

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-37846

QUOIN PHARMACEUTICALS LTD.

(Exact name of registrant as specified in its charter)

State of Israel (State or other jurisdiction of incorporation or organization)	92-2593104 (I.R.S. Employer Identification No.)
42127 Pleasant Forest Court Ashburn, VA (Address of principal executive offices)	20148-7349 (Zip Code)

(703) 980-4182

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 Ordinary Shares, no par value per share*	QNRX	The Nasdaq Stock Market LLC N/A

* Not for trading, but only in connection with the registration of the American Depositary Shares ("ADSs") pursuant to requirements of the Securities and Exchange Commission.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 8, 2023, there were 987,220 ordinary shares, no par value per share, of the registrant outstanding, and 987,220 ADSs of the registrant outstanding (assuming all ordinary shares are represented by ADSs), with each ADS representing 1 ordinary share.

QUOIN PHARMACEUTICALS LTD.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (“Form 10-Q”) contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Form 10-Q, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. Forward-looking statements are subject to risks and uncertainties that could cause actual results to be materially different from those indicated (both favorably and unfavorably). These risks and uncertainties include, but are not limited to, those described in Part I – Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2022 (“Form 10-K”), as well as our subsequent reports filed with the Securities and Exchange Commission (“SEC”). Caution should be taken not to place undue reliance on any such forward-looking statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this Form 10-Q and the documents that we reference in this Form 10-Q and have filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Form 10-Q by these cautionary statements.

Unless otherwise indicated or the context otherwise requires, all references in this Form 10-Q to the terms “Quoin,” “Quoin Ltd.,” the “Company,” “us,” “we”, and “our” refer to Quoin Pharmaceuticals Ltd. and its consolidated subsidiaries.

PART I – FINANCIAL INFORMATION**Item 1. Financial Statements.****QUOIN PHARMACEUTICALS LTD.****Condensed Consolidated Balance Sheets**

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	<u>(Unaudited)</u>	
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	<u>14,141,328</u>	<u>13,370,112</u>
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	<u>4,580,428</u>	<u>3,527,556</u>
Due to officers – long term	3,073,733	3,523,733
Total liabilities	<u>\$ 7,654,161</u>	<u>\$ 7,051,289</u>
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	<u>7,413,696</u>	<u>7,406,774</u>
Total liabilities and shareholders' equity	<u>\$ 15,067,857</u>	<u>\$ 14,458,063</u>

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements

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

	<u>Nine months ended September 30,</u>		<u>Three months ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
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	<u>7,160,837</u>	<u>7,171,771</u>	<u>2,125,223</u>	<u>2,327,565</u>
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	<u>(524,142)</u>	<u>208,765</u>	<u>(198,544)</u>	<u>702,002</u>
Net loss	<u>\$ (6,636,695)</u>	<u>\$ (7,380,536)</u>	<u>\$ (1,926,679)</u>	<u>\$ (3,029,567)</u>
Deemed dividend on warrant modification	—	(65,266)	—	(65,266)
Net loss attributable to shareholders	<u>\$ (6,636,695)</u>	<u>\$ (7,445,802)</u>	<u>\$ (1,926,679)</u>	<u>\$ (3,094,833)</u>
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

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements

QUOIN PHARMACEUTICALS LTD.

Condensed Consolidated Statements of Shareholders' Equity (Unaudited)

Three and Nine months ended September 30, 2022

	Ordinary Shares	ADS's	No Par Value	Treasury Stock	Additional Paid in Capital	Accumulated Deficit	Total
Balance at January 1, 2022	55,913	55,913	—	\$ (2,932,000)	\$ 31,659,017	\$ (28,069,985)	\$ 657,032
Net loss	—	—	—	—	—	(1,682,802)	(1,682,802)
Cashless exercise of warrants	1	1	—	—	—	—	—
Reclassification of warrant liability upon issuance of Exchange warrant	—	—	—	—	296,362	—	296,362
Balance at March 31, 2022	<u>55,914</u>	<u>55,914</u>	<u>—</u>	<u>\$ (2,932,000)</u>	<u>\$ 31,955,379</u>	<u>\$ (29,752,787)</u>	<u>\$ (729,408)</u>
Net loss	—	—	—	—	—	(2,668,167)	(2,668,167)
Stock based compensation	—	—	—	—	229,441	—	229,441
Cashless exercise of warrants	28,508	28,508	—	—	—	—	—
Balance at June 30, 2022	<u>84,422</u>	<u>84,422</u>	<u>—</u>	<u>\$ (2,932,000)</u>	<u>\$ 32,184,820</u>	<u>\$ (32,420,954)</u>	<u>\$ (3,168,134)</u>
Net loss	—	—	—	—	—	(3,029,567)	(3,029,567)
Stock based compensation	—	—	—	—	267,283	—	267,283
Issuance of ADS and Pre-Funded Warrants, net	280,000	280,000	—	—	14,904,569	—	14,904,569
Cashless exercise of warrants	35,783	35,783	—	—	—	—	—
Settlement of accrued expenses	3,682	3,682	—	—	193,537	—	193,537
Deemed dividend on warrant modification	—	—	—	—	65,266	(65,266)	—
Balance at September 30, 2022	<u>403,887</u>	<u>403,887</u>	<u>—</u>	<u>\$ (2,932,000)</u>	<u>\$ 47,615,475</u>	<u>\$ (35,515,787)</u>	<u>\$ 9,167,688</u>

Three and Nine months ended September 30, 2023

	Ordinary Shares	ADS's	No Par Value	Treasury Stock	Additional Paid in Capital	Accumulated Deficit	Total
Balance at January 1, 2023	403,887	403,887	—	\$ (2,932,000)	\$ 47,855,521	\$ (37,516,747)	\$ 7,406,774
Net loss	—	—	—	—	—	(2,603,069)	(2,603,069)
Issuance of ADS and Pre-Funded Warrants, net	583,333	583,333	—	—	5,849,266	—	5,849,266
Stock based compensation	—	—	—	—	261,472	—	261,472
Balance at March 31, 2023	<u>987,220</u>	<u>987,220</u>	<u>—</u>	<u>\$ (2,932,000)</u>	<u>\$ 53,966,259</u>	<u>\$ (40,119,816)</u>	<u>\$ 10,914,443</u>
Net loss	—	—	—	—	—	(2,106,947)	(2,106,947)
Stock based compensation	—	—	—	—	264,376	—	264,376
Balance at June 30, 2023	<u>987,220</u>	<u>987,220</u>	<u>—</u>	<u>\$ (2,932,000)</u>	<u>\$ 54,230,635</u>	<u>\$ (42,226,763)</u>	<u>\$ 9,071,872</u>
Net loss	—	—	—	—	—	(1,926,679)	(1,926,679)
Stock based compensation	—	—	—	—	268,503	—	268,503
Balance at September 30, 2023	<u>987,220</u>	<u>987,220</u>	<u>—</u>	<u>\$ (2,932,000)</u>	<u>\$ 54,499,138</u>	<u>\$ (44,153,442)</u>	<u>\$ 7,413,696</u>

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements

QUOIN PHARMACEUTICALS LTD.**Condensed Consolidated Statements of Cash Flows (unaudited)**

