

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): **March 26, 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	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 2.02 Results of Operations and Financial Condition.

On March 26, 2026 Quoin Pharmaceuticals Ltd. (the “Company”) announced its fourth quarter and fiscal year 2025 financial results. A copy of the Company’s press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

The information set forth and incorporated by reference in this Item 2.02 shall not be deemed to be “filed” with the Securities and Exchange Commission 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, and the Company does not incorporate it by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 26, 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: March 26, 2026

QUOIN PHARMACEUTICALS LTD.

By: /s/ Sally Lawlor

Name: Sally Lawlor

Title: Chief Financial Officer

Quoin Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Full-Year 2025 Financial Results

- Closes Private Placement Financing of Up to \$104.5 Million*
- Secures Orphan Drug Designations for QRX003 for Netherton Syndrome (NS) in the U.S. and Europe*
- Advances Proposed Expedited Regulatory Approval Pathways in Japan and Saudi Arabia and Secures Fast Track Designation in the U.S. for QRX003 for NS Subsequent to the End of Q4*
- Reports Continued Clinical Progress for QRX003 in Netherton Syndrome Clinical Studies including Data Supporting Longer Term Durable Treatment Effect and Safety Profile*
 - Pediatric NS Study Expanded to 7 Children Now Actively Treated with QRX003, Largest Cohort of This Age Group Ever Studied*
 - Ongoing Clinical Data Continues to Support Development of QRX003 as a Treatment for Peeling Skin Syndrome with Study Being Expanded to 6 subjects*
 - Proprietary Rapamycin Topical Platforms Achieve Target Loadings; Clinical Studies Planned in 2H 2026*
 - NETHERTON NOW Awareness Campaign Surpasses 2 Million Video Views and 24 Million Global Impressions*

ASHBURN, Va., March 26, 2026 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the "Company" or "Quoin"), a late clinical-stage specialty pharmaceutical company focused on rare and orphan diseases, today announced recent corporate achievements and provided an update on its fourth quarter and full-year 2025 progress for the period ended December 31, 2025.

“2025 was a defining year for Quoin as we transitioned from clinical stage to a company actively preparing for commercial readiness,” said Michael Myers, Chief Executive Officer and Co-Founder of Quoin Pharmaceuticals. “We strengthened our balance sheet with a significant financing, secured key regulatory designations across our core territories, and continued to advance the clinical development of QRX003 supported by encouraging long-term efficacy data demonstrating durable treatment effect with no reported safety concerns. With Orphan Drug Designations in place in the United States and Europe, and confirmation of eligibility for Orphan Drug Designation and Fast Track review in Japan, QRX003 is now aligned with expedited regulatory pathways in our key target markets. In the United States, QRX003 was also awarded Rare Pediatric Disease Designation by the U.S. Food and Drug Administration (FDA) for Netherton Syndrome, which, if approved, could result in the receipt of a freely tradable Priority Review Voucher, with a potential value to Quoin of \$150-\$200 million in non-dilutive cash. Based on positive initial clinical data from our ongoing Peeling Skin Syndrome study, we are increasing the size of this study to 6 subjects, and we are planning to submit an Investigational New Drug application to the FDA in the second half of this year. In addition, we are planning to initiate clinical testing of QRX003 in Ichthyosis and SAM syndrome potentially putting the product on track for approval for four rare genetic diseases where there are currently no approved treatments. Finally, we are moving forward with our topical rapamycin program. We are targeting initiating clinical testing in at least one indication in the second half of this year and we believe our optimized delivery technologies may offer competitive advantages over more conventional topical formulations of rapamycin. All in all, we are excited at what 2026 could bring for our company and the patient populations we serve. We have begun the year with strong forward momentum with a platform poised to succeed on multiple fronts.”

Recent Accomplishments

On January 20, 2026, Quoin filed an application for Breakthrough Medicine Designation with the Saudi Food and Drug Authority (SFDA) for QRX003. If granted, the designation could enable accelerated regulatory review and availability in Saudi Arabia as early as the second half of 2026.

On January 27, 2026, Quoin submitted an application to Japan's Ministry of Health, Labour and Welfare (MHLW) seeking Orphan Drug Designation for QRX003. The MHLW confirmed that QRX003 qualifies for both Orphan Drug Designation and Fast Track review in Japan.

