

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): **November 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 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 November 8, 2023, Quoin Pharmaceuticals Ltd. (the “Company”) announced its financial results for the quarter ended September 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|----------------------|---|
| 99.1 | Press Release, dated November 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: November 9, 2023

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer



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

Company reported positive clinical data for QRX003 from first six evaluable subjects in ongoing open-label Netherton Syndrome study

Positive benefits were observed across a number of clinical endpoints including pruritus, Investigator skin scoring system and patient global assessment.

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

Quoin expects its cash runway will extend through the end of 2024

ASHBURN, Va., November 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 quarter ended September 30, 2023.

Quoin CEO, Dr. Michael Myers, said, "While still early-stage, we are extremely excited by the positive clinical data generated to date across a number of endpoints from our ongoing open-label clinical study in Netherton Syndrome patients. We are particularly pleased with the pruritus results observed for five of the six subjects evaluated. Given the overall strong efficacy data and the exemplary safety profile demonstrated thus far, we are moving into an optimization phase for both of our Netherton Syndrome studies, which we believe could lead to an even more robust clinical data set."

Corporate Highlights –

- 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.
 - Five of the six subjects evaluated had negligible or absent pruritus, or itch, following treatment with QRX003, a significant improvement from prior to the study.
 - All six subjects exhibited improvement in the Investigator assessed skin scoring system with three subjects showing improvement throughout the study and the other three at various points during the study.
 - All six subjects expressed a favorable impression of QRX003 across multiple assessed metrics.
 - No safety concerns have been reported to date for any subject in either of Quoin's studies.
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- Company plans to further optimize its clinical program by making a number of protocol amendments including: eliminating the lower 2% dose in the double blinded study, changing the dosing frequency to twice-daily from once-daily and increasing the number of subjects in both studies.
- Company secured long term, exclusive supply of the only fully GMP grade active ingredient in QRX003.
- On September 6th, Quoin signed its ninth commercial agreement for QRX003, increasing the number of partnered countries to sixty-one.

Financial Highlights

- Quoin had approximately \$14.0 million in cash, cash equivalents and marketable securities as of September 30, 2023.
- Net loss for the quarter ended September 30, 2023 was approximately \$2.1 million compared to approximately \$2.3 million for the quarter ended September 30, 2022, and net loss for the nine months ended September 30, 2023 was \$7.2 million compared to \$7.2 million for the nine months ended September 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 September 30, 2023.

Quoin will host a conference call and webcast at 8:30am ET on Thursday, November 9, 2023. The call will include a discussion of third quarter 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 call webcast will be available at: <https://event.choruscall.com/mediaframe/webcast.html?webcastid=sPhSaNGJ>.

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:

PCG Advisory

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-Tables Follow-

QUOIN PHARMACEUTICALS LTD.

Consolidated Balance Sheets

| | September 30, 2023 | December 31, 2022 |
|---|-------------------------------|------------------------------|
| | (Unaudited) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 3,163,426 | \$ 2,860,628 |
| Investments | 10,818,051 | 9,992,900 |
| Prepaid expenses | 159,851 | 516,584 |
| Total current assets | 14,141,328 | 13,370,112 |
| Prepaid expenses - long term | 300,000 | 383,390 |
| Intangible assets, net | 626,529 | 704,561 |
| Total assets | <u>\$ 15,067,857</u> | <u>\$ 14,458,063</u> |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 239,978 | \$ 605,600 |
| Accrued expenses | 2,594,199 | 1,175,705 |
| Accrued interest and financing expense | 1,146,251 | 1,146,251 |
| Due to officers - short term | 600,000 | 600,000 |
| Total current liabilities | 4,580,428 | 3,527,556 |
| Due to officers - long term | 3,073,733 | 3,523,733 |
| Total liabilities | \$ 7,654,161 | \$ 7,051,289 |
| Commitments and contingencies | | |
| Shareholders' equity: | | |
| Ordinary shares, no par value per share, 8,333,334 ordinary shares authorized - 987,220 (987,220 ADS's) ordinary shares issued and outstanding at September 30, 2023 and 403,887 (403,887 ADS's) at December 31, 2022 | \$ - | \$ - |
| Treasury stock, 45 ordinary shares | (2,932,000) | (2,932,000) |
| Additional paid in capital | 54,499,138 | 47,855,521 |
| Accumulated deficit | (44,153,442) | (37,516,747) |
| Total shareholders' equity | 7,413,696 | 7,406,774 |
| Total liabilities and shareholders' equity | <u>\$ 15,067,857</u> | <u>\$ 14,458,063</u> |

QUOIN PHARMACEUTICALS LTD.

Statements of Operations (Unaudited)

| | Nine months ended September 30, | | Three months ended September 30, | |
|---|--|-----------------------|---|-----------------------|
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses | | | | |
| General and administrative | \$ 4,685,241 | \$ 5,112,002 | \$ 1,366,464 | \$ 1,582,059 |
| Research and development | 2,475,596 | 2,059,769 | 758,759 | 745,506 |
| Total operating expenses | 7,160,837 | 7,171,771 | 2,125,223 | 2,327,565 |
| Other (income) and expenses | | | | |
| Forgiveness of accounts payable | - | (416,000) | - | - |
| Warrant liability (income) expense | - | (77,237) | - | - |
| Unrealized loss (gain) | 11,926 | 3,053 | (2,119) | 3,053 |
| Interest income | (536,068) | (15,132) | (196,425) | (15,132) |
| Interest and financing expense | - | 714,081 | - | 714,081 |
| Total other (income) expense | (524,142) | 208,765 | (198,544) | 702,002 |
| Net loss | \$ (6,636,695) | \$ (7,380,536) | \$ (1,926,679) | \$ (3,029,567) |
| Deemed dividend on warrant modification | - | (65,266) | - | (65,266) |
| Net loss attributable to shareholders | \$ (6,636,695) | \$ (7,445,802) | \$ (1,926,679) | \$ (3,094,833) |
| Loss per ADS | | | | |
| Loss per ADS | | | | |
| Basic | \$ (7.61) | \$ (55.79) | \$ (1.95) | \$ (11.28) |
| Fully-diluted | \$ (7.61) | \$ (55.79) | \$ (1.95) | \$ (11.28) |
| Weighted average number of ADS's outstanding | | | | |
| Basic | 871,835 | 133,450 | 987,220 | 274,317 |
| Fully-diluted | 871,835 | 133,450 | 987,220 | 274,317 |