	Nine Months Ended September 30,	
	2023	2022
Cash flows used in operating activities:		
Net loss	\$ (6,636,695)	\$ (7,380,536)
Change in fair value of warrant liability	—	(77,237)
Stock based compensation	794,351	496,724
Forgiveness of trade payable	—	(416,000)
Amortization of intangibles	78,032	78,032
Increase in accrued interest and financing expense	—	402,411
Unrealized gain and accrued interest on investments	(369,467)	(12,079)
Changes in assets and liabilities:		
Increase in accounts payable and accrued expenses	1,052,872	(148,493)
Decrease in prepaid expenses & other assets	440,123	518,788
Net cash used in operating activities	\$ (4,640,784)	\$ (6,538,390)
Cash flows used in investing activities:		
Purchase of investments	\$ (18,090,684)	\$ (9,899,121)
Proceeds from maturity of investments	17,635,000	—
Payment for license acquisition	—	(250,000)
Net cash used in investing activities	\$ (455,684)	\$ (10,149,121)
Cash flows provided by financing activities:		
Payment of amounts due to officers	\$ (450,000)	\$ (449,999)
Proceeds from sale of equity securities, net	5,849,266	14,904,569
Net cash provided by financing activities	\$ 5,399,266	\$ 14,454,570
Net change in cash and cash equivalents:	302,798	(2,232,941)
Cash and cash equivalents - beginning of period	2,860,628	7,482,773
Cash and cash equivalents - end of period	<u>\$ 3,163,426</u>	<u>\$ 5,249,832</u>
Supplemental information - Non cash items:		
Reclassification of warrant liability to equity upon issuance of "Exchange warrants"	\$ —	\$ 296,362
Deemed dividend on warrant modification	\$ —	\$ 65,266
Offering expenses associated with warrant modification	\$ 238,231	\$ 491,601
Settlement of accrued expenses	\$ —	\$ 193,537

The accompanying footnotes are an integral part of these unaudited condensed consolidated financial statements

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2023 and 2022

NOTE 1 – ORGANIZATION AND BUSINESS

Quoin Pharmaceuticals Ltd. (“Quoin Ltd.,” or the “Company”), formerly known as Collect Biotechnology Ltd. (“Collect”), is the holding company for Quoin Pharmaceuticals, Inc., a Delaware corporation (“Quoin Inc.”). Quoin Inc. was incorporated in Delaware on March 5, 2018. On October 28, 2021, Collect completed the business combination with Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Collect (the “Merger”). Immediately after completion of the Merger, Collect changed its name to “Quoin Pharmaceuticals Ltd.”

Effective July 18, 2023, the ratio of American Depositary Shares (“ADSs”) evidencing ordinary shares changed from 1 ADS representing five thousand (5,000) ordinary shares to 1 ADS representing sixty thousand (60,000) ordinary shares, which resulted in a 1 for 12 reverse split of the issued and outstanding ADSs. Effective November 8, 2023, the Company completed a 1 for 60,000 reverse split of the ordinary shares which resulted in the ratio of ADSs evidencing ordinary shares to be changed from 1 ADS representing sixty thousand (60,000) ordinary shares to 1 ADS representing one (1) ordinary share. All ordinary share, ADSs and related option and warrant information presented in these financial statements and accompanying footnotes has been retroactively adjusted to reflect the number of ordinary shares and ADSs resulting from the aforementioned ordinary share reverse split and ADS ratio changes.

The Company is a clinical stage specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently no approved treatments or cures. The Company’s initial focus is on the development of products, using proprietary owned and in-licensed drug delivery technologies, that could help address rare skin diseases. The Company’s first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary in-licensed Invisicare® technology, is under development as a potential treatment for Netherton Syndrome (“NS”), a rare hereditary genetic disease. QRX003 is currently being tested in two clinical studies in the United States (“U.S.”) under an open Investigational New Drug (“IND”) application with the Food and Drug Administration (“FDA”). Dosing of patients commenced in December 2022 for the first study and in March 2023 for the second study. The Company is also developing QRX004 as a potential treatment for Recessive Dystrophic Epidermolysis Bullosa (“RDEB”). In addition, the Company has entered into Research Agreements with the Queensland University of Technology (“QUT”), which include an option for global licenses to QRX007 for the potential treatment of NS and QRX008 for the potential treatment of scleroderma. To date, no products have been commercialized and revenue has not been generated.

NOTE 2 - LIQUIDITY RISKS AND OTHER UNCERTAINTIES

The unaudited condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (“U.S. GAAP”), which contemplates continuation of the Company as a going concern. The Company has incurred net losses every year since inception and has an accumulated deficit of approximately \$44.2 million at September 30, 2023. The Company has limited operating history and has historically funded its operations through debt and equity financings. The Company incurred net losses of approximately \$6.6 million, and negative cash flows from operations of \$4.6 million for the nine months ended September 30, 2023. At September 30, 2023, the Company had cash balances totaling \$3.2 million and investments of \$10.8 million. The Company has determined that it has sufficient cash and liquidity to effect its business plan for at least one year from the issuance of these unaudited condensed consolidated financial statements.

Additional financing will still be required to complete the research and development of the Company’s therapeutic targets and its other operating requirements until it achieves commercial profitability, if ever. Such financing may not be available at acceptable terms, if at all. If the Company is unable to obtain additional funding when it becomes necessary, the development of its product candidates will be impacted and the Company would likely be forced to delay, reduce, or terminate some or all of its development programs, all of which could have a material adverse effect on the Company’s business and financial condition.

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2023 and 2022

Other risks and uncertainties:

The Company is subject to risks common to development stage biopharmaceutical companies including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, pre-clinical and clinical trial outcome risks, regulatory approval risks, uncertainty of market acceptance and additional financing requirements.

The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. There can be no assurance that the Company's products will receive all of the required approvals or clearances. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products.

There can be no assurance that the Company's products, if approved, will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed.

The Company is also dependent on several third party suppliers, in some cases a single source supplier including the contract research organization managing both of the Company's current clinical studies, the supplier of the active pharmaceutical ingredient (API), as well as the contract manufacturer of the drug substance for the expected clinical development.

Nasdaq Listing

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 ADS was below the required minimum of \$1.00 for a period of 30 consecutive business days and that the Company did not meet the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2). Pursuant to Nasdaq Rule 5810(c)(3)(A), the Company had a period of one hundred eighty (180) calendar days, or until October 2, 2023 (the "Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement. On August 1, 2023, the Company received a letter from Nasdaq stating 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 the matter was closed.

There can be no assurance that the Company will be able to maintain compliance with Nasdaq's minimum bid-price requirement for continued listing. If the Company's ADSs are delisted from Nasdaq, it will have a material negative impact on the actual and potential liquidity of the Company's securities, as well as a material negative impact on the Company's ability to raise future capital.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited condensed consolidated financial statements of the Company as of September 30, 2023 and for the three and nine months then ended. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the operating results for the year or any other period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and related disclosures as of December 31, 2022 and for the year then ended which are included in the Company's Annual Report on Form 10-K, filed with the SEC on March 15, 2023. The Company operates in one segment.

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2023 and 2022

Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in developing the estimates and assumptions that are used in the preparation of these financial statements including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: stock-based compensation research and development expense recognition, intangible asset estimated useful lives and impairment assessments, allowances of deferred tax assets, and cash flow assumptions regarding going concern considerations.

