

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): August 2, 2023

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 sixty thousand (60,000) 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 August 2, 2023, Quoin Pharmaceuticals Ltd. (the “Company”) announced its financial results for the quarter ended June 30, 2023. 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 8.01 Other Events

On April 5, 2023, the Company received a letter from the Listing Qualifications staff of The Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that the closing bid price per American Depositary Share (“ADS”) representing ordinary shares of the Company was below the required minimum of \$1.00 for a period of 30 consecutive business days and that the Company did not meet the Nasdaq minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2). On August 1, 2023, the Company received a letter from Nasdaq which stated that the Company’s closing bid price per ADS was at \$1.00 or greater for the last 10 consecutive business days. Accordingly, the Company regained compliance with Listing Rule 5550(a)(2), and this matter was closed.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 2, 2023
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: August 2, 2023

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer



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

Company reports positive clinical data for first subject to complete testing in ongoing open-label Netherton Syndrome study

Subject's skin was assessed to be fully clear by Investigator at QRX003 treatment areas

Subject also demonstrated key improvements across all other clinical endpoints, including pruritis

A majority of patients in both Netherton Syndrome studies are expected to be enrolled by the end of August

Both studies are demonstrating an exemplary safety profile for QRX003

Quoin expects its cash runway will extend well into 2H 2024

ASHBURN, Va., August 2, 2023 (GLOBE NEWSWIRE) -- 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 second quarter of 2023, ended June 30, 2023.

Quoin CEO, Dr. Michael Myers, said, "We are excited to announce positive clinical data for the first subject to complete our ongoing open-label clinical study in Netherton Syndrome patients. While we strongly caution that this data is just from a single subject, the positive nature of the data across all assessed clinical endpoints is indeed noteworthy. With both of our clinical studies on track to having a majority of patients enrolled by the end of August, we look forward to releasing additional clinical data in due course. I am also pleased to announce that across both ongoing clinical studies to date, QRX003 is demonstrating an exemplary safety profile. The generation of this first clinical data is a milestone for Quoin and we hope that it could represent an important step towards providing a safe and effective treatment for such a devastating disease."

Corporate Highlights –

- On May 24th 2023, less than 3 months after the first patient had been dosed in its open label clinical trial in Netherton Syndrome patients, Quoin announced that the study had achieved 50% enrollment. The trial is a single arm, open label study, investigating the safety and efficacy of Quoin's lead candidate, QRX003, in Netherton Syndrome patients who are currently receiving off-label systemic therapy, primarily biologic therapy, and will continue to do so throughout the duration of the study.
 - Today, the company is announcing positive clinical data for the first patient to complete testing in the company's open-label study in Netherton Syndrome patients. As determined by the clinical site Investigator, the subject's skin was assessed to be fully clear at the QRX003 treatment sites on completion of the study. The subject's skin was also assessed to be clear by a well-recognized visual scoring index. Importantly, the subject also had a positive impression of QRX003 across a number of metrics. Furthermore, the patient's pruritis or itch at the QRX003 treatment site was negligible, representing a substantial improvement from baseline.
 - During the quarter, the company began assessing a number of other potential supportive studies for QRX003 in Netherton Syndrome outside of the US, including one in pediatric patients, and one in pre-identified patients in the Middle East.
 - Also, during the quarter, Quoin continued to advance its two rare disease research programs with Queensland University of Technology for treatment of Scleroderma and Netherton Syndrome and anticipates initiation of clinical testing in Australia for at least one of these programs in 2H 2023.
 - Progress was made during the quarter towards the initiation of proof of concept clinical testing for QRX003 in other indications including SAM Syndrome, Peeling Skin Syndrome and Palmoplantar Keratoderma
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Financial Highlights

- Quoin had approximately \$15.4 million in cash, cash equivalents and marketable securities as of June 30, 2023.
- Net loss for the quarter ended June 30, 2023 was approximately \$2.1 million compared to approximately \$2.7 million for the quarter ended June 30, 2022, and net loss for the six months ended June 30, 2023 was \$4.7 million compared to \$4.4 million for the six months ended June 30, 2022.
- Investors are encouraged to read the Company's Quarterly Report on Form 10-Q 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 June 30, 2023.

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. 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, 2022 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:

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QUOIN PHARMACEUTICALS LTD.
Condensed Consolidated Balance Sheets

	June 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,759,129	\$ 2,860,628
Investments	10,680,160	9,992,900
Prepaid expenses	234,226	516,584
Total current assets	<u>15,673,515</u>	<u>13,370,112</u>
Prepaid expenses - long term	383,390	383,390
Intangible assets, net	652,539	704,561
Total assets	<u>\$ 16,709,444</u>	<u>\$ 14,458,063</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 707,935	\$ 605,600
Accrued expenses	1,834,653	1,175,705
Accrued interest and financing expense	1,146,251	1,146,251
Due to officers – short term	725,000	600,000
Total current liabilities	<u>4,413,839</u>	<u>3,527,556</u>
Due to officers – long term	3,223,733	3,523,733
Total liabilities	<u>\$ 7,637,572</u>	<u>\$ 7,051,289</u>
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value per share, 500,000,000,000 ordinary shares authorized – 59,233,024,799 (987,217 ADS's) ordinary shares issued and outstanding at June 30, 2023 and 24,233,024,799 (403,884 ADS's) at December 31, 2022		
	\$ —	\$ —
Treasury stock, 2,641,693, ordinary shares	(2,932,000)	(2,932,000)
Additional paid in capital	54,230,635	47,855,521
Accumulated deficit	(42,226,763)	(37,516,747)
Total shareholders' equity	<u>9,071,872</u>	<u>7,406,774</u>
Total liabilities and shareholders' equity	<u>\$ 16,709,444</u>	<u>\$ 14,458,063</u>

QUOIN PHARMACEUTICALS LTD.
Condensed Consolidated Statements of Operations (Unaudited)

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Operating expenses				
General and administrative	\$ 1,634,960	\$ 1,941,473	\$ 3,318,777	\$ 3,529,943
Research and development	625,104	726,694	1,716,837	1,314,263
Total operating expenses	<u>2,260,064</u>	<u>2,668,167</u>	<u>5,035,614</u>	<u>4,844,206</u>
Other (income) and expenses				
Forgiveness of accounts payable	—	—	—	(416,000)
Warrant liability (income) expense	—	—	—	(77,237)
Unrealized loss	34,472	—	14,045	—
Interest income	(187,589)	—	(339,643)	—
Total other income	<u>(153,117)</u>	<u>—</u>	<u>(325,598)</u>	<u>(493,237)</u>
Net loss	<u>\$ (2,106,947)</u>	<u>\$ (2,668,167)</u>	<u>\$ (4,710,016)</u>	<u>\$ (4,350,969)</u>
Loss per ADS				
Loss per ADS				
Basic	\$ (2.13)	\$ (38.91)	\$ (5.79)	\$ (69.90)
Fully-diluted	\$ (2.13)	\$ (38.91)	\$ (5.79)	\$ (69.90)
Weighted average number of ADS's outstanding				
Basic	987,217	68,573	813,184	62,242
Fully-diluted	987,217	68,573	813,184	62,242