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): **January 20, 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 January 20, 2026, Quoin Pharmaceuticals Ltd. (the "Company" or "Quoin") issued a press release announcing that it has filed an application for Breakthrough Medicine Designation with the Saudi Food and Drug Authority (SFDA) for QRX003, the Company's lead investigational, late-stage topical 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 Application for Breakthrough Medicine Designation with the SFDA for QRX003

On January 20, 2026, the Company announced that it has filed an application for Breakthrough Medicine Designation with the SFDA for QRX003, its lead investigational, late-stage topical product candidate for the treatment of Netherton Syndrome.

The SFDA's Breakthrough Medicine Designation program is designed to expedite the development, review, and potential availability of medicines that address serious or life-threatening conditions with high unmet medical need and which meet SFDA eligibility requirements, which include:

- Targets serious debilitating or life-threatening conditions with unmet medical need.
- The medicinal product is likely to offer major advantages over methods currently used.
- The potential adverse effects of the medicinal product are considered to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit/risk balance.
- The product is not registered with any regulatory authority at the time of submission of the designation request.

Quoin believes that QRX003 meets each of these eligibility requirements.

If granted, the designation will allow for accelerated regulatory review and could enable earlier patient access in Saudi Arabia, potentially as early as the second half of 2026.

QRX003 has received Orphan Drug and Pediatric Rare Disease Designations from the U.S. Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency for the potential treatment of Netherton Syndrome. Quoin has an established distribution partnership with Genpharm for QRX003 for Saudi Arabia and other MENA countries.

QRX003 lotion (4%) is currently being evaluated in two late-stage whole-body pivotal clinical trials in patients with Netherton Syndrome. Enrollment in both studies is expected to be completed in the first half of 2026, with top-line data anticipated in the second half of 2026. Quoin plans to submit a New Drug Application (NDA) in the United States and other territories in late 2026/early 2027, subject to successful clinical outcomes.

Additional Information

The Company further reports that as of January 20, 2026, it had 1,616,179 American Depositary Shares ("ADSs") outstanding, with each ADS representing thirty-five (35) of its ordinary shares, no par value.

Cautionary Note Regarding Forward Looking Statements

The Company cautions that statements in this Report that are not descriptions 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," "hope," "plan," "potential," "anticipate," "look forward," "believe," "may," 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: QRX003 being approved for sale and reimbursement in Saudi Arabia as a treatment for Netherton Syndrome in the second half of 2026, QRX003 meeting the eligibility requirements for the SFDA's Breakthrough Medicine Designation program, completing enrollment for QRX003 lotion (4%) in two late-stage whole-body pivotal clinical trials in patients with Netherton Syndrome in the first half of 2026, top-line data anticipated in the second half of 2026, and plans to submit a NDA in the United States and other territories in late 2026/early 2027, subject to successful clinical outcomes. 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 deliver a safe and effective treatment for Netherton Syndrome; 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; the Company experiencing unanticipated or higher than expected clinical trial costs; the Company's ability to obtain the capital necessary to fund its activities; and other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 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.

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 January 20, 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: January 20, 2026

QUOIN PHARMACEUTICALS LTD.

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

Exhibit 99.1

Quoin Pharmaceuticals Files Breakthrough Medicine Designation Application in Saudi Arabia for QRX003 in Netherton Syndrome

If granted, QRX003 could be approved for sale and reimbursement in Saudi Arabia as a treatment for Netherton Syndrome in 2H 2026

QRX003 could become the first ever approved treatment for Netherton Syndrome

ASHBURN, Va., Jan. 20, 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 it has filed an application for Breakthrough Medicine Designation with the Saudi Food and Drug Authority (SFDA) for QRX003, its lead investigational, late-stage topical product candidate for the treatment of Netherton Syndrome.

The SFDA's Breakthrough Medicine Designation program is designed to expedite the development, review, and potential availability of medicines that address serious or life-threatening conditions with high unmet medical need and which meet SFDA eligibility requirements, which include:

- Targets serious debilitating or life-threatening conditions with unmet medical need.
- The medicinal product is likely to offer major advantages over methods currently used.
- The potential adverse effects of the medicinal product are considered to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit/risk balance.
- The product is not registered with any regulatory authority at the time of submission of the designation request.

Quoin believes that QRX003 meets each of these eligibility requirements.

If granted, the designation will allow for accelerated regulatory review and could enable earlier patient access in Saudi Arabia, potentially as early as 2H 2026.

QRX003 has received Orphan Drug and Pediatric Rare Disease Designations from the U.S. Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency for the potential treatment of Netherton Syndrome. Quoin has an established distribution partnership with Genpharm for QRX003 for Saudi Arabia and other MENA countries.

"Filing for Breakthrough Medicine Designation with the SFDA marks a historic milestone for both Quoin and the Netherton Syndrome community," said Dr. Michael Myers, Chief Executive Officer of Quoin Pharmaceuticals. "If granted, it is possible that QRX003 could be available for sale and reimbursement in Saudi Arabia in the second half of this year. This would make QRX003 the first ever approved treatment anywhere in the world for this devastating disease. We look forward to working with our commercial partner in the region to make QRX003 available to Netherton patients in Saudi Arabia as expeditiously as possible, if the designation is granted."

QRX003 lotion (4%) is currently being evaluated in two late-stage whole-body pivotal clinical trials in patients with Netherton Syndrome. Enrollment in both studies is expected to be completed in the first half of 2026, with top-line data anticipated in the second half of 2026. Quoin plans to submit a New Drug Application (NDA) in the United States and other territories in late 2026/early 2027, subject to successful clinical outcomes.

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 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, SAM Syndrome, Palmoplantar Keratoderma, Scleroderma, Microcystic Lymphatic Malformations, Venous Malformations, Angiofibroma 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 descriptions 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,” “hope,” “plan,” “potential,” “anticipate,” “look forward,” “believe,” “may,” 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: QRX003 being approved for sale and reimbursement in Saudi Arabia as a treatment for Netherton Syndrome in 2H 2026, QRX003 becoming the first ever approved treatment for Netherton Syndrome, QRX003 meeting the eligibility requirements for the SFDA’s Breakthrough Medicine Designation program, working with Quoin’s commercial partner in the region to make QRX003 available to Netherton patients in Saudi Arabia as expeditiously as possible, if the designation is granted, completing enrollment for QRX003 lotion (4%) in two late-stage whole-body pivotal clinical trials in patients with Netherton Syndrome in the first half of 2026, with top-line data anticipated in the second half of 2026, plans to submit a NDA in the United States and other territories in late 2026/early 2027, subject to successful clinical outcomes, and Quoin’s products in development collectively having the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, SAM Syndrome, Palmoplantar Keratoderma, Scleroderma, Microcystic Lymphatic Malformations, Venous Malformations, Angiofibroma 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 deliver a safe and effective treatment for Netherton Syndrome; 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; the Company experiencing unanticipated or higher than expected clinical trial costs; the Company’s ability to obtain the capital necessary to fund its activities; and other factors discussed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2024 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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