Cash and cash equivalents:

The Company considers all highly liquid investments and short-term debt instruments with original maturities of three months or less to be cash equivalents. The Company, from time to time during the periods presented, has had bank account balances in excess of federally insured limits where substantially all cash is held in the United States. The Company has not experienced losses in such accounts. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Warrants:

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement) provided that such contracts are indexed to the Company's own stock. The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The Company assesses classification of its warrants and other free-standing derivatives at each reporting date to determine whether a change in classification between assets, liabilities and equity is required. The Company evaluated the warrants to assess their proper classification using the applicable criteria enumerated under U.S. GAAP and determined that such warrants meet the criteria for equity classification in the accompanying unaudited condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022, respectively.

Investments:

Investments as of September 30, 2023 and December 31, 2022 consist of U.S. Treasury Bills, which are classified as trading securities, totaling \$10.8 million and \$10.0 million, respectively. The Company determines the appropriate balance sheet classification of its investments at the time of purchase and evaluates the classification at each balance sheet date.

Long-lived assets:

Long-lived assets are comprised of acquired technology and licensed rights to use technology, which are considered platform technology with alternative future uses beyond the current products in development. Such intangible assets are being amortized on a straight-line basis over their expected useful life of 10 years.

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2023 and 2022

The Company assesses the impairment for long-lived assets whenever events or circumstances indicate the carrying value may not be recoverable. Factors we consider that could trigger an impairment review include the following:

- Significant changes in the manner of the Company's use of the acquired assets or the strategy for its overall business,
- Significant underperformance relative to expected historical or projected development milestones,
- Significant negative regulatory or economic trends, and
- Significant technological changes which could render the platform technology obsolete.

The Company recognizes impairment when the sum of the expected undiscounted future cash flows is less than the carrying amount of the asset. Impairment losses, if any, are measured as the excess of the carrying amount of the asset over its estimated fair value. During the three and nine months ended September 30, 2023 and 2022, there were no impairment indicators which required an impairment loss measurement.

Research and development:

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials when applicable, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expenses in future periods as the related services are rendered.

Income taxes:

The Company accounts for its income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company maintains a full valuation allowance on its existing deferred tax assets.

The Company also accounts for uncertain tax positions using the more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. As of September 30, 2023 and December 31, 2022, the Company had no uncertain tax positions which affected its financial position and its results of operations or its cash flows and will continue to evaluate for uncertain tax positions in the future. If at any time the Company should record interest and penalties in connection with income taxes, the interest and the penalties will be expensed within the interest and general and administrative expenses, respectively.

Stock based compensation:

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-

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Notes to Consolidated Financial Statements
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pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

Since the Company has a limited history of trading as a public company, the Company's expected stock volatility is based on a weighting of its historical volatility along with a group of a publicly traded set of peer companies. The Company utilizes the simplified method to estimate the expected term. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield was assumed to be zero as the Company has not paid and dividends since its inception and does not anticipate paying dividends in the foreseeable future.

Fair value of financial instruments:

The Company considers its cash and cash equivalents, investments, accounts payable, accrued expenses to meet the definition of financial instruments. The carrying amounts of these financial instruments approximated their fair values due to the short maturities.

The Company measures fair value as required by ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

Earnings (loss) per share:

The Company reports loss per share in accordance with ASC 260-10, *Earnings Per Share*, which provides for calculation of "basic" and "diluted" earnings per share. Basic earnings per share includes no dilution and is computed by dividing net income or loss available to common shareholders by the weighted average common shares outstanding for the period. Diluted earnings per share reflect the potential dilution of securities that could share in the earnings of an entity. The calculation of diluted net earnings (loss) per share gives effect to ordinary shares equivalents; however, potential common shares are excluded if their effect is anti-dilutive.

For the three and nine months ended September 30, 2023, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 864,068 ADS and outstanding stock options to purchase 26,667 ADS. For the three and nine months ended September 30, 2022, the number of shares excluded from the diluted net earnings (loss) per share included warrants to purchase 280,735 ADSs and outstanding options to purchase 25,760 ADSs, respectively. The inclusion of these stock options and warrants from both periods in 2023 and 2022 in the denominator would be anti-dilutive.

NOTE 4 – ACCRUED INTEREST AND FINANCING EXPENSE

On October 2, 2020, Quoin Inc. issued promissory notes (the "2020 Notes") and warrants to certain investors ("2020 Noteholders"). The 2020 Notes were mandatorily convertible into 432 ADSs in 2021. The ADSs issued to the 2020 Noteholders did not include the accrued interest estimated to be approximately \$744,000 at December 31, 2021. A total of \$312,000 was paid to two of the five 2020 Noteholders during the year ended December 31, 2022 and based on the terms of this cash settlement, the Company's estimate of the liability to the remaining three 2020 Noteholders increased to \$1,146,000 as of September 30, 2023 and December 31, 2022. There was no interest expense in the three and nine month periods ended September 30, 2023.

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NOTE 5 - FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company applies fair value accounting for all assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities the Company considers the principal or most advantageous market in which it would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risk. For certain instruments, including cash and cash equivalents, accounts payable, and accrued expenses, it was estimated that the carrying amount approximated fair value because of the short maturities of these instruments.

Fair value is estimated using various valuation models, which utilize certain inputs and assumptions that market participants would use in pricing the asset or liability. The inputs and assumptions used in valuation models are classified in the fair value hierarchy as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Quoted market prices for similar instruments in an active market; quoted prices for identical or similar assets and liabilities in markets that are not active; and model-derived valuations inputs of which are observable and can be corroborated by market data.

Level 3: Unobservable inputs and assumptions that are supported by little or no market activity and that are significant to the fair value of the asset and liability. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining the appropriate hierarchy levels, the Company analyzes the assets and liabilities that are subject to fair value disclosure. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to their fair value measurement.

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis by fair value hierarchy at September 30, 2023 and December 31, 2022:

<u>September 30, 2023</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
US Treasury Bills	\$ 10,818,051	\$ —	\$ —	\$ 10,818,051
Total US Treasury Bills Asset	<u>\$ 10,818,051</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,818,051</u>
<u>December 31, 2022</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
US Treasury Bills	\$ 9,992,900	\$ —	\$ —	\$ 9,992,900
Total US Treasury Bills Asset	<u>\$ 9,992,900</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 9,992,900</u>

QUOIN PHARMACEUTICALS LTD.

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NOTE 6 – STOCK BASED COMPENSATION

In March 2022, the Board of Directors of the Company approved the Amended and Restated Equity Incentive Plan (the “Amended Plan”), which was approved by the shareholders at the Company’s Annual General Meeting of Shareholders held on April 12, 2022. The Amended Plan increased the number of ordinary shares reserved for issuance under such equity incentive plan to 15% of the Company’s outstanding ordinary shares on a fully-diluted basis, or 281,532 ordinary shares represented by 281,532 ADSs as of September 30, 2023. Under the Amended Plan, the Company may grant options to its directors, officers, employees, consultants, advisers and service providers. As of September 30, 2023, 254,865 ADSs remained available for grant under the Amended Plan.

The following table summarizes stock-based activities under the Amended Plan:

	ADS Underlying Options	Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2022	25,595	\$ 210.00	9.28
Granted	1,071	\$ 210.00	
Forfeited/Cancelled	—	\$ —	
Outstanding at September 30, 2023	26,666	\$ 210.00	8.64
Exercisable options at September 30, 2023	7,381	\$ 210.00	8.57

The intrinsic value of outstanding options at September 30, 2023 was \$0.

