Table of Contents

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, 2024

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	**92-2593104**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
42127 Pleasant Forest Court Ashburn, VA	**20148-7349**
(Address of principal executive offices)	**(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 Shares, no par value per share	QNRX	The Nasdaq Stock Market LLC
Ordinary Shares, no par value per share*		N/A

* Not for trading, but only in connection with the registration of the American Depositary Shares ("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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 6, 2024, the registrant had 5,049,720 ordinary shares, no par value per share, outstanding, and 5,049,720 ADSs outstanding (assuming all ordinary shares are represented by ADSs), with each ADS representing one (1) ordinary share.

QUOIN PHARMACEUTICALS LTD.

INDEX

GENERAL INFORMATION

Unless otherwise indicated or the context otherwise requires, all references in this Quarterly Report on Form 10-Q (the "Quarterly Report") to the terms "Quoin," "Quoin Ltd.," the "Company," "us," "we", "our" and the "Registrant" refer to Quoin Pharmaceuticals Ltd., an Israeli company, and its consolidated subsidiaries. In this Quarterly Report, the U.S. Securities and Exchange Commission is referred to as the "SEC", the Securities Act of 1933, as amended, is referred to as the "Securities Act" and the Securities Exchange Act of 1934, as amended, is referred to as the "Exchange Act."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND SUMMARY OF RISK FACTORS

Certain information included in this Quarterly Report may be deemed to be "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue," "believe," "should," "intend," "project" or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our limited operating history and the difficulties encountered by a small developing company;
- our history of losses and need for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all;
- our lack of revenue generated from product sales since inception, and potential inability to be profitable;
- uncertainties of cash flows and inability to meet working capital needs;
- our ability to obtain regulatory approvals;
- our ability to generate favorable pre-clinical and clinical trial results;
- our ability to identify and develop potential product candidates;
- additional costs or delays associated with unsuccessful clinical trials;
- the inability to predict the timing of revenue from sales of a future product;
- the extensive regulatory requirements and future developmental and regulatory challenges we will still face even if we obtain approval for a product candidate;
- our ability to obtain or maintain orphan drug designation or data exclusivity for our product candidates;
- our ability to obtain Orphan Disease and Rare Pediatric Disease designations for our product candidates;

- the potential oversight of programs or product candidates that may be more profitable or more successful;
- our manufacturing processes may not be validated and our methodology may not be accepted by the scientific community;
- the ability to conduct clinical trials, because of difficulties enrolling patients or other reasons;
- the requirements of being a publicly traded company may strain our resources;
- potential adverse effects resulting from failure to maintain effective internal controls;
- our ability to comply with the applicable continued listing requirements of Nasdaq;
- the potential negative impact on our securities price and trading volume if securities or industry analysts do not publish reports about us or if they adversely change their recommendations about our business;
- failure to meet the continued listing requirements of the Nasdaq Capital Market could result in a delisting of our ADSs;
- the potential volatility of the market price for our ADSs;
- the potential dilution of our shareholders' potential ownership due to future issuances of share capital;
- the requirement for holders of ADSs to act through the depositary to exercise their rights;
- the potential limitations on ADS holders with respect to the transfer of their ADSs;
- the risks of securities class action litigation; and
- other risks and uncertainties, including those listed under described in Part I – Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2023 ("Form 10-K"), as well as our subsequent reports filed with the SEC

You are urged to carefully review and consider the various disclosures made throughout this Quarterly Report which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

You should not put undue reliance on any forward-looking statements. Although the forward-looking statements in this Quarterly Report are based on our beliefs, assumptions and expectations, taking into account all information currently available to us, we cannot guarantee future transactions, results, performance, achievements or outcomes. No assurance can be made that the expectations reflected in our forward-looking statements will be attained, or that deviations from them will not be material and adverse. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

QUOIN PHARMACEUTICALS LTD.

Condensed Consolidated Balance Sheets

	September 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,116,750	$ 2,401,198
Investments	7,190,138	8,293,663
Prepaid expenses and other current assets	190,541	591,034
Total current assets	10,497,429	11,285,895
Prepaid expenses - long term	383,390	300,000
Intangible assets, net	508,334	583,334
Total assets	$ 11,389,153	$ 12,169,229
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 222,636	$ 526,523
Accrued expenses	1,504,852	1,308,706
Accrued interest and financing expense	1,146,251	1,146,251
Due to officers - short term	600,000	600,000
Total current liabilities	3,473,739	3,581,480
Due to officers - long term	2,473,733	2,923,733
Total liabilities	$ 5,947,472	$ 6,505,213
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value per share, 100,000,000 ordinary shares authorized at September 30, 2024 and December 31, 2023, respectively - 5,049,720 (5,049,720 ADS's) ordinary shares issued and outstanding at September 30, 2024 and 987,220 (987,220 ADS's) at December 31, 2023	$ —	$ —
Additional paid in capital	58,296,199	51,867,336
Accumulated deficit	(52,854,518)	(46,203,320)
Total shareholders' equity	5,441,681	5,664,016
Total liabilities and shareholders' equity	$ 11,389,153	$ 12,169,229

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

QUOIN PHARMACEUTICALS LTD.

