Quoin Pharmaceuticals Provides Corporate Update and Reports First Quarter 2026 Financial Results

May 7, 2026

– Filed Breakthrough Medicine Designation Application with Saudi FDA for QRX003 in Netherton Syndrome

– Submitted Application to Japanese MHLW for Orphan Drug Designation (ODD) for QRX003; MHLW Confirmed QRX003 Qualifies for Both Orphan Drug Designation and Fast Track Review

– U.S. FDA Granted Fast Track Designation to QRX003 lotion (4%) for the treatment of Netherton Syndrome, Complementing Previously Granted Orphan Drug and Rare Pediatric Disease Designations

– Constructive Type C Meeting with FDA: Single Phase 3 Study May Be Sufficient to Support U.S. Marketing Approval; FDA Open to Trial Design Without Traditional Vehicle or Placebo Control

– Rare Pediatric Disease Priority Review Voucher Program Extended by Congress Through September 30, 2029

– On Track to Complete Phase 3 Patient Recruitment by End of 2026, with Potential NDA Filing in 2027 for QRX003 as the First Approved Treatment for Netherton Syndrome

ASHBURN, Va., May 07, 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 first quarter 2026 progress for the period ended March 31, 2026.

“The first quarter of 2026 delivered meaningful regulatory progress on a number of fronts for QRX003 for Netherton Syndrome,” said Dr. Michael Myers, Chief Executive Officer and Co-Founder of Quoin Pharmaceuticals. “In the United States, we were granted Fast Track Designation by the U.S. Food and Drug Administration (FDA). In addition, we had a constructive Type C meeting with FDA where the agency indicated that a single Phase 3 study may be sufficient to support marketing approval, with expressed openness to an alternative study design for Phase 3 that would likely not include a traditional upfront vehicle or placebo control. In Japan, we submitted our Orphan Drug Designation application following confirmation from MHLW that QRX003 qualifies for both ODD and Fast Track review. In Saudi Arabia, we filed for Breakthrough Medicine Designation, which could expedite the path to patient access, if granted. We also remain on track to complete Phase 3 recruitment this year and potentially file for NDA approval in 2027. On top of this, we have made substantial progress this year with our QRX009 topical rapamycin platform. Through engagement with KOLs and advocacy foundations, we are now in a position to initiate clinical testing in a number of indications later this year including investigator studies for Pachyonychia Congenita, Gorlin Syndrome and Tuberous Sclerosis Complex. We are also planning to submit an Investigational New Drug (IND) Application to the FDA for QRX009 for an additional indication by Q3 of this year. We believe the combination of our QRX003 platform for Netherton Syndrome and related diseases combined with our QRX009 topical rapamycin platform represents an intriguing value proposition for investors and we look forward to sharing more information on both throughout this year."

First Quarter 2026 Highlights

Regulatory Progress for QRX003 in Netherton Syndrome:

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. Quoin has an established distribution partnership with Genpharm for QRX003 in Saudi Arabia and other MENA countries.

On January 27, 2026, Quoin submitted an application to Japan's Ministry of Health, Labour and Welfare (MHLW) seeking Orphan Drug Designation for QRX003. MHLW confirmed that QRX003 qualifies for both Orphan Drug Designation and Fast Track review in Japan. The Company has also initiated the establishment of a Japanese subsidiary to facilitate self-commercialization of QRX003 in Japan, if approved.

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 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 March 11, 2026, the U.S. FDA granted Fast Track Designation to QRX003 lotion (4%) for the treatment of Netherton Syndrome. Fast Track status enables 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 FDA for QRX003 in Netherton Syndrome. 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, such as a randomized withdrawal or randomized delayed start, that would likely not include a traditional upfront vehicle or placebo control. Quoin will submit clinical data from the ongoing Phase 2 and pediatric investigator studies and plans to request a meeting to discuss this data with the FDA prior to initiating the Phase 3 pivotal program to gain alignment on the design of the program. Quoin remains on track to complete patient recruitment into its Phase 3 program by the end of 2026 and to potentially file for FDA approval for QRX003 as the first treatment for Netherton Syndrome in 2027.

On April 28, 2026, Quoin provided a clinical and regulatory update for its QRX009 topical rapamycin development program, announcing the planned initiation of an investigator-led clinical study in Pachyonychia Congenita led by Professor Edel O'Toole, Queen Mary University of London as well as additional investigator-led studies in Gorlin Syndrome and Tuberous Sclerosis Complex. In addition, Quoin is targeting to submit an IND to the FDA for QRX009 for an additional indication in Q3 of 2026.

Clinical Development:

QRX003 lotion (4%) continues to be evaluated in late-stage whole-body clinical trials for the treatment of Netherton Syndrome, with topline data anticipated in the second half of 2026. The ongoing pediatric investigator-led study has been expanded to six children actively being treated with QRX003 in Ireland, Austria, the Netherlands, and New Zealand, representing the largest pediatric cohort of this age group ever studied in Netherton Syndrome.

Pipeline Programs:

Additional QRX003 Indications: Quoin continues to advance its Peeling Skin Syndrome (PSS) program, with the ongoing investigator-led study being expanded to six subjects. The Company plans to submit an IND to the FDA for PSS in Q2 of 2026.