Stock based compensation expense was approximately \$269,000 (\$34,000 included in research and development expense and \$235,000 included in general and administrative expenses) in the three months ended September 30, 2023 and approximately \$794,000 (\$103,000 included in research and development expense and \$691,000 included in general and administrative expenses) in the nine months ended September 30, 2023.

Stock based compensation expense was approximately \$267,000 (\$35,000 included in research and development expense and \$232,000 included in general and administrative expenses) in the three months ended September 30, 2022 and approximately \$497,000 (\$65,000 included in research and development expense and \$432,000 included in general and administrative expenses) in the nine months ended September 30, 2022.

At September 30, 2023, the total unrecognized compensation expense related to non-vested options was approximately \$2,413,000 and is expected to be recognized over the remaining weighted average service period of approximately 2.33 years.

NOTE 7 – PREPAID EXPENSES

Prepaid expenses are as follows:

	September 30, 2023	December 31, 2022
Prepaid R&D costs	\$ 383,390	\$ 383,390
Prepaid insurance	56,211	508,084
Prepaid expense	20,250	8,500
Total	\$ 459,851	\$ 899,974
Less: Short-term portion	(159,851)	(516,584)
Long-term portion	\$ 300,000	\$ 383,390

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NOTE 8 - ACCRUED EXPENSES

Accrued expenses are as follows:

	September 30, 2023	December 31, 2022
Research contract expenses (note 12)	\$ 684,899	\$ 105,071
Payroll	1,426,435	788,169
Payroll taxes (note 11)	165,610	159,593
Professional fees	206,254	44,278
Other Expenses	111,001	78,594
Total	<u>\$ 2,594,199</u>	<u>\$ 1,175,705</u>

NOTE 9 – IN-LICENSED TECHNOLOGY**Polytherapeutics:**

On March 24, 2018, Quoin Inc. entered into a securities purchase agreement (the “Acquisition Agreement”), in which it agreed to acquire all of the equity interests in Polytherapeutics, Inc. (the “Seller” or “Polytherapeutics”) for \$40,833 and future royalties provided Quoin Inc. commercializes products using the technology developed by the Seller. The terms of any royalty payments to the Seller are 4.0% of the net revenue of royalty products, as defined in the Acquisition Agreement during the ten (10) year period commencing from the date of first sale of a royalty product. If a generic product is introduced by a third party to the market, during the royalty period, the royalty fees shall be reduced from 4% to 2%. If, during the royalty period, two or more generic products are introduced, the royalty fees shall be reduced from 2% to 0%. There were no royalty obligations due at September 30, 2023 and December 31, 2022.

Skinvisible:

In October 2019, Quoin Inc. entered into the Exclusive Licensing Agreement (as amended from time to time, the “License Agreement”) with Skinvisible Pharmaceuticals, Inc. (“Skinvisible”), under which Skinvisible granted the Company an exclusive royalty-bearing license relating to the production and manufacture of prescription drug products related to certain patents held by Skinvisible, including those related to QRX003 and QRX004. The Company made Skinvisible a one-time non-refundable, non-creditable license fee of \$1 million (the “License Fee”). In addition, the Company agreed to pay Skinvisible a single digit royalty percentage of the Company’s net sales revenues for any licensed product covered by the patent rights licensed under the License Agreement. The Company also agreed to pay Skinvisible 25% of any revenues the Company receives as royalties in the event that the Company sublicense any licensed products to a third party. The License Agreement also requires that the Company make a \$5 million payment to Skinvisible upon receiving approval in the U.S. or European Union, whichever occurs first, for the first drug product developed using intellectual property licensed thereunder. There were no milestone or royalty obligations due at September 30, 2023 and December 31, 2022.

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Notes to Consolidated Financial Statements
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NOTE 10 - INTANGIBLE ASSETS

Intangible assets are as follows:

	September 30, 2023	December 31, 2022
Acquired technology – Polytherapeutics	\$ 40,433	\$ 40,433
Technology license – Skinvisible	1,000,000	1,000,000
Total cost	1,040,433	1,040,433
Accumulated amortization	(413,904)	(335,872)
Net book value	\$ 626,529	\$ 704,561

The Company recorded amortization expense of approximately \$78,000 for the nine months ended September 30, 2023 and 2022 and approximately \$26,000 for the three months ended September 30, 2023 and 2022. The annual amortization expense expected to be recorded for existing intangible assets for the years 2023 through 2026, and thereafter, is approximately \$26,000, \$104,000, \$104,000, \$104,000 and \$288,000, respectively.

NOTE 11 - RELATED PARTY TRANSACTIONS**Due to Officers/Founders:**

Due to the limited funding of Quoin Inc. prior to the consummation of the Merger, the compensation, including salary, office and car allowances and other benefits, due to Dr. Myers and Ms. Carter under their respective employment agreements, as well as reimbursement of expenses and other amounts paid to third parties on behalf of Quoin Inc., were accrued as indebtedness to Dr. Myers and Ms. Carter. Following the closing of the Merger, Quoin Inc. began making payments of \$25,000 per month to each of Dr. Myers and Ms. Carter to repay the above-described non-interest-bearing indebtedness. The Company repaid \$75,000 and \$75,000 of such indebtedness to Dr. Myers and \$200,000 and \$75,000 to Ms. Carter in the three months ended September 30, 2023 and 2022, respectively. The Company repaid \$225,000 and \$225,000 of such indebtedness to Dr. Myers and \$225,000 and \$225,000 to Ms. Carter in the nine months ended September 30, 2023 and 2022, respectively.

As of September 30, 2023, approximately \$2,034,000 and \$1,640,000 of such indebtedness was outstanding to Dr. Myers and Ms. Carter, respectively.

Amounts due to officers at September 30, 2023 and December 31, 2022 consisted of the following:

	September 30, 2023	December 31, 2022
Salaries and other compensation	\$ 3,673,733	\$ 4,108,500
Invoices paid on behalf of the Company	—	15,232
Total	\$ 3,673,733	\$ 4,123,732
Less: Short-term portion	(600,000)	(600,000)
Long-term portion	\$ 3,073,733	\$ 3,523,733

Expenses:

Research and development expense, incurred in the three months ended September 30, 2023 and 2022, was \$0 and \$12,000 and \$12,000 and \$36,000 in the nine months ended September 30, 2023 and 2022, respectively, for payments to the CEO Dr. Myers' son, who had been consulting for the Company on research and development matters from time to time. As of March 31, 2023, Dr. Myers' son no longer provided consulting services to the Company.

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Interest Payable:

See Note 4 for interest payable on the 2020 Notes.

NOTE 12 – RESEARCH, CONSULTING AGREEMENTS AND COMMITMENTS

Research agreements

In November 2020, Quoin Inc. entered into a Master Service Agreement for an initial term of three years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. A work order was entered into in June 2022 for the first QRX003 clinical study at an expected estimated cost of approximately \$4.4 million through 2024. A further work order was entered into in December 2022 for the second QRX003 clinical study at an expected estimated cost of approximately \$830,000 through 2024. For the three and nine months ended September 30, 2023 and 2022, the Company incurred a research and development expense under these agreements of approximately \$155,000 and \$1,113,000, and \$423,000 and \$904,000 respectively. During the three months ended September 30, 2023, the Company received a credit of approximately \$278,000 applied to prior expenses incurred during the period of March 2023 to July 2023.

