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): **December 19, 2024**

QUOIN PHARMACEUTICALS LTD.

(Translation of registrant's name into English)

State of Israel	**001-37846**	**92-2593104**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

42127 Pleasant Forest Court **Ashburn, VA**	**20148-7349**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(703) 980-4182**

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 240.13e-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**
American Depositary Shares, each representing one (1) Ordinary Share, no par value per share	QNRX	The Nasdaq Stock Market LLC
Ordinary Shares, no par value per share*		N/A

* Not for trading, but only in connection with the registration of the American Depositary Shares pursuant to requirements of the Securities and Exchange Commission.

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 8.01. Other Events.

Quoin Pharmaceuticals Ltd. (the "Company" or "Quoin"), a clinical stage, specialty pharmaceutical company focused on rare and orphan diseases, today announced FDA clearance to initiate a new additional Netherton Syndrome (NS) clinical study for QRX003. QRX003 is a topical lotion that contains a broad-spectrum serine protease inhibitor designed to target the kallikreins in the skin responsible for the excessive skin shedding associated with this disease.

The study will be conducted by Dr. Amy Paller, of Northwestern University. It is planned that up to eight subjects will be enrolled into the study and will have QRX003 applied twice daily to greater than 80% of their entire body surface area (BSA) over a 12-week period. By comparison, in Quoin's ongoing open-label and double-blinded clinical studies, QRX003 is applied to approximately 20% of the subject's BSA, typically the arms and lower leg. This new study, designed to mimic how NS patients will use QRX003 if approved, represents the most extensive use of QRX003 in a clinical setting to date. It is anticipated that the data generated from this study will be used to supplement the data package to support the potential regulatory approval of QRX003 as a treatment for NS.

Cautionary Note Regarding Forward Looking Statements

The Company cautions that statements in this report that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as "expect," "intend," "plan," "anticipate," "believe," "look forward to," and "will," among others. All statements that reflect the Company's expectations, assumptions, projections, beliefs, or opinions about the future, other than statements of historical fact, are forward-looking statements, including, without limitation, statements relating to: plans to initiate whole body study and the data generated from this study to be used to supplement the data package to support the potential regulatory approval of QRX003 as a treatment for NS. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties including, but not limited to, the timing of the clinical studies may be delayed, the clinical studies may not generate the results anticipated, the Company needing to raise additional funds sooner than planned, or the clinical studies not generating data which is sufficiently robust and comprehensive to support an NDA filing and the Company's ability to obtain regulatory approvals. More detailed information about the risks and uncertainties affecting the Company is summarized in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and in other filings the Company has made and may make with the SEC in the future. One should not place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as may be required by law.

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.

Date: December 19, 2024

QUOIN PHARMACEUTICALS LTD.

By: /s/ Michael Myers
Name: Dr. Michael Myers
Title: Chief Executive Officer