On February 3, 2026, the U.S. Rare Pediatric Disease Priority Review Voucher (PRV) program was extended by Congress through September 30, 2029 as part of the Give Kids a Chance Reauthorization Act. QRX003 previously received Rare Pediatric Disease Designation from the U.S. Food and Drug Administration (FDA) in June 2025. Upon approval of QRX003, Quoin would be eligible to receive a Priority Review Voucher which, if awarded, may be used to obtain priority review for another product or sold or transferred.

On February 26, 2026, in recognition of Rare Disease Day 2026, Quoin highlighted continued momentum of its NETHERTON NOW awareness campaign, which has reached nearly 2 million video views and more than 24 million impressions globally since launch.

Fourth Quarter and Full-Year 2025 Highlights

Closed Private Placement Financing

On October 10, 2025, Quoin closed a private placement financing raising up to \$104.5 million in gross proceeds, including \$16.5 million at closing and up to \$88.0 million upon potential exercise of accompanying warrants.

Advancement of QRX003 for Netherton Syndrome

On October 21, 2025, the U.S. FDA granted Orphan Drug Designation to QRX003 for the treatment of Netherton Syndrome. Orphan status in the United States, together with previously granted Orphan Drug Designation in Europe, provides important potential benefits, including market exclusivity upon approval, tax credits for clinical testing and fee reductions.

On October 28, 2025, Quoin reported positive nine-month pediatric data demonstrating sustained skin healing, complete elimination of pruritus, and no adverse events in an investigator-led study of QRX003. This data further supports the long-term safety and efficacy profile of QRX003. This study has been expanded to 7 pediatric NS patients currently being treated with QRX003 in Ireland, Austria, the Netherlands and New Zealand.

On March 11, 2026, the U.S. FDA granted Fast Track Designation to QRX003 for the treatment of Netherton Syndrome. The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. A therapy granted Fast Track Designation may benefit from more frequent interactions with the FDA, eligibility for rolling review of regulatory submissions, and potential qualification for Accelerated Approval and Priority Review, if relevant criteria are met.

On March 25, 2026, Quoin provided a clinical and regulatory update from its constructive Type C meeting with the U.S. FDA for QRX003 in NS. Quoin reported that the FDA indicated that a single Phase 3 study may be sufficient to support marketing approval in the U.S. and expressed openness to an alternative study design for Phase 3 that would likely not include a traditional upfront vehicle or placebo control. Quoin remains on track to initiate its Phase 3 Study and complete Phase 3 patient recruitment in 2026 and potentially file for NDA approval in 2027.

QRX003 is currently being evaluated in two whole-body clinical trials for the treatment of Netherton Syndrome and Quoin anticipates reporting topline data in the second half of 2026.

Peeling Skin and Topical Rapamycin Pipeline Programs

On May 14, 2025, the Company announced positive initial data from its investigator led Peeling Skin Syndrome (PSS) clinical study which is being conducted in a single patient in New Zealand. The Company is actively working to recruit up to an additional 5 pediatric subjects into this study and is planning to submit an IND to the FDA in the second half of this year.

On November 11, 2025, the Company announced that the target rapamycin loadings of 4% and 5% for its proprietary topical lotion and dermal patch platforms had been achieved. The Company plans to initiate proof of concept clinical testing in the second half of 2026 in at least one clinical indication. Quoin believes that its proprietary technologies have the potential to optimize the local delivery of rapamycin at the target site and may provide a key competitive advantage over other platforms.

Financial Highlights

Quoin had approximately \$18.7 million in cash, cash equivalents and marketable securities as of December 31, 2025. The Company believes its year-end cash position will fund the Company's operations into 2027.

Net loss for the quarter ended December 31, 2025, was approximately \$4.3 million compared to approximately \$2.3 million for the quarter ended December 31, 2024. Net loss for the twelve months ended December 31, 2025, was approximately \$15.8 million compared to approximately \$9.0 million for the twelve months ended December 31, 2024.

Investors are encouraged to read the Company's Annual Report on Form 10-K when filed with the Securities and Exchange Commission, which will contain additional details about Quoin's financial results as of and for the period ended December 31, 2025.