In November 2021, the Company entered into a commitment with Queensland University of Technology for research related services associated with Netherton Syndrome of approximately \$250,000 for an expected period of eighteen months. In May 2022, the Company entered into a commitment with Queensland University of Technology for research related services associated with Scleroderma of approximately \$610,000 for an expected period of eighteen months. For the three and nine months ended September 30, 2023 and 2022, the Company incurred research and development costs related to these agreements of approximately \$85,000 and \$361,000, and \$173,000 and \$250,000 respectively.

Consulting agreement:

Quoin Inc. entered into a consulting agreement with an Investor Relations (IR) firm, which provided for a monthly fee of \$14,000. The agreement had an automatic annual renewal clause and was in effect in November 2017. The Company owed the IR firm \$584,000 as of December 31, 2021. Effective March 31, 2022, the Company entered into a settlement agreement with the IR firm reducing the liability to \$168,000 and recognized \$416,000 as other income in the accompanying consolidated statement of operations. The liability was fully repaid as of April 1, 2023. No expenses were incurred in both the three and nine months ended September 30, 2023 and 2022, respectively.

Performance milestones and Royalties

See Note 9 for asset and in-licensed technology commitments.

NOTE 13 – SHAREHOLDERS' EQUITY

The Company held its Annual General Meeting on April 12, 2022, at which the Company's shareholders approved an increase to the authorized share capital to 833,334 ordinary shares, no par value. The Company held another Annual General Meeting on November 3, 2022, at which the Company's shareholders approved an increase to the authorized share capital to 8,333,334 ordinary shares from 833,334, no par value. The Company held its 2023 Annual General Meeting on October 26, 2023, at which the Company's shareholders approved an increase to the authorized share capital to 100,000,000 ordinary shares from 8,333,334, no par value. These ordinary shares are not redeemable and do not have any preemptive rights.

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Holders of the Company's ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholders meeting. The board of directors shall determine and provide a record date for each shareholders meeting and all shareholders at such record date may vote. Unless stipulated differently in the Companies Law or in the articles of association, all shareholders' resolutions shall be approved by a simple majority vote.

Under Israeli law, the Company may declare and pay dividends only if, upon the determination of its board of directors, there is no reasonable concern that the distribution will prevent the Company from being able to meet the terms of its existing and foreseeable obligations as they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution according to the Company's then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of distribution. In the event that the Company does not have retained earnings or earnings generated over the two most recent years legally available for distribution, the Company may seek the approval of the court in order to distribute a dividend. The court may approve the Company's request if it determines that there is no reasonable concern that the payment of a dividend will prevent the Company from satisfying existing and foreseeable obligations as they become due.

Each ADS will also represent any other securities, cash or other property which may be held by the depository. ADSs may be held either (a) directly (1) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs or (2) by having uncertificated ADSs, or (b) indirectly by holding a security entitlement in ADSs through a broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC.

February 2023 Offering

On February 24, 2023 (the "February Closing Date"), the Company completed an offering (the "February Offering") of 412,500 ordinary shares represented by 412,500 ADSs at a purchase price of \$12.00 per ADS and a pre-funded warrant (the "February Pre-Funded Warrant") to purchase 170,833 ordinary shares represented by 170,833 ADSs at a per pre-funded warrant price of \$11.9988, with each ADS and February Pre-Funded Warrant accompanied by an ordinary warrant (the "February Common Warrant") for aggregate gross proceeds of \$7.0 million, resulting in net proceeds of approximately \$5.8 million, after deducting the placement agent's fees and offering expenses. Each February Common Warrant has an exercise price of \$12.00 per ADS and expires on the fifth anniversary of the February Closing Date. On the February Closing Date, the holder of the February Pre-Funded Warrant exercised its Pre-Funded Warrant in full.

In connection with the February Offering, the Company entered into a Securities Purchase Agreement (the "February Purchase Agreement") with certain institutional investors. Under the February Purchase Agreement, subject to certain exemptions, the Company agreed not to: (i) for a period of ninety (90) days after the closing date of the February Offering, issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs, ordinary shares or ordinary share equivalents or (ii) file any registration statement or amendment or supplement thereto, other than a registration statement on Form S-8 in connection with any employee benefit plan or any post-effective amendment to a registration statement declared effective by the Securities and Exchange Commission (the "SEC") and (ii) for a period of 180 days after the closing date of the February Offering, enter into an agreement to effect a "variable rate transaction" as defined in the Purchase Agreement.

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In connection with the February Offering, the Company entered into an Amendment No. 1 to Warrant to Purchase Ordinary Shares Represented by American Depositary Shares, dated February 24, 2023 (collectively, the “Warrant Amendments”), with each of the purchasers (the “2022 Purchasers”) who participated in both the Company’s public offering completed in August 2022 (the “August Offering”) and February Offering. The Warrant Amendments amended certain terms of the Common Warrants issued in the August Offering to such 2022 Purchasers. Specifically, the Warrant Amendments reduced the exercise price of Common Warrants to purchase 236,670 ADSs out of the total 280,000 issued in the August Offering from \$60.00 to \$13.20 and extended the term during which those warrants could remain exercisable until February 24, 2028. The incremental fair value of the modified warrants was approximately \$238,000, which was accounted for as an offering expense in connection with the February Offering.

Warrants

The following table summarizes warrant activities during the nine months ended September 30, 2023:

	ADSs Underlying Warrants	Weighted Average Exercise Price Per ADS
Outstanding at December 31, 2022	280,735	\$ 24.71 *
Granted Common Warrants	583,333	12.00
Granted Pre-Funded Warrants	170,833	—
Exercised Pre-Funded Warrants	(170,833)	—
Outstanding and exercisable at September 30, 2023	864,068	\$ 16.13

* Includes the reduction of the exercise price from \$60.00 per ADS to \$13.20 per ADS for Common Warrants issued in the August Offering to investors who participated in both the Company’s August Offering and February Offering, see above.

NOTE 14 – CONTINGENCIES

From time to time, the Company may become involved in various legal matters arising in the ordinary course of business. Management is unaware of any matters requiring accrual for related losses in the financial statements.

NOTE 15 – LICENSE AGREEMENTS

As of September 30, 2023, the Company has entered into nine license and supply agreements, whereby the Company will receive a royalty or other proceeds from the specified product revenues in select non-US markets from the licensor, if and when the underlying products are approved and commercialized. No royalty revenues have been received through September 30, 2023 under any of these agreements.

NOTE 16 - SUBSEQUENT EVENTS

On October 26, 2023, the Company held an Annual General Meeting of Shareholders, at which the shareholders approved, among other items, the following:

- The reverse split of the Company’s ordinary shares at a ratio of 1 for 60,000, which resulted in one ADS representing one ordinary share. The reverse split became effective on November 8, 2023.
- The increase of authorized share capital to 100,000,000 ordinary shares from 8,333,334 ordinary shares.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes thereto included in Part I-Item 1 of this Form 10-Q, as well as our consolidated financial statements and notes thereto included in our Form 10-K. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements" in this Form 10-Q.