Condensed Consolidated Statements of Operations (Unaudited)

	Nine months ended September 30,		Three months ended September 30,	
	2024	2023	2024	2023
Operating expenses				
General and administrative	$ 4,590,936	$ 4,685,241	$ 1,357,715	$ 1,366,464
Research and development	2,532,468	2,475,596	1,170,287	758,759
Total operating expenses	7,123,404	7,160,837	2,528,002	2,125,223
Other (income) and expenses				
Unrealized (gain) loss	(23,043)	11,926	(31,729)	(2,119)
Realized and accrued interest income	(449,163)	(536,068)	(146,388)	(196,425)
Total other income	(472,206)	(524,142)	(178,117)	(198,544)
Net loss	$ (6,651,198)	$ (6,636,695)	$ (2,349,885)	$ (1,926,679)
Loss per ADS				
Loss per ADS				
Basic	$ (1.63)	$ (7.61)	$ (0.47)	$ (1.95)
Fully-diluted	$ (1.63)	$ (7.61)	$ (0.47)	$ (1.95)
Weighted average number of ADS's outstanding				
Basic	4,071,162	871,835	5,049,720	987,220
Fully-diluted	4,071,162	871,835	5,049,720	987,220

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, 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	987,220	987,220	—	$ (2,932,000)	$ 53,966,259	$ (40,119,816)	$ 10,914,443
Net loss	—	—	—	—	—	(2,106,947)	(2,106,947)
Stock based compensation	—	—	—	—	264,376	—	264,376
Balance at June 30, 2023	987,220	987,220	—	$ (2,932,000)	$ 54,230,635	$ (42,226,763)	$ 9,071,872
Net loss	—	—	—	—	—	(1,926,679)	(1,926,679)
Stock based compensation	—	—	—	—	268,503	—	268,503
Balance at September 30, 2023	987,220	987,220	—	$ (2,932,000)	$ 54,499,138	$ (44,153,442)	$ 7,413,696

Three and Nine months ended September 30, 2024

	Ordinary Shares	ADS's	No Par Value	Treasury Stock	Additional Paid in Capital	Accumulated Deficit	Total
Balance at January 1, 2024	987,220	987,220	—	$ —	$ 51,867,336	$ (46,203,320)	5,664,016
Net loss	—	—	—	—	—	(2,327,280)	(2,327,280)
Issuance of ADS's, pre-funded warrants and warrants, net	2,808,750	2,808,750	—	—	5,482,472	—	5,482,472
Stock based compensation	—	—	—	—	306,314	—	306,314
Balance at March 31, 2024	3,795,970	3,795,970	—	$ —	$ 57,656,122	$ (48,530,600)	$ 9,125,522
Net loss	—	—	—	—	—	(1,974,033)	(1,974,033)
Exercise of pre-funded warrants	184,000	184,000	—	—	18	—	18
Reversal of accrued offering expenses	—	—	—	—	13,707	—	13,707
Stock based compensation	—	—	—	—	313,122	—	313,122
Balance at June 30, 2024	3,979,970	3,979,970	—	$ —	$ 57,982,969	$ (50,504,633)	$ 7,478,336
Net loss	—	—	—	—	—	(2,349,885)	(2,349,885)
Exercise of pre-funded warrants	1,069,750	1,069,750	—	—	108	—	108
Stock based compensation	—	—	—	—	313,122	—	313,122
Balance at September 30, 2024	5,049,720	5,049,720	—	$ —	$ 58,296,199	$ (52,854,518)	$ 5,441,681

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,	
	2024	2023
Cash flows used in operating activities:		
Net loss	$ (6,651,198)	$ (6,636,695)
Stock based compensation	932,558	794,351
Amortization of intangibles	75,000	78,032
Unrealized gain and accrued interest on investments	(186,512)	(369,467)
Changes in assets and liabilities:		
Increase (decrease) in accounts payable and accrued expenses	(107,741)	1,052,872
Decrease in prepaid expenses and other assets	317,103	440,123
Net cash used in operating activities	$ (5,620,790)	$ (4,640,784)
Cash flows provided (used) in investing activities:		
Purchase of investments	$ (11,255,963)	$ (18,090,684)
Proceeds from maturity of investments	12,546,000	17,635,000
Net cash provided (used) in investing activities	$ 1,290,037	$ (455,684)
Cash flows provided by financing activities:		
Payment of amounts due to officers	$ (450,000)	$ (450,000)
Proceeds from sale of equity securities, net	5,496,305	5,849,266
Net cash provided by financing activities	$ 5,046,305	$ 5,399,266
Net change in cash and cash equivalents:	715,552	302,798
Cash and cash equivalents - beginning of period	2,401,198	2,860,628
Cash and cash equivalents - end of period	$ 3,116,750	$ 3,163,426
Supplemental information - Non cash items:		
Offering expenses associated with warrant modification	$ 209,225	$ 238,231

