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): **June 23, 2026**

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 thirty-five (35) Ordinary Shares, 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 7.01. Regulation FD Disclosure.

On June 23, 2026, Quoin Pharmaceuticals Ltd. (the "Company" or "Quoin") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has conditionally approved QYLEKI™ as the proposed brand name for QRX003, the Company's investigational product candidate for the treatment of Netherton Syndrome. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Report") and is incorporated by reference herein.

The information in this Item 7.01 and Exhibit 99.1 attached hereto are furnished and shall not be deemed to be "filed" with the Securities and Exchange Commission (the "SEC") 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 such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

Announcement of Conditional Approval of QYLEKI™ as the Proposed Brand Name for QRX003 for Netherton Syndrome

On June 23, 2026, the Company announced that the FDA has conditionally approved QYLEKI™ as the proposed brand name for QRX003, the Company's investigational product candidate for the treatment of Netherton Syndrome. The proposed name QYLEKI (pronounced "Key-Lek-ee") was developed in accordance with the FDA's guidance on proprietary names. The Company further stated that FDA acceptance of the Company's proposed brand name represents a milestone for the Company as it executes on its mission to deliver the first approved treatment for Netherton Syndrome. The Company expects to include a request for proprietary name review and final approval for QYLEKI in a New Drug Application (NDA) for QRX003.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed or furnished, as applicable, with this Report:

Exhibit Number	**Description**
99.1	Press Release of the Company, dated June 23, 2026
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: June 23, 2026

QUOIN PHARMACEUTICALS LTD.

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

Exhibit 99.1

Quoin Pharmaceuticals Receives FDA Conditional Approval of QYLEKI™ as the Proposed Brand Name for QRX003 for Netherton Syndrome

- *QRX003 Holds Orphan Drug Designation in the United States, the European Union, and Japan, Plus Fast Track and Rare Pediatric Disease Designations from the FDA*

- *Pivotal Phase 3 Study Expected to Initiate in the Second Half of 2026, with Potential NDA Filing in 2027*

- *Positive Clinical Update from Ongoing Pediatric Compassionate Use Program Released on June 16*

- *QRX003 remains on track to Potentially Become the First Approved Treatment for Netherton Syndrome*

ASHBURN, Va., June 23, 2026 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) ("Quoin" or the "Company"), a late clinical-stage specialty pharmaceutical company focused on rare and orphan diseases, today announced that the U.S. Food and Drug Administration (FDA) has conditionally approved QYLEKI™ as the proposed brand name for QRX003, the Company's investigational product candidate for the treatment of Netherton Syndrome. FDA acceptance of the Company's proposed brand name represents yet another important milestone for Quoin as it executes on its mission to deliver the first approved treatment for Netherton Syndrome. A request for proprietary name review and final approval for QYLEKI will be included in a New Drug Application (NDA) for QRX003.

Key Facts

- The FDA has conditionally accepted QYLEKI™ as the proposed brand name for QRX003, Quoin's investigational topical treatment for Netherton Syndrome.
- QRX003 holds Orphan Drug Designation in the United States, the European Union, and Japan.
- The FDA has also granted QRX003 Fast Track and Rare Pediatric Disease Designations.
- Quoin's pivotal Phase 3 study is expected to initiate in the second half of 2026.
- A potential NDA filing is anticipated in 2027.
- There is currently no approved treatment for Netherton Syndrome. If approved, QRX003 could become the first.

The proposed name QYLEKI (pronounced "Key-Lek-ee") was developed in accordance with the FDA's guidance on proprietary names. Final approval of the QYLEKI brand name will be obtained upon FDA marketing approval of QRX003.

“The designation of a brand name for the first potentially approved treatment for Netherton Syndrome represents another important step for Quoin, our commercial partners and most importantly, the Netherton community as a whole.” said Dr. Michael Myers, Chief Executive Officer and Co-Founder of Quoin Pharmaceuticals. “FDA conditional approval of the QYLEKI brand name reflects the continued progress we are making toward potential commercialization of the product and complements the regulatory recognition the product has received in the United States, Europe, and Japan. Having just released a positive update from our ongoing Pediatric Compassionate Use Program and with our pivotal Phase 3 study expected to commence later this year, this is an extremely exciting time for Quoin as we remain fully focused on delivering QYLEKI to patients as what could be the first approved treatment for Netherton Syndrome.”

QYLEKI Development and Regulatory Status

QYLEKI lotion (4%) is currently being evaluated in Phase 2 whole-body clinical trials in patients with Netherton Syndrome. Quoin’s pivotal Phase 3 study is expected to initiate in the second half of 2026, with a potential NDA filing in 2027. QYLEKI has received Orphan Drug Designation in the United States, the European Union, and Japan, along with Fast Track and Rare Pediatric Disease Designations from the FDA, providing regulatory recognition across Quoin’s three core commercial territories.

About Netherton Syndrome

Netherton Syndrome is a rare, inherited skin disorder caused by mutations in the SPINK5 gene, leading to severe skin barrier dysfunction, chronic inflammation, and a heightened risk of infections and allergic complications. Patients often experience widespread skin redness, scaling, persistent itching, and significant impairment in quality of life. There are currently no FDA-approved therapies for the treatment of Netherton Syndrome, and treatment options are limited to supportive care and off-label therapies.

About Quoin Pharmaceuticals Ltd.

Quoin Pharmaceuticals Ltd. is a late clinical-stage 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 is focused on two key platform products, QRX003 and QRX009, that collectively have the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Pachyonychia Congenita, Gorlin Syndrome and Tuberous Sclerosis Complex, microcystic lymphatic malformations, venous malformations, angiofibromas and others. For more information, visit: www.quoinpharma.com or LinkedIn for updates.

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," "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: **QYLEKI being the proposed brand name for QRX003 for Netherton Syndrome;** Quoin executing on its mission to deliver the first approved treatment for Netherton Syndrome; initiating a pivotal Phase 3 study in the second half of 2026 with a potential NDA filing anticipated in 2027; obtaining final approval of the QYLEKI brand name upon FDA marketing approval of QRX003; continuing the progress being made toward potential commercialization of QRX003; delivering the first approved treatment for Netherton Syndrome; and Quoin's belief that its products in development collectively have the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Pachyonychia Congenita, Gorlin Syndrome, Tuberous Sclerosis Complex, microcystic lymphatic malformations, venous malformations, angiofibromas and 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 including, but not limited to, the Company's ability to pursue its regulatory strategy; the Company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements; the Company's ability to complete clinical trials on time and achieve desired results and benefits as expected; and other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 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.

For further information, contact:

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