Overview

We are a clinical stage specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently no approved treatments or cures. Our initial focus is on the development of products, using our proprietary owned and in-licensed drug delivery technologies, that could help address rare skin diseases. Our first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary in-licensed Invisicare® technology, is under development as a potential treatment for Netherton Syndrome ("NS"), a rare hereditary genetic disease. QRX003 is currently being tested in two clinical studies in the United States ("U.S.") under an open Investigational New Drug ("IND") application with the Food and Drug Administration ("FDA"). We are also developing QRX004 as a potential treatment for Recessive Dystrophic Epidermolysis Bullosa ("RDEB"). In addition, we entered into Research Agreements with the Queensland University of Technology ("QUT"), under which we have obtained an option for global licenses to QRX007 for the potential treatment of NS and QRX008 for the potential treatment of scleroderma.

Our objective is to develop and commercialize proprietary therapeutic drug products. To this effect, we intend to develop and seek marketing approvals from the FDA and other worldwide regulatory bodies for rare and orphan diseases. To achieve these objectives, we plan to:

- complete the late-stage clinical testing of QRX003 and, if successful, file for marketing approval in the United States and other territories;
- prepare to commercialize QRX003 by establishing our own sales infrastructure in the U.S. and Europe and entering into distribution partnerships in other territories such as those currently established for Canada, Australia/New Zealand, the Middle East, China, Hong Kong, Taiwan, Latin America, Central and Eastern Europe, Turkey and Singapore; and
- pursue business development activities by seeking partnering, licensing, merger and acquisition opportunities or other transactions to further expand our pipeline and drug-development capabilities.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the commercialization of QRX003 or any other product candidate. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to continue our operations. See "Liquidity and Capital Resources".

ADS Ratio Change and Ordinary Share Reverse Split

Effective July 18, 2023, the ratio of American Depositary Shares (“ADSs”) evidencing ordinary shares changed from 1 ADS representing five thousand (5,000) ordinary shares to 1 ADS representing sixty thousand (60,000) ordinary shares, which resulted in a 1 for 12 reverse split of the issued and outstanding ADSs. Effective November 8, 2023, the Company completed a 1 for 60,000 reverse split of the ordinary shares which resulted in the ratio ADSs evidencing ordinary shares to be changed from 1 ADS representing sixty thousand (60,000) ordinary shares to 1 ADS representing one (1) ordinary share. All ordinary share, ADSs and related option and warrant information presented in this section, as well as our financial statements and accompanying footnotes, has been retroactively adjusted to reflect the number of ordinary shares and ADSs resulting from the aforementioned ordinary share reverse split and ADS ratio changes.

Key Events

Clinical Development

Quoin’s lead asset, QRX003, is currently in late-stage clinical development in the U.S. under an open IND application with the FDA. Five clinical sites in the U.S. have been opened for this study, patients are actively being screened and recruited into the study and dosing commenced in December 2022. This study is a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in NS patients. The test materials are applied once daily, over a twelve-week period, to pre-selected areas of the patient’s body. Based on discussions with the FDA, a number of different clinical endpoints are being assessed in the study, including but not limited to, an Investigators Global Assessment (IGA), Patient’s Global Assessment (PaGA) and Pruritis.

In November 2022, we submitted a protocol for our second clinical study in NS patients to the FDA under our currently open IND (the “Open Label Study”). This study was cleared by the FDA to initiate in December 2022. Dosing commenced in March 2023, patients are actively being screened and recruited into the study. This study is being conducted in ten NS patients who are currently receiving off-label systemic therapy, primarily systemic biologic therapy. This is an open-label study with no placebo control. While there is no assurance regarding the final results of the Open Label Study, we have received the initial positive clinical data based on the available data from six evaluable subjects completing the Open Label Study. Both of our NS clinical studies are running concurrently and utilize the same clinical trial sites and investigators.

Public Offering

On February 24, 2023 (the “February Closing Date”), we completed an offering (the “February Offering”) of 412,500 ordinary shares represented by 412,500 ADSs at a purchase price of \$12.00 per ADS and a pre-funded warrant (the “February Pre-Funded Warrant”) to purchase 170,833 ordinary shares represented by 170,833 ADSs at a per pre-funded warrant price of \$11.9988, with each ADS and February Pre-Funded Warrant accompanied by an ordinary warrant (the “February Common Warrant”) for aggregate gross proceeds of \$7.0 million, resulting in net proceeds of approximately \$5.8 million, after deducting the placement agent’s fees and offering expenses paid by us, and excluding the proceeds, if any, from the subsequent exercise of the February Common Warrants. Each February Common Warrant has an exercise price of \$12.00 per ADS and expires on the fifth anniversary of the February Closing Date. On the February Closing Date, the holder of the February Pre-Funded Warrant exercised its Pre-Funded Warrant in full.

In connection with the February Offering, we entered into a Securities Purchase Agreement (the “February Purchase Agreement”) with certain institutional investors. Under the February Purchase Agreement, subject to certain exemptions, we agreed not to: (i) for a period of ninety (90) days after the closing date of the February Offering, issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs, ordinary shares or ordinary share equivalents or (ii) file any registration statement or amendment or supplement thereto, other than a registration statement on Form S-8 in connection with any employee benefit plan or any post-effective amendment to a registration statement declared effective by the Securities and Exchange Commission (the “SEC”) and (ii) for a period of 180 days after the closing date of the February Offering, enter into an agreement to effect a “variable rate transaction” as defined in the February Purchase Agreement.

In connection with the February Offering, we entered into an Amendment No. 1 to Warrant to Purchase Ordinary Shares Represented by American Depositary Shares, dated February 24, 2023 (collectively, the “Warrant Amendments”), with each of the purchasers (the “2022 Purchasers”) who participated in both our offering completed in August 2022 (the “August Offering”) and the February Offering. The Warrant Amendments amended certain terms of the Common Warrants issued to such 2022 Purchasers in the August Offering.

Specifically, the Warrant Amendments reduced the exercise price of such warrants to \$13.20 and extended the term during which those warrants could remain exercisable until February 24, 2028.

Nasdaq Listing

On April 5, 2023, we received a letter from Listing Qualifications staff of The Nasdaq Stock Market, LLC (“Nasdaq”) notifying us that the closing bid price per ADS was below the required minimum of \$1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Rule 5550(a)(2). Pursuant to Nasdaq Rule 5810(c)(3)(A), we had a period of one hundred eighty (180) calendar days, or until October 2, 2023 (the “Compliance Period”), to regain compliance with Nasdaq’s minimum bid price requirement. On August 1, 2023, we received a letter from Nasdaq stating that the closing bid price per ADS was at \$1.00 or greater for the last 10 consecutive business days. Accordingly, we regained compliance with Listing Rule 5550(a)(2) and the matter was closed.

There can be no assurance that we will be able to maintain compliance with Nasdaq’s minimum bid-price requirement for continued listing. If our ADSs are delisted from Nasdaq, it will have a material negative impact on the actual and potential liquidity of our securities, as well as a material negative impact on our ability to raise future capital.

Components of Our Results of Operations

Operating Expenses

Our current operating expenses consist of two components - research and development expenses, and general and administrative expenses.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. We utilize outside consultants and third parties to conduct the majority of our research and development, under the supervision of our management team.

Future research and development expenses may include:

- employee-related expenses, such as salaries, bonuses and benefits, consultant-related expenses, share-based compensation, overhead related expenses and travel related expenses for our research and development personnel;
- expenses incurred under agreements with CROs, as well as consultants that support the implementation of the clinical studies described above;
- manufacturing and packaging costs in connection with conducting clinical trials and for stability and other studies required to support the NDA filing as well as manufacturing drug product for commercial launch;
- formulation, research and development expenses related to QRX003; and other products we may choose to develop; and
- costs for sponsored research.

