accelerating enrollment of our pivotal Phase 3 NEAT clinical trial in Ataxia-Telangiectasia (A-T). As of today, we have enrolled 32 patients with A-T across clinical sites in the U.S., U.K., and European Union. Additionally, the majority of planned NEAT study sites are now activated and open for enrollment. We expect enrollment momentum to continue as we work toward our commitment to complete enrollment in the second quarter of 2025 and report topline results in the fourth quarter of 2025."

Pivotal Phase 3 NEAT Clinical Trial

- Enrolled 32 participants to date in the company's Phase 3 NEAT (**N**eurologic **E**ffects of EryDex on Subjects with **A**-**T**; IEDAT-04-2022/NCT06193200) clinical trial to evaluate the neurological effects of EryDex in patients with A-T.
- 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.
- Participants who complete the full treatment period, complete study assessments, and provide informed consent will be eligible to transition to an open label extension study, which will begin in the fourth quarter of 2024.
- 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, multi-center, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of the company's lead asset, EryDex (dexamethasone sodium phosphate [DSP] encapsulated in autologous red blood cells), in patients with A-T.
- Participants will be randomized (1:1) between EryDex 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

- Participation at scientific congresses, including a poster presentation of safety data from the previously completed ATTeST study at the 53rd Child Neurology Society Annual Meeting. Quince is also sponsoring and participating at the 2024 International Congress for Ataxia Research in November 2024 with two poster presentations, including growth and bone mineral density in patients with A-T treated with EryDex, and an analysis of the International Cooperative Ataxia Rating Scale (ICARS) subcomponent scores in patients with A-T.
- Generating Phase 2 clinical trial study designed to evaluate EryDex for the potential treatment of patients with Duchenne muscular dystrophy (DMD), including those with corticosteroid intolerance, who represent the majority of the DMD population. Quince plans to initiate a DMD Phase 2 study in 2025, which the company expects to conduct utilizing capital efficient study approaches.
- Completed evaluation process of other potential rare disease indications beyond A-T and Duchenne muscular dystrophy for EryDex where chronic corticosteroid treatment is – or has the potential to become – a standard of care, if there were not corticosteroid-related safety concerns. The prioritized list of other potential rare disease targets under consideration includes: 1) autoimmune hepatitis, 2) dermatomyositis, 3) pemphigus vulgaris, 4) Hashimoto's encephalopathy, 5) Becker muscular dystrophy, 6) pediatric lupus, 7) juvenile idiopathic arthritis, 8) myasthenia gravis, 9) limb-girdle muscular dystrophy, 10) chronic inflammatory demyelinating polyradiculoneuropathy, and 11) pulmonary sarcoidosis.

Third Quarter and Year-to-Date 2024 Financial Results

- Reported cash, cash equivalents, and short-term investments of $47.8 million for the third quarter ended September 30, 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.
- Expect strong cash position to fully fund lead asset, EryDex, through Phase 3 NEAT topline results in the fourth quarter of 2025 and prepare for NDA and MAA submissions in 2026, assuming positive study results. This includes approximately $20 million for the NEAT clinical trial and approximately $15 million in direct trial costs for an open label extension study.
- Reported research and development (R&D) expenses of $4.9 million for the third quarter ended September 30, 2024. R&D expenses during the quarter primarily included costs related to ongoing Phase 3 NEAT clinical trial activities and related manufacturing costs.
- Reported general and administrative (G&A) expenses of $3.6 million for the third quarter ended September 30, 2024. G&A expenses for the quarter 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 $5.5 million, or a net loss of $0.13 per basic and diluted share, for the third quarter ended September 30, 2024. Weighted average shares outstanding for the quarter were 43.2 million.
- Reported net cash used in operating activities of $24.4 million for the nine months ended September 30, 2024, which included a net loss of $44.4 million for the period, adjusted for $22.4 million of non-cash items, including $17.1 million goodwill impairment charge, $2.1 million change in the fair value of contingent consideration liabilities, $3.6 million in stock-based compensation, a net increase in operating assets of $2.5 million, and a net increase in accounts payable, accrued expenses, and other current liabilities of $0.1 million. Additionally, Quince made a cash milestone payment of $5 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 current and future clinical development of EryDex, including for the potential treatment of Ataxia-Telangiectasia (A-T), Duchenne muscular dystrophy (DMD), and other potential indications, related development and commercial-stage inflection point for EryDex, and expansion of the company's proprietary Autologous Intracellular Drug Encapsulation (AIDE) technology for treatment of other rare diseases; the strategic development path for EryDex; planned regulatory agency submissions and clinical trials and timeline, prospects, and milestone expectations; the timing, success, and reporting of results of the clinical trials and related data, including plans and the ability to initiate, fund, enroll, conduct, and/or complete current and additional studies; research and development costs; the company's future development plans and related timing; cash position and projected cash runway; the company's focus, objectives, plans, and strategies; and the potential benefits of EryDex, AIDE technology 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 August 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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