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 13, 2023**

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. ☐

On December 13, 2023, Quoin Pharmaceuticals Ltd. (the "Company") issued a press release announcing that it had received clearance from the U.S. Food and Drug Administration to implement a number of protocol amendments to its two ongoing clinical trials for QRX003, which is being developed as a potential treatment for Netherton Syndrome. Both trials are being conducted under the Company's open Investigational New Drug Application (IND) for QRX003.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Information contained on or accessible through any website reference in the press release is not part of, or incorporated by reference in, this Current Report on Form 8-K, and the inclusion of such website addresses in this Current Report on Form 8-K by incorporation by reference of the press release is as inactive textual references only.

Item 8.01 Other Events.

On December 13, 2023, the Company issued a press release announcing that it had received clearance from the U.S. Food and Drug Administration to implement a number of protocol amendments to its two ongoing clinical trials for QRX003, which is being developed as a potential treatment for Netherton Syndrome. Both trials are being conducted under the Company's open Investigational New Drug Application (IND) for QRX003.

The number of subjects in the blinded trial is increased to 30 from 18. In addition, the lower 2% dose has been eliminated from the trial going forward. All subjects will now receive either 4% QRX003 or a placebo vehicle, both of which will be applied twice-daily instead of the current once-daily treatment.

The number of subjects in the open-label trial is increased to 20 from 10, and the dosing frequency will also be twice-daily going forward. All subjects in this trial will continue to receive off-label systemic therapy throughout the duration of treatment.

All current clinical endpoints for both trials will remain the same.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 13, 2023
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.

Date: December 18, 2023

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn
Name: Gordon Dunn
Title: Chief Financial Officer

Exhibit 99.1

Quoin Pharmaceuticals Announces FDA Clearance of Clinical Optimization Plan for QRX003 for Netherton Syndrome

Positive initial data and clean safety profile catalyze optimization plan
Size of both ongoing clinical trials significantly increased
Lower dose eliminated from blinded trial
Dosing frequency changed to twice-daily from once-daily for both trials

ASHBURN, Va., December 13, 2022 – Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the "Company" or "Quoin"), a specialty pharmaceutical company focused on rare and orphan diseases, today announced that it has received U.S. Food and Drug Administration (FDA) clearance to implement a number of protocol amendments to its two ongoing clinical trials for QRX003, which is being developed as a potential treatment for Netherton Syndrome (NS). Both trials are being conducted under Quoin's open Investigational New Drug Application (IND) for QRX003.

"We are extremely pleased to announce clearance of our clinical trial optimization plan for QRX003 in NS. Armed with positive initial data and a clean safety profile to date, we believe that these protocol amendments could ultimately result in the generation of a highly compelling data set which could support regulatory filings and approval for QRX003 as the first treatment for this terrible disease. These latest developments underscore Quoin's continued commitment to delivering a safe and effective treatment for this very underserved patient population," said Dr. Michael Myers, Chief Executive Officer of Quoin.

As a result of positive initial clinical data across multiple endpoints and a strong safety profile to date, Quoin has made a number of protocol amendments to both ongoing trials. The company believes that implementation of these protocol amendments may result in an even more robust data set and potentially more rapid approval with a broader label.

The number of subjects in the blinded trial is increased to 30 from 18. As a result of the positive safety profile observed to date, the lower 2% dose has been eliminated from the trial going forward. All subjects will now receive either 4% QRX003 or a placebo vehicle, both of which will be applied twice-daily instead of the current once-daily treatment.

The number of subjects in the open-label trial is increased to 20 from 10, and the dosing frequency will also be twice-daily going forward. All subjects in this trial will continue to receive off-label systemic therapy throughout the duration of treatment.

All current clinical endpoints for both trials will remain the same and Quoin plans to open additional clinical sites to efficiently accommodate this increase in the number of enrolled subjects. Interest from subjects and clinical investigators continues to be very high and Quoin remains the only company actively recruiting subjects into NS clinical trials that are being conducted under an open IND.

About Netherton Syndrome

Netherton Syndrome, a form of Ichthyosis, is a rare, hereditary skin disorder caused by a mutation in the SPINK5 gene (serine protease inhibitor, Kazal Type 5) that leads to severe skin barrier defects and recurring infections, as well as a pronounced predisposition to allergies, asthma, and eczema. Patients also often suffer from severe dehydration, chronic skin inflammation and stunted growth.

Currently, there is no cure for Netherton Syndrome, nor are there any approved therapeutic treatments.

About QRX003

QRX003 is a topical lotion, formulated with a proprietary delivery technology, and contains a broad- spectrum serine protease inhibitor, whose mechanism of action is intended to perform the function of a specific protein, called LEKTI. The absence of LEKTI in Netherton patients leads to excessive skin shedding resulting in a highly porous and compromised skin barrier. QRX003 is designed to lead to a more normalized skin shedding process and the formation of a stronger and more effective skin barrier.

About Quoin Pharmaceuticals Ltd.

Quoin Pharmaceuticals Ltd. is an emerging specialty pharmaceutical company focused on developing and commercializing therapeutic products that treat rare and orphan diseases. We are committed to addressing unmet medical needs for patients, their families, communities and care teams. Quoin's innovative pipeline comprises three products in development that collectively have the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Epidermolysis Bullosa and others. For more information, go to: www.quoinpharma.com.

Cautionary Note Regarding Forward Looking Statements

The Company cautions that statements in this press release 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," and "will," among others. 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. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" included in the Company's Annual Report on Form 20-F filed with the SEC on April 14, 2022, 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. 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.

For further information, contact:

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