Research and development activities will continue to be central to our business plan. Products in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to be significant over the next several years as personnel and compensation costs increase and we conduct late-stage clinical studies and prepare to seek regulatory approval for QRX003 and any other future product.

The duration, costs and timing of clinical trials of QRX003 and any other future product will depend on a variety of factors that include, but are not limited to:

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and employee related expenses including non-cash stock-based compensation, professional fees and other corporate expenses.

We anticipate that our general and administrative expenses may increase during the remainder of 2023 to support our continued research and development activities. These increases will include compensation and employee-related expenses including stock-based compensation, increased costs related to the potential hiring of personnel, travel costs and fees to outside consultants, lawyers and accountants.

Other Expenses (income)

Other expenses (income) consist primarily of non cash fair value adjustments of warrants, forgiveness of trade payable, interest income and unrealized loss on investments.

Results of Operations – Three months ended September 30, 2023 compared to the three months ended September 30, 2022

The following table sets forth our results of operations for the three months ended September 30, 2023, compared to the three months ended September 30, 2022:

	<u>Three months ended September 30,</u>		<u>Change</u>
	<u>2023</u>	<u>2022</u>	
Operating expenses			
General and administrative	\$ 1,366,464	\$ 1,582,059	\$ (215,595)
Research and development	758,759	745,506	13,253
Total operating expenses	<u>2,125,223</u>	<u>2,327,565</u>	<u>(202,342)</u>
Other (income) and expenses			
Unrealized loss and (gain)	(2,119)	3,053	(5,172)
Interest income	(196,425)	(15,132)	(181,293)
Interest expense	—	714,081	(714,081)
Total other (income) expense	<u>(198,544)</u>	<u>702,002</u>	<u>(900,546)</u>
Net loss	<u>\$ (1,926,679)</u>	<u>\$ (3,029,567)</u>	<u>\$ 1,102,888</u>

General and Administrative Expenses

General and administrative expenses were approximately \$1,366,000 and \$1,582,000, in the three months ended September 30, 2023 and 2022, respectively, representing a decrease of approximately \$216,000, or approximately 14%. The decrease was primarily due to a decrease in public company costs of \$73,000, decreased travel costs for \$41,000 and a decrease in insurance costs of \$53,000.

Research and Development Expenses

Our research and development expenses during the three months ended September 30, 2023 and 2022 were approximately \$759,000 and \$746,000, respectively, representing an increase of approximately \$13,000, or approximately 2%. The increase was primarily due to an increase of \$303,000 worth of expenditures on our development programs, including work related to the clinical studies for the development of QRX003 and our research collaborations with Queensland University of Technology, offset by an approximately \$278,000 credit for prior expenses incurred during the period of March 2023 to July 2023. We expect to increase our research and development efforts during the remainder of 2023 as we continue to conducting the studies necessary for the development and approval of QRX003, see “Components of Our Results of Operations - Research and Development Expenses” above.

We amortize licensed or acquired intellectual property over its expected useful life, included in research and development expenses set forth above. The license from Skinvisible was obtained in October 2019. Amortization of intangible assets was approximately \$26,000 in each of the three month periods ended September 30, 2023 and 2022.

Other (Income) and Expenses:*Interest income and unrealized loss*

We earned approximately \$196,000 in interest income and approximately \$2,000 in unrealized gain, and earned approximately \$15,000 in interest income and incurred approximately \$3,000 in unrealized loss in the three months ended September 30, 2023 and September 30, 2022, respectively, from our cash and cash equivalents and investments in marketable debt securities.

Interest expense on promissory notes we issued in 2020 “the 2020 Notes” was \$714,000 in the three months ended September 30, 2022.

Results of Operations – Nine months ended September 30, 2023 compared to the nine months ended September 30, 2022

The following table sets forth our results of operations for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022:

	<u>Nine months ended September 30,</u>		<u>Change</u>
	<u>2023</u>	<u>2022</u>	
Operating expenses			
General and administrative	\$ 4,685,241	\$ 5,112,002	\$ (426,761)
Research and development	2,475,596	2,059,769	415,827
Total operating expenses	7,160,837	7,171,771	(10,934)
Other (income) and expenses			
Forgiveness of trade payable	—	(416,000)	416,000
Warrant liability (income) expense	—	(77,237)	77,237
Unrealized loss	11,926	3,053	8,873
Interest income	(536,068)	(15,132)	(520,936)
Interest expense	—	714,081	(714,081)
Total other (income) expense	(524,142)	208,765	(732,907)
Net loss	\$ (6,636,695)	\$ (7,380,536)	\$ 743,841

General and Administrative Expenses

General and administrative expenses were approximately \$4,685,000 and \$5,112,000, in the nine months ended September 30, 2023 and 2022, respectively, representing a decrease of approximately \$427,000, or approximately 8%. The decrease was primarily due to a decrease in legal fees and other public company expenses of \$528,000, a decrease in insurance of \$156,000, offset by an increase of \$259,000 in non-cash stock-based compensation expense.

Research and Development Expenses

Our research and development expenses during the nine months ended September 30, 2023 and 2022 were approximately \$2,476,000 and \$2,060,000, respectively, representing an increase of approximately \$416,000, or approximately 20%. The increase was primarily due to an increase of \$668,000 worth of expenditures on our development programs, including work related to the clinical studies for the development of QRX003 and our research collaborations with Queensland University of Technology, offset by an approximately \$278,000 credit for prior expenses incurred during the period of March 2023 to July 2023. We expect to increase our research and development efforts during the remainder of 2023 as we continue to conduct the studies necessary for the development and approval of QRX003, see “Components of Our Results of Operations - Research and Development Expenses” above.

We amortize licensed or acquired intellectual property over its expected useful life, included in research and development expenses set out above. The license from Skinvisible was obtained in October 2019. Amortization of intangible assets was approximately \$78,000 in each of the nine month periods ended September 30, 2023 and 2022.

Other (Income) and Expenses:*Interest and unrealized loss*

We earned approximately \$536,000 in interest income and incurred approximately \$12,000 in unrealized loss, and earned approximately \$15,000 in interest income and incurred approximately \$3,000 in unrealized loss, in the nine months ended September 30, 2023 and September 30 2022, respectively, from our cash and cash equivalents and investments in marketable debt securities.

Interest expense on the 2020 Notes was approximately \$714,000 in the nine months ended September 30, 2022.

Warrant liability income

We determined our warrants issued to investors in our 2020 Notes (the “2020 Noteholder Warrants”) required liability treatment at fair value, which was remeasured at each reporting period up to March 2022. The 2020 Noteholder Warrants were exchanged for new warrants and reclassified as an equity instrument in March 2022. In the nine months ended September 30, 2022, we incurred a fair value gain of (\$77,000) related to the 2020 Noteholder Warrants.

Forgiveness of trade payable

In our balance sheet as of December 31, 2021 we had a liability of \$584,000 representing amounts due to an investor relations firm for services commencing in 2017. Effective March 31, 2022, we entered into a settlement with such firm to decrease the liability to \$168,000 which resulted in approximately \$416,000 of income recognized in the nine months ended September 30, 2022.

