UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 13, 2024

QUINCE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38890**	**90-1024039**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

601 Gateway Boulevard , Suite 1250 **South San Francisco, California**	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 910-5717

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13d-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	QNCX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2024, Quince Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2024 and provided recent business highlights. A copy of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Quince Therapeutics, Inc. dated November 13, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

QUINCE THERAPEUTICS, INC.

By: /s/ Dirk Thye

Name: Dirk Thye

Title: Chief Executive Officer and Chief Medical Officer

Date: November 13, 2024

Exhibit 99.1

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

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. – November 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 (Neurologic Effects 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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QUINCE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands except share amounts)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,675	$ 20,752
Short-term investments	45,172	54,307
Prepaid expenses and other current assets	3,871	2,381
Total current assets	51,718	77,440
Property and equipment, net	208	234
Operating lease right-of-use assets	559	385
Goodwill	—	17,625
Intangible assets	64,528	63,672
Other assets	9,506	8,544
Total assets	$ 126,519	$ 167,900
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,622	$ 2,033
Short-term contingent consideration	—	4,103
Accrued expenses and other current liabilities	3,803	3,436
Total current liabilities	5,425	9,572
Long-term debt	14,899	13,429
Long-term operating lease liabilities	450	321
Long-term contingent consideration	54,788	53,603
Deferred tax liabilities	5,382	5,304
Other long-term liabilities	643	587
Total liabilities	81,587	82,816
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 authorized, (100,000 shares of which are designated as Series A Junior Participating Preferred Stock), no shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 43,276,606 and 42,973,215 issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.	43	43
Additional paid in capital	405,484	401,638
Accumulated other comprehensive income	3,419	3,047
Accumulated deficit	(364,014)	(319,644)
Total stockholders' equity	44,932	85,084
Total liabilities and stockholders' equity	$ 126,519	$ 167,900

QUINCE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 4,916	$ 1,431	$ 12,765	$ 6,013
General and administrative	3,630	4,663	13,296	12,786
Goodwill impairment charge	—	—	17,130	—
Intangible asset impairment charge	—	—	—	5,900
Fair value adjustment for contingent consideration	(2,683)	—	2,082	—
Total operating expenses [1]	5,863	6,094	45,273	24,699
Loss from operations	(5,863)	(6,094)	(45,273)	(24,699)
Fair value adjustment for long-term debt	(449)	—	(1,252)	—
Interest income	683	959	2,393	2,464
Other income (expense), net	150	(216)	(158)	(504)
Net loss before income tax benefit	(5,479)	(5,351)	(44,290)	(22,739)
Income tax (expense) benefit	(13)	—	(80)	248
Net loss	(5,492)	(5,351)	(44,370)	(22,491)
Net loss per share - basic and diluted	$ (0.13)	$ (0.15)	$ (1.03)	$ (0.63)
Weighted average shares of common stock outstanding - basic and diluted	43,164,136	36,073,040	43,090,632	35,941,234

(1) Expenses include the following amount of non-cash stock-based compensation expense.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General and administrative expense	$ 786	$ 945	$ 3,096	$ 3,014
Research and development expense	338	386	525	1,120
Total stock-based compensation	$ 1,124	$ 1,331	$ 3,621	$ 4,134