

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 13, 2024**

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 one (1) Ordinary Share, 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 13, 2024, Quoin Pharmaceuticals Ltd. (the “Company”) announced its fourth quarter and fiscal year 2023 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 13, 2024
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 13, 2024

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

Quoin Pharmaceuticals Provides Corporate Update and Announces Fourth Quarter and 2023 Financial Results

Company reported positive initial clinical data for QRX003 from first six evaluable subjects in ongoing open-label Netherton Syndrome study with positive benefits observed across a number of clinical endpoints

Eligibility age for enrollment into both studies has been lowered to fourteen years and older

No safety concerns have been observed to date in either ongoing clinical study

Quoin expects its cash runway will extend into the second half of 2025 following \$6.5 million offering on March 5th

Cash Runway to be further extended by \$8 million Equity Line of Credit arrangement signed January 25, 2024

ASHBURN, Va., March 13, 2024 -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) (the “Company” or “Quoin”), a clinical stage, specialty pharmaceutical company focused on rare and orphan diseases, today provides a business update and announces financial results for the quarter and year ended December 31, 2023.

Quoin CEO, Dr. Michael Myers, said, “2023 marked another year of significant progress for Quoin and for the development of QRX003 for the treatment of Netherton Syndrome. Notably, we released initial positive data from our open label clinical study, representing a first for the very underserved Netherton community. That progress has continued, and based on the strength of the initial positive clinical data, we implemented a number of important protocol changes that we believe could lead to a more streamlined development program overall.

“We have also strengthened our balance sheet through the recently completed \$6.5 million capital raise and we have the capacity to further solidify our cash position via the \$8.0 million equity line of credit transaction we entered into earlier this year, once shareholder approval is received. We continue to believe that Quoin is in position to deliver the first approved treatment for this terrible disease.”

Recent Corporate Highlights –

- On March 4th, Quoin announced FDA Clearance to recruit teen subjects into both ongoing Netherton Syndrome clinical studies.
 - On February 8th, 2024, Quoin filed U.S. and International patent applications for a novel Netherton Syndrome combination product.
 - On December 13th, Quoin announced FDA clearance of the Clinical Optimization Plan for QRX003 for Netherton Syndrome
 - On October 24th, Quoin announced positive clinical data from the first six evaluable patients in the company’s open-label clinical trial in Netherton Syndrome patients.
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- o Five of the six subjects reported that their pruritus, or itch, was either negligible or absent following treatment with QRX003, a significant improvement from prior to the study.
- o All six subjects exhibited improvement in the Investigator assessed skin scoring system with three subjects showing improvement at the completion of the study and the other three at various points during the study.
- o All six subjects expressed a favorable impression of QRX003 across multiple assessed metrics.
- o No safety concerns have been reported to date for any subject in either of Quoin's studies.

Financial Highlights

- Quoin had approximately \$10.7 million in cash, cash equivalents and marketable securities as of December 31, 2023. This does not include the proceeds from the \$6.5 million public offering of common shares that the company announced on March 5, 2024, nor the anticipated proceeds from the \$8 million equity line of credit transaction which was entered into in January of this year. Implementation of this remains subject to shareholder approval.
- Net loss for the quarter ended December 31, 2023 was approximately \$2.0 million compared to approximately \$2.0 million for the quarter ended December 31, 2022. Net loss for the twelve months ended December 31, 2023 was \$8.7 million compared to \$9.4 million for the twelve months ended December 31, 2022.
- Investors are encouraged to read the Company's Annual Report on Form 10-K when it is filed with the Securities and Exchange Commission (the "SEC"), which will contain additional details about Quoin's financial results as of and for the period ended December 31, 2023.

Quoin will host a conference call and webcast at 8:30am ET on Thursday, March 14, 2024. The call will include a discussion of fourth quarter and full year 2023 financial results and a corporate update. The live call can be accessed by dialing 1-800-603-0527 (domestic) or 1-412-317-0688 (international). The live and archived webcast of the call will also be available on the Quoin Pharmaceuticals website under the Investors section or by following this link: <https://event.choruscall.com/mediaframe/webcast.html?webcastid=ZmehVyN5>

About Quoin Pharmaceuticals Ltd.