QRX009 Development: Quoin also continues to advance its proprietary topical rapamycin platforms, which have achieved target loadings of 4% and 5% for the topical lotion and dermal patch, respectively. Investigator-led clinical studies are being planned for a number of indications including Pachyonychia Congenita, Gorlin Syndrome and Tuberous Sclerosis Complex and the Company is planning to submit an IND to the FDA for QRX009 for an additional indication before the end of Q3 of this year.

Awareness and Advocacy:

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.

Financial Highlights

Quoin had approximately $14 million in cash, cash equivalents and marketable securities as of March 31, 2026. The Company believes its current cash position will fund operations into 2027.

Net loss for the quarter ended March 31, 2026, was approximately $5 million compared to approximately $3.8 million for the quarter ended March 31, 2025.

Investors are encouraged to read the Company's Quarterly Report on Form 10-Q 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 March 31, 2026.

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, PC, GS, TSC, 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: a single Phase 3 study being sufficient to support US marketing approval of QRX003 for Netherton Syndrome; the FDA being open to a trial design that would likely not include a traditional upfront vehicle or placebo control; a Breakthrough Medicine Designation expediting the path to patient access in Saudi Arabia; being in a position to initiate clinical testing for QRX009 in a number of indications later this year, including investigator studies for Pachyonychia Congenita, Gorlin Syndrome and Tuberous Sclerosis Complex; plans to submit an IND Application to the FDA for an additional indication by the Q3 of this year; the combination of the Company's QRX003 platform for Netherton Syndrome and related diseases combined with its QRX009 topical rapamycin platform representing an intriguing value proposition for investors; sharing more information on both throughout this year; establishing a Japanese subsidiary to facilitate self-commercialization of QRX003 in Japan, if approved; submitting clinical data from the Company's ongoing Phase 2 and pediatric investigator studies; requesting a meeting with the FDA to discuss the data prior to initiating the Phase 3 pivotal program to gain alignment on the design of the program; remaining on track to complete patient recruitment into the Company's Phase 3 program by the end of 2026; filing for FDA approval for QRX003 as the first treatment for Netherton Syndrome in 2027; continuing to evaluate QRX003 lotion in late-stage whole-body clinical trials for the treatment of Netherton Syndrome, with topline data anticipated in the second half of 2026; continuing to advance the Company's PSS program; plans to submit an IND Application to the FDA for PSS in the Q2 2026; the Company's current cash position funding operations into 2027; 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, PC, GS, TSC, 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

QUOIN PHARMACEUTICALS, LTD.
Consolidated Balance Sheets

	March 31, 2026	December 31, 2025
ASSETS	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$ 3,124,522	$ 3,818,096
Investments	10,918,778	14,927,165
Prepaid expenses and other current assets	1,291,256	1,261,974
Total current assets	15,334,556	20,007,235
Intangible assets, net	358,334	383,334
Total assets	$ 15,692,890	$ 20,390,569
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,776,231	$ 1,262,222
Accrued expenses	1,823,544	2,538,457
Accrued interest and financing expense	1,146,251	1,146,251
Due to officers - short term	600,000	600,000
Total current liabilities	5,346,026	5,546,930
Due to officers - long term	1,573,733	1,723,733
Total liabilities	$ 6,919,759	$ 7,270,663
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value per share, 5,000,000,000 authorized at March 31, 2026 and December 31, 2025, respectively - 68,642,195 (1,961,206 ADS's) ordinary shares issued and outstanding at March 31, 2026 and 52,441,360 (1,498,325 ADS's) ordinary shares issued and outstanding at December 31, 2025	$ -	$ -
Accumulated other comprehensive loss	(159)	(613)
Additional paid in capital	84,741,473	84,090,966
Accumulated deficit	(75,968,183)	(70,970,447)
Total shareholders' equity	8,773,131	13,119,906
Total liabilities and shareholders' equity	$ 15,692,890	$ 20,390,569

QUOIN PHARMACEUTICALS, LTD.
Consolidated Statement of Operations & Other Comprehensive Loss (Unaudited)

	Three months ended March 31,	
	2026	2025
Operating expenses		
General and administrative	$ 1,697,448	$ 1,583,038
Research and development	3,433,763	2,374,139
Total operating expenses	5,131,211	3,957,177
Other (income) and expenses		
Unrealized gain (loss)	13,300	(126)
Realized and accrued interest income	(146,775)	(144,872)
Total other income	(133,475)	(144,998)
Net loss	$ (4,997,736)	$ (3,812,179)
Deemed dividend on warrant modification	-	-
Net loss	$ (4,997,736)	$ (3,812,179)
Other comprehensive loss		
Foreign currency translation	454	-
Comprehensive loss	$ (4,997,282)	$ (3,812,179)
Loss per ADS		
Loss per ADS		
Basic	$ (1.77)	$ (6.50)
Fully-diluted	$ (1.77)	$ (6.50)
Weighted average number of ADS's outstanding		
Basic	2,830,970	586,331
Fully-diluted	2,830,970	586,331