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 several 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, 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 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: expanding the Company's ongoing study of Peeling Skin Syndrome, planning clinical studies of the Company's topical rapamycin in 2H 2026, actively preparing for commercial readiness, receiving a Priority Review Voucher, submitting an Investigative New Drug application to the FDA in the second half of this year, initiating clinical testing of QRX003 in Ichthyosis and SAM Syndrome, putting QRX003 on track for approval for four rare genetic diseases where there are currently no approved treatments, enabling accelerated regulatory review and availability in Saudi Arabia as early as the second half of 2026 if the application for Breakthrough Medicine Designation with the SFDA for QRX003 is granted, the potential for an accelerated regulatory review pathway for QRX003, actively working to recruit up to an additional 5 pediatric subjects into the Peeling Skin Syndrome clinical study, Phase 3 study being sufficient to support marketing approval in the US, the Company using an alternative study design for Phase 3 study that would likely not include a traditional upfront vehicle or placebo control, Company being on track to initiate its Phase 3 Study and complete Phase 3 patient recruitment in 2026, Company potentially filing NDA approval in 2027, reporting topline data from two whole-body clinical trials for the treatment of Netherton Syndrome in the second half of 2026, initiating proof of concept clinical testing in the second half of 2026 in at least one clinical indication for Quoin's rapamycin topical lotion and dermal patch platforms, the Company's year-end cash position funding operations into 2027, 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, 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 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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Investor Relations

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QUOIN PHARMACEUTICALS, LTD.
Consolidated Balance Sheets

	<u>December 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,818,096	\$ 3,623,343
Investments	14,927,165	10,433,535
Prepaid expenses and other current assets	1,261,974	869,126
Total current assets	<u>20,007,235</u>	<u>14,926,004</u>
Prepaid expenses - long term	—	300,000
Intangible assets, net	383,334	483,334
Total assets	<u>\$ 20,390,569</u>	<u>\$ 15,709,338</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,262,222	\$ 905,704
Accrued expenses	2,538,457	1,528,977
Accrued interest and financing expense	1,146,251	1,146,251
Due to officers - short term	600,000	600,000
Total current liabilities	<u>5,546,930</u>	<u>4,180,932</u>
Due to officers - long term	1,723,733	2,323,733
Total liabilities	<u>\$ 7,270,663</u>	<u>\$ 6,504,665</u>
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value per share, 5,000,000,000 and 100,000,000 ordinary shares authorized at December 31, 2025 and December 31, 2024, respectively - 52,441,360 (1,498,325 ADS's) ordinary shares issued and outstanding at December 31, 2025 and 8,948,164 (255,661 ADS's) ordinary shares issued and outstanding at December 31, 2024	\$ —	\$ —
Accumulated other comprehensive loss	(613)	—
Additional paid in capital	84,090,966	64,370,465
Accumulated deficit	(70,970,447)	(55,165,792)
Total shareholders' equity	<u>13,119,906</u>	<u>9,204,673</u>
Total liabilities and shareholders' equity	<u>\$ 20,390,569</u>	<u>\$ 15,709,338</u>

QUOIN PHARMACEUTICALS, LTD.
Consolidated Statement of Operations and Other Comprehensive Loss

	Years Ended December 31,		Three months ended December 31,	
	2025	2024	2025	2024
	(Audited)	(Audited)	(Unaudited)	(Unaudited)
Operating expenses				
General and administrative	\$ 6,487,909	\$ 5,925,833	\$ 1,423,526	\$ 1,410,717
Research and development	9,802,807	3,602,632	3,096,909	994,344
Total operating expenses	16,290,716	9,528,465	4,520,435	2,405,061
Other (income) and expenses				
Unrealized gain	(3,980)	(7,502)	(364)	15,541
Realized and accrued interest income	(482,081)	(558,491)	(171,698)	(109,328)
Total other income	(486,061)	(565,993)	(172,062)	(93,787)
Net loss	\$ (15,804,655)	\$ (8,962,472)	\$ (4,348,373)	\$ (2,311,274)
Other comprehensive loss				
Foreign currency translation	(613)	—	(613)	—
Total other comprehensive loss	\$ (613)	\$ —	\$ (613)	\$ —
Comprehensive loss	\$ (15,805,268)	\$ (8,962,472)	\$ (4,348,986)	\$ (2,311,274)
Loss per ADS				
Loss per ADS				
Basic	\$ (14.80)	\$ (68.02)	\$ (1.74)	\$ (12.39)
Fully-diluted	\$ (14.80)	\$ (68.02)	\$ (1.74)	\$ (12.39)
Weighted average number of ADS's outstanding				
Basic	1,068,152	131,759	2,494,255	186,514
Fully-diluted	1,068,152	131,759	2,494,255	186,514