Liquidity and Capital Resources

We have incurred net losses every year since inception and had an accumulated deficit of approximately \$44.2 million at September 30, 2023. We have a limited operating history and have historically funded our operations through debt and equity financings. We incurred net losses of approximately \$6.6 million and negative cash flows from operations of \$4.6 million for the nine months ended September 30, 2023. At September 30, 2023, we had cash and cash equivalent balances totaling \$3.2 million and investments of \$10.8 million. We have determined that we have sufficient resources to effect our business plan for at least one year from the issuance of the unaudited consolidated financial statements included in this report. However, we do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will continue to increase in 2023 as we advance the clinical development of QRX003.

Future Funding Requirements

We will need to obtain further funding through public or private offerings of our capital stock, debt financing, collaboration and licensing arrangements or other sources, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug development efforts, preclinical development activities, the timing of laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems; and
- the costs associated with being a public company.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of QRX003, any future product, or potentially discontinue operations.

To the extent that we raise additional capital through the sale of our equity or convertible debt securities, and pursuant to the exercise of warrants issued to our investors in the August Offering and February Offering, the ownership interest of our equity holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our equity holders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or proposed products, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market any future product that we would otherwise prefer to develop and market ourselves.

Summary Statement of Cash Flows

As of September 30, 2023, we had approximately \$3,163,000 in cash and cash equivalents and \$10,818,000 in investments in marketable securities. The table below presents our cash flows for the nine month periods ended September 30, 2023 and 2022:

	<u>Nine months ended September 30,</u>	
	<u>2023</u>	<u>2022</u>
Net cash used in operating activities	\$ (4,640,784)	\$ (6,538,390)
Net cash used in investing activities	(455,684)	(10,149,121)
Net cash provided by financing activities	5,399,266	14,454,570
Net increase (decrease) in cash and cash equivalents	\$ 302,798	\$ (2,232,941)

Operating Activities

Net cash used in operating activities was approximately \$4,641,000 and \$6,538,000 in the nine months ended September 30, 2023 and 2022, respectively. The decrease in 2023 was primarily due to a decrease in prepaid expenses and increase in accrued expenses, offset by a decrease in accounts payable.

Investing Activities

Net cash used in investing activities was approximately \$456,000 and \$10,149,000 in the nine months ended September 30, 2023 and 2022, respectively. The cash used in investing activities for the nine months ended September 30, 2023 consisted of net purchases of short maturity US Treasury Bills from the proceeds of the February Offering, and the cash used in investing activities in the nine months ended September 30, 2022 consisted of net purchases of short maturity US Treasury Bills from the proceeds of the August Offering and payments of remaining amounts due under our license agreement with Skinvisible, see “Research and Development Commitments” below.

Financing Activities

Net cash provided by financing activities was approximately \$5,399,000 for the nine months ended September 30, 2023. The net cash provided increased due to the receipt of approximately \$5,849,000 in net proceeds from the February Offering partially offset by repayments of amounts due to officers of \$450,000. Net cash provided by financing activities in the nine months ended September 30, 2022 was \$14,545,000, representing net proceeds of \$14.9 million from the August 2022 Offering, offset by repayments of amounts due to officers of \$450,000.

Research and Development Commitments

In October 2019, Quoin Inc. entered into the Exclusive Licensing Agreement (as amended from time to time, the “License Agreement”) with Skinvisible Pharmaceuticals, Inc. (“Skinvisible”), under which Skinvisible granted us an exclusive royalty-bearing license relating to the production and manufacture of prescription drug products related to certain patents held by Skinvisible, including those related to QRX003 and QRX004. We made Skinvisible a one-time non-refundable, non-creditable license fee of \$1 million (the “License Fee”). In addition, we agreed to pay Skinvisible a single digit royalty percentage of our net sales revenues for any licensed product covered by the patent rights licensed under the License Agreement. We also agreed to pay Skinvisible 25% of any revenues we receive as royalties in the event that we sublicense any licensed products to a third party. The License Agreement also requires that we make a \$5 million payment to Skinvisible upon receiving approval in the U.S. or European Union, whichever occurs first, for the first drug product developed using intellectual property licensed thereunder.

In November 2020, Quoin Inc. entered into a Master Service Agreement for an initial term of three years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. A work order was entered into in June 2022 for the first QRX003 clinical study at an expected estimated cost of approximately \$4.4 million through 2024. A further work order was entered into in December 2022 for the second QRX003 clinical study at an expected estimated cost of approximately \$830,000 through 2024. For the three and nine months ended September 30, 2023 and 2022, we incurred a research and development expense under these agreements of approximately \$155,000 and \$1,113,000, and \$423,000 and \$904,000, respectively. During the three months ended September 30, 2023, we received a credit of approximately \$278,000 applied to prior expenses incurred during the period of March 2023 to July 2023.

In November 2021, we entered into a commitment with Queensland University of Technology for research related services associated with Netherton Syndrome of approximately \$250,000 for an initial expected period of eighteen months. In May 2022, we entered into a commitment with Queensland University of Technology for research related services associated with Scleroderma of approximately \$610,000 for an initial expected period of eighteen months. For the three and nine months ended September 30, 2023 and 2022, we incurred research and development costs related to these agreements of approximately \$85,000 and \$361,000, and \$173,000 and \$250,000, respectively.

Critical Accounting Policies and Use of Estimates

There have been no material changes to our critical accounting policies and estimates from the information provided in Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and are not required to provide the information otherwise required under this Item 3.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, which are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of September 30, 2023, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2023. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and implemented, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2023, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal or administrative proceedings or be subject to claims arising in the ordinary course of our business. We are currently not a party to any material legal or administrative proceedings, and we are not aware of any pending or threatened material legal or administrative proceedings against us.

Item 1A. Risk Factors.

There have been no material changes in our risk factors from the risks previously reported in Part 1, Item 1A, “Risk Factors” of our Form 10-K. You should carefully consider the factors discussed in Form 10-K, which could materially affect our business, financial condition or future results. The risks described in our Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Repurchases of Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following exhibits are included in this Form 10-Q or incorporated herein by reference:

Exhibit No.	Exhibit Description
3.1	Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on February 28, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on February 8, 2022).
3.2	Amendment to the Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on April 12, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022).
3.3	Amendment to the Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on November 3, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on September 21, 2022).
3.4	Amendment to the Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on October 26, 2023 (incorporated by reference to Annex A included in the proxy statement filed with the SEC on September 12, 2023).
10.1	License and Distribution Agreement, by and between Quoin Pharmaceuticals Ltd. and Farma Mondo (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 13, 2023.(certain provisions of this exhibit have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv)).
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350
101*	Information formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Shareholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.
104*	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101)

* Filed herewith

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 thereunto duly authorized.

Quoin Pharmaceuticals Ltd.

November 9, 2023

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Dr. Michael Myers, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quoin Pharmaceuticals Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

/s/ Dr. Michael Myers

Name: Dr. Michael Myers

Title: Chief Executive Officer

Date: November 9, 2023

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Gordon Dunn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quoin Pharmaceuticals Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

/s/ Gordon Dunn

Name: Gordon Dunn
Title: Chief Financial Officer
Date: November 9, 2023

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Quoin Pharmaceuticals Ltd. (the "Company") for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Dr. Michael Myers

Name: Dr. Michael Myers

Title: Chief Executive Officer

Date: November 9, 2023

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Quoin Pharmaceuticals Ltd. (the "Company") for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gordon Dunn

Name: Gordon Dunn
Title: Chief Financial Officer
Date: November 9, 2023

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
