

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 8, 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 five thousand (5,000) 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 March 8, 2023, Quoin Pharmaceuticals Ltd. (the “Company”) announced its fiscal year 2022 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</u> <u>No.</u>	<u>Description</u>
99.1	Press Release, dated March 8, 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: March 8, 2023

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

Quoin Pharmaceuticals Provides Corporate Update and Announces Fourth Quarter And Full Year 2022 Financial Results

- *Quoin announced dosing of first patient in double blinded clinical study to evaluate QRX003 for Netherton Syndrome*
- *Quoin announced initiation of a second clinical trial to evaluate QRX003 in Netherton Syndrome patients currently receiving off-label systemic therapy*
- *Continued advancement of pipeline products with Queensland University of Technology towards potential initiation of clinical testing in 2H 2023*
- *Company working with its global distribution partnership network to determine requirements for Early Access Programs participation for QRX003*
- *Subsequent to quarter end, Quoin completed a public offering, with aggregate net proceeds of approximately \$6 million, further extending its cash runway into 2H 2024*

ASHBURN, Va., March 8, 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 fourth quarter and full year of 2022.

Quoin CEO, Dr. Michael Myers, said, “2022 as a whole was a year of significant progress for Quoin and the fourth quarter continued that trend of operational execution across a number of important metrics. We were very pleased to announce the dosing of the first patient in our ongoing double blinded, placebo controlled study in Netherton Syndrome patients. This study has continued to recruit and dose patients since then and overall interest in participation in the study remains very high.

We were also excited to announce in October our plans to initiate a second clinical trial in Netherton Syndrome patients which we believe further establishes the company’s leadership position related to this disease. Since then, Quoin has been cleared by the Food and Drug Administration (FDA) to initiate this study under the Company’s currently open Investigational New Drug (IND). This second study is investigating the safety and efficacy of QRX003 in Netherton Syndrome patients currently receiving off-label systemic therapy, primarily biologic therapy. Both of our clinical studies will be run concurrently with each other and utilize the same investigators and clinical sites, resulting in high levels of operational synergies and cost savings. As this second trial is a single arm, open label study, Quoin will have access to the data, which we look forward to sharing in the coming months. We believe Quoin is the only pharmaceutical company currently conducting two clinical trials in Netherton Syndrome patients under an open IND application.

We also continued to work closely with our 8 partners covering the 60 countries under our current commercial arrangements to determine requirements to advance QRX003 into Compassionate Use or Early Access Programs in the various local markets, in advance of formal regulatory approval. With the anticipated generation of clinical data this year, we are hopeful that this will provide a major step forward towards that goal.

Both of our dermatological rare disease research programs with Queensland University of Technology for treatment of Scleroderma and Netherton Syndrome continue to make progress under the expert scientific guidance of the program coordinators and we are working towards the initiation of clinical testing in Australia for at least one of these programs in 2H 2023.

Finally, last month we completed a public offering of our shares with aggregate net proceeds of approximately \$6 million, which further extends our cash runway into 2H 2024.”

Financial Highlights

- Quoin ended the 2022 year with approximately \$12.9 million in cash and marketable securities.
- Net loss for the quarter ended December 31, 2022 was approximately \$2.0 million. Net loss for the year ended December 31, 2022 was approximately \$9.4 million.
- 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 December 31, 2022, and for the full year ended December 31, 2022.

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 filings the Company has made with the SEC and the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 that the Company will file 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. 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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Quoin Pharmaceuticals Ltd. Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash	\$ 2,860,628	\$ 7,482,773
Investments	9,992,900	-
Prepaid expenses	516,584	715,474
Total current assets	<u>13,370,112</u>	<u>8,198,247</u>
Prepaid expenses - long term	383,390	300,000
Intangible assets, net	704,561	808,604
Other assets	-	50,000
Total assets	<u>\$ 14,458,063</u>	<u>\$ 9,356,851</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	605,600	\$ 923,239
Accrued expenses	1,175,705	1,685,409
Accrued license acquisition	-	250,000
Accrued interest and financing expense	1,146,251	743,840
Due to officers - short term	600,000	600,000
Warrant liability	-	373,599
Total current liabilities	<u>3,527,556</u>	<u>4,576,087</u>
Due to officers - long term	3,523,733	4,123,732
Total liabilities	<u>\$ 7,051,289</u>	<u>\$ 8,699,819</u>
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value per share, 500,000,000,000 ordinary shares authorized - 24,233,024,799 (4,846,605 ADS's) ordinary shares issued and outstanding at December 31, 2022 and 3,354,650,799 (670,930 ADS's) at December 31, 2021	\$ -	\$ -
Treasury stock, 2,641,693 ordinary shares	(2,932,000)	(2,932,000)
Additional paid in capital	47,855,521	31,659,017
Accumulated deficit	(37,516,747)	(28,069,985)
Total shareholders' equity	<u>7,406,774</u>	<u>657,032</u>
Total liabilities and shareholders' equity	<u>\$ 14,458,063</u>	<u>\$ 9,356,851</u>

Quoin Pharmaceuticals Ltd. Consolidated Statements of Operations

	Years Ended December 31,		Three months ended December 31,	
	2022	2021	2022	2021
	(Audited)	(Audited)	(Unaudited)	(Unaudited)
Operating expenses				
General and administrative	\$ 6,584,868	\$ 4,499,923	\$ 1,472,866	\$ 1,974,557
Research and development	2,672,836	1,562,927	613,067	1,006,863
Total operating expenses	9,257,704	6,062,850	2,085,933	2,981,420
Other (income) and expenses				
Forgiveness of accounts payable	(416,000)	-	-	-
Fair value adjustment to convertible notes payable	-	1,250,000	-	-
Warrant liability (income) expense	(77,237)	12,784,329	-	8,261,485
Financing expense	-	275,000	-	-
Unrealized income	(1,307)	-	(4,360)	-
Interest income	(95,745)	-	(80,613)	-
Interest and financing expense	714,081	1,090,409	-	574,133
Total other expense	123,792	15,399,738	(84,973)	8,835,618
Net loss	\$ (9,381,496)	\$ (21,462,588)	\$ (2,000,960)	\$ (11,817,038)
Deemed dividend on warrant modification	(65,266)	-	-	-
Net loss attributable to shareholders	\$ (9,446,762)	\$ (21,462,588)	\$ (2,000,960)	\$ (11,817,038)
Loss per ADS				
Loss per ADS				
Basic	\$ (3.90)	\$ (67.96)	\$ (0.41)	\$ (21.70)
Fully-diluted	\$ (3.90)	\$ (67.96)	\$ (0.41)	\$ (21.70)
Weighted average number of ADS's outstanding				
Basic	2,421,916	315,801	4,846,605	544,547
Fully-diluted	2,421,916	315,801	4,846,605	544,547