

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): September 8, 2026

QUOIN PHARMACEUTICALS LTD.

(Translation of registrant's name into English)

State of Israel

(State or other jurisdiction
of incorporation)

001-37846

(Commission File Number)

92-2593104

(I.R.S. Employer
Identification No.)

42127 Pleasant Forest Court
Ashburn, VA

(Address of Principal Executive Offices)

20148-7349

(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 Ordinary Shares, no par value per share*	QNRX	The Nasdaq Stock Market LLC 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 September 8, 2026, Quoin Pharmaceuticals Ltd. (the “Company” or “Quoin”) issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) has granted Rare Pediatric Disease (RPD) Designation for QRX003, the Company’s investigational product candidate, for the treatment of Peeling Skin Syndrome (PSS). 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 is 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 FDA Granting Rare Pediatric Disease Designation for QRX003 in Peeling Skin Syndrome

On September 8, 2026, the Company announced that the FDA has granted Rare Pediatric Disease (RPD) Designation for the Company’s lead asset, QRX003, for the treatment of Peeling Skin Syndrome (PSS). The Company believes that the designation reinforces the potential of QRX003 as a therapeutic candidate for a profoundly underserved pediatric population. This is the second RPD designation granted for QRX003, following the previously granted RPD designation for Netherton Syndrome.

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 September 8, 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: September 10, 2026

QUOIN PHARMACEUTICALS LTD.

By: /s/ Michael Myers

Name: Dr. Michael Myers

Title: Chief Executive Officer

Quoin Pharmaceuticals Announces FDA Grants Rare Pediatric Disease Designation for QRX003 in Peeling Skin Syndrome

- *Second Rare Pediatric Disease (RPD) Designation for QRX003*
- *FDA Previously Granted RPD Designation for QRX003 in Netherton Syndrome*
- *If a New Drug Application (NDA) for QRX003 Is Approved for Peeling Skin Syndrome, Quoin May Receive a Freely Tradable Priority Review Voucher (PRV)*
- *Quoin Expects to Initiate Phase 2 Study in 2H 2026; Study Plans to Enroll up to 12 Pediatric and Adult Peeling Skin Patients in the U.S. and Europe*
- *There are Currently No Approved Treatments for Peeling Skin Syndrome*

ASHBURN, Va., September 8, 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 granted Rare Pediatric Disease (RPD) Designation for the Company’s lead asset, QRX003, for the treatment of Peeling Skin Syndrome (PSS).

The designation reinforces the potential of QRX003 as a therapeutic candidate for a profoundly underserved pediatric population. This is the second RPD designation granted for QRX003, following the previously granted RPD designation for Netherton Syndrome.

The FDA’s Rare Pediatric Disease Designation program is intended to encourage the development of new therapies for serious and life-threatening diseases that primarily affect individuals under 18 years of age. If a New Drug Application (NDA) for QRX003 is approved, Quoin may qualify to receive a Priority Review Voucher (PRV), which can be redeemed to receive priority review for another marketing application or may be sold or transferred.

“We are very pleased to announce the receipt of Rare Pediatric Disease Designation for QRX003 for Peeling Skin Syndrome,” said Dr. Michael Myers, Chief Executive Officer of Quoin Pharmaceuticals. “With the IND cleared by FDA, the Quoin team is preparing to initiate the Phase 2 clinical study before the end of this year with plans to enroll up to 12 pediatric and adult Peeling Skin patients in the U.S. and Europe. This will be the first formal study ever conducted in the U.S. for this disease under an open IND.”

About Peeling Skin Syndrome (PSS)

Generalized inflammatory peeling skin syndrome (PSS) is a rare autosomal recessive genodermatosis caused by loss-of-function disease-causing variants of the corneodesmosin gene (CDSN), resulting in excessive shedding of the superficial layers of the epidermis. Patients generally suffer from a variety of conditions including severe pain and chronic pruritus (itch). There is currently no approved treatment for PSS.

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.quinopharma.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: the potential of QRX003 as a therapeutic candidate for Peeling Skin Syndrome and a profoundly underserved pediatric population, Quoin’s eligibility to receive Priority Review Vouchers upon approval of a New Drug Application for QRX003; the initiation of a Phase 2 clinical study for Peeling Skin Syndrome before the end of 2026 with plans to enroll up to 12 pediatric and adult patients in the U.S. and Europe; 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 and 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:

Quoin Pharmaceuticals Ltd.
Michael Myers, Ph.D., CEO
mmyers@quoinpharma.com

Investor Relations

PCG Advisory
Jeff Ramson
jramson@pcgadvisory.com
(646) 863-6341