Quoin Pharmaceuticals Ltd. is a 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 four 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, Epidermolysis Bullosa 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,” 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 Company’s expected cash runway, the belief that certain protocol changes could lead to a more streamlined development program and the belief that the Company is in a position to deliver the first approved treatment for Netherton Syndrome. 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. More detailed information about the risks and uncertainties affecting the Company is contained under the heading “Risk Factors” included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 that the Company filed with the SEC. 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:

PCG Advisory

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-Tables Follow-

QUOIN PHARMACEUTICALS, LTD.
Consolidated Balance Sheets

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,401,198	\$ 2,860,628
Investments	8,293,663	9,992,900
Prepaid expenses and other current assets	591,034	516,584
Deferred offering costs	-	-
Total current assets	11,285,895	13,370,112
Prepaid expenses - long term	300,000	383,390
Intangible assets, net	583,334	704,561
Total assets	\$ 12,169,229	\$ 14,458,063
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 526,523	\$ 605,600
Accrued expenses	1,308,706	1,175,705
Accrued license acquisition	-	-
Accrued interest and financing expense	1,146,251	1,146,251
Due to officers - short term	600,000	600,000
Total current liabilities	3,581,480	3,527,556
Due to officers - long term	2,923,733	3,523,733
Total liabilities	\$ 6,505,213	\$ 7,051,289
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value per share, 100,000,000 and 8,333,334 ordinary shares authorized at December 31, 2023 and 2022, respectively - 987,220 (987,220 ADS's) ordinary shares issued and outstanding at December 31, 2023 and 403,887 (403,887 ADS's) at December 31, 2022	\$ -	\$ -
Treasury stock, -0- ordinary shares issued at December 31, 2023 and 45 ordinary shares issued at December 31, 2022	-	(2,932,000)
Additional paid in capital	51,867,336	47,855,521
Accumulated deficit	(46,203,320)	(37,516,747)
Total shareholders' equity	5,664,016	7,406,774
Total liabilities and shareholders' equity	\$ 12,169,229	\$ 14,458,063

QUOIN PHARMACEUTICALS LTD.
Consolidated Statements of Operations

	<u>Years Ended December 31,</u>		<u>Three months ended December 31,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
	(Audited)	(Audited)	(Unaudited)	(Unaudited)
Operating expenses				
General and administrative	\$ 6,070,517	\$ 6,584,868	\$ 1,385,276	\$ 1,472,866
Research and development	3,307,987	2,672,836	832,391	613,067
Total operating expenses	<u>9,378,504</u>	<u>9,257,704</u>	<u>2,217,667</u>	<u>2,085,933</u>
Other (income) and expenses				
Forgiveness of accounts payable	-	(416,000)	-	-
Warrant liability (income) expense	-	(77,237)	-	-
Unrealized loss (gain)	2,683	(1,307)	(9,243)	(4,360)
Realized and accrued interest income	(694,614)	(95,745)	(158,546)	(80,613)
Interest and financing expense	-	714,081	-	-
Total other (income) expense	<u>(691,931)</u>	<u>123,792</u>	<u>(167,789)</u>	<u>(84,973)</u>
Net loss	<u>\$ (8,686,573)</u>	<u>\$ (9,381,496)</u>	<u>\$ (2,049,878)</u>	<u>\$ (2,000,960)</u>
Deemed dividend on warrant modification	-	(65,266)	-	-
Net loss attributable to shareholders	<u>\$ (8,686,573)</u>	<u>\$ (9,446,762)</u>	<u>\$ (2,049,878)</u>	<u>\$ (2,000,960)</u>
Loss per ADS				
Basic	\$ (9.64)	\$ (46.81)	\$ (2.08)	\$ (4.95)
Fully-diluted	\$ (9.64)	\$ (46.81)	\$ (2.08)	\$ (4.95)
Weighted average number of ADS's outstanding				
Basic	900,919	201,826	987,220	403,884
Fully-diluted	900,919	201,826	987,220	403,884