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

August 13, 2024

Strong cash position expected to provide sufficient operating runway into 2026;
Phase 3 topline results expected in the fourth quarter of 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 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 second quarter ended June 30, 2024.

Dirk Thye, M.D., Quince's Chief Executive Officer and Chief Medical Officer, said, "We achieved a major clinical milestone during the second quarter of 2024 with the first patient enrolled in our pivotal Phase 3 NEAT clinical trial in Ataxia-Telangiectasia (A-T). As of today, we have enrolled seven patients with A-T across clinical sites in the U.S., U.K., and European Union. We are encouraged by this strong start and expect NEAT site activation and patient screening activities to accelerate over the next quarter."

Pivotal Phase 3 NEAT Clinical Trial

- Dosed the first patient 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 in June 2024.
- Enrolled seven patients with A-T in the NEAT clinical trial to date. 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.
- 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.
- Pivotal Phase 3 NEAT clinical trial is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration (FDA).
- 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.
- 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.
- Expect to report Phase 3 NEAT topline results in the fourth quarter of 2025 with a potential 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.

Pipeline and Corporate Updates

- Granted Fast Track designation by the FDA for the company's EryDex System for the treatment of patients with A-T based on the potential for EryDex to address a high unmet medical need in A-T.
- Updated 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, an increase from previous estimates of approximately 3,400 diagnosed patients. There are currently no approved therapeutic treatments for A-T, and the market represents a $1+ billion peak commercial opportunity globally, based on the company's internal estimates and assumptions.
- Generating proof-of-concept clinical trial study designs 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 proof-of-concept study in 2025, which the company expects to conduct utilizing capital efficient study approaches.
- Planned participation at upcoming scientific congresses, including a poster presentation of EryDex safety data at the

upcoming 53rd Child Neurology Society Annual Meeting in November 2024. Quince will also be a sponsor of and participate 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.

- Strengthening of leadership team with the addition of Brent Roeck as Vice President of Program and Alliance Management and Katie George as Executive Director Clinical Operations, bringing more than 50 years of collective experience across rare disease and the pharmaceutical and biotech industry to support Quince's pivotal Phase 3 NEAT study and focus on strategic business partnerships.

- Investigating other potential indications 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. This evaluation process is expected to span across ataxias, neuromuscular indications, hematology, cancer, and autoimmune diseases, with a focus on rare diseases.

- Evaluating potential strategic partnerships to out-license ex-U.S. rights to extend operational runway to support potential NDA approval of EryDex in the U.S., as well as further advance other potential indications and programs using the company's proprietary Autologous Intracellular Drug Encapsulation (AIDE) technology platform.

- Participating at the H.C. Wainwright 26th Annual Global Investment Conference the week of September 9, 2024. A webcast of the presentation will be accessible here.

Second Quarter and Year-to-Date 2024 Financial Results

- Reported cash, cash equivalents, and short-term investments of $59.4 million for the second quarter ended June 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 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 potential 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 $4.2 million for the second quarter ended June 30, 2024. R&D expenses during the quarter primarily included start-up costs related to Phase 3 NEAT clinical trial activities and related manufacturing costs.

- Reported general and administrative (G&A) expenses of $4.7 million for the second quarter ended June 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 $27.7 million, or a net loss of $0.64 per basic and diluted share, for the second quarter ended June 30, 2024. During the quarter, Quince recognized a non-cash goodwill impairment charge of $17.1 million as the quantitative analysis resulted in the company's fair value being below its carrying value. Weighted average shares outstanding for the quarter were 43.1 million.

- Reported net cash used in operating activities of $17.1 million for the six months ended June 30, 2024, which included a net loss of $38.9 million for the period, adjusted for $24.0 million of non-cash items, including a $4.8 million change in the fair value of contingent consideration liabilities, $2.5 million in stock-based compensation, and a net decrease in current assets of $2.3 million, offset by a net decrease in accounts payable, accrued expenses, and other current liabilities of $0.1 million compared to the same period last year.

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 May 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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