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

NOTE 1 – ORGANIZATION AND BUSINESS

Quoin Pharmaceuticals Ltd. ("Quoin Ltd.," or the "Company"), formerly known as Cellect Biotechnology Ltd. ("Cellect"), 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, Cellect completed the business combination with Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Cellect (the "Merger"). Immediately after completion of the Merger, Cellect changed its name to "Quoin Pharmaceuticals Ltd."

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, QRX003, is a 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, and with the University College Cork ("UCC") for the development of novel topical formulations of rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are currently no approved therapies or cures. To date, no products have been commercialized and no revenue has 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 $52.9 million at September 30, 2024. The Company has a limited operating history and has historically funded its operations through debt and equity financings. The Company incurred net losses of approximately $6.7 million, and negative cash flows from operations of $5.6 million for the nine months ended September 30, 2024. At September 30, 2024, the Company had cash and cash equivalents balances totaling $3.1 million and investments of $7.2 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, results of operations and financial condition.

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 product for clinical development.

On April 29, 2024, the Company received a letter from the Listing Qualifications Department of The Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that the closing bid price per ADS of the Company was below the required minimum of $1.00 for a period of 31 consecutive business days and that the Company did not meet the minimum bid price requirements set forth in Nasdaq Rule 5550(a)(2).

Pursuant to Nasdaq Rule 5810(c)(3)(A), the Company had an initial period of one hundred eighty (180) calendar days, or until October 28, 2024 (the "Compliance Period") to regain compliance with Nasdaq's minimum bid price requirement. Compliance could be achieved without further action if the closing bid price of the Company's ADS was at or above $1.00 for a minimum of ten consecutive business days at any time during the Compliance Period, in which case Nasdaq would notify the Company if it determined the Company was in compliance and the matter would be closed; however Nasdaq could require the closing bid price to equal or to exceed the $1.00 minimum bid price requirement for more than 10 consecutive business days before determining that a company complies. In the event the Company did not regain compliance by October 28, 2024, the Company could be eligible for an additional 180 calendar day grace period. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held ADSs and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and would need to provide written notice of its intention to cure the deficiency during the second compliance period. Please refer to Note 16 regarding the extension letter received from the Staff on October 29, 2024.

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, 2024 and for the three and nine months then ended. The results of operations for the three and nine months ended September 30, 2024 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, 2023 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 14, 2024. The Company operates in one segment.

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. Except as specifically provided, ADSs and related option and warrant information presented in these unaudited condensed consolidated 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.

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 unaudited condensed consolidated 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: settlement of debt or other obligations, 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 its warrants outstanding 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, 2024 and December 31, 2023, respectively.

Investments:

Investments as of September 30, 2024 and December 31, 2023 consist of U.S. Treasury Bills and Notes, which are classified as trading securities, totaling $7.2 million and $8.3 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. All of the Company's U.S. Treasury Bills and Notes held on September 30, 2024 have maturities within one year from the balance sheet date. As of September 30, 2024, the carrying value of the Company's U.S. Treasury Bills and Notes approximates their fair value due to their short-term maturities.

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.

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, 2024 and 2023, 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.

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-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 any 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, other than unexercised prefunded warrants as described below, potential common shares are excluded if their effect is anti-dilutive.

For the three and nine months ended September 30, 2024, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 8,988,346 ADS and outstanding stock options to purchase 278,011 ADS, and 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, respectively, as their inclusion 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") to certain investors ("2020 Noteholders"). The 2020 Notes were mandatorily convertible into 432 ADSs, subject to adjustment and were converted in 2021. The ADSs issued to the 2020 Noteholders did not include accrued interest. Two of the five 2020 Noteholders received their amount due during the year ended December 31, 2022 and the Company's estimate of the liability to the remaining three 2020 Noteholders was estimated to be $1,146,000 as of September 30, 2024 and December 31, 2023.

There was no interest expense recognized in both the three and nine month periods ended September 30, 2024 and 2023.

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, 2024 and December 31, 2023:

September 30, 2024	Level 1	Level 2	Level 3	Total
US Treasury Bills and Notes	$ 7,190,138	$ —	$ —	$ 7,190,138
Total US Treasury Bills amd Notes Asset	$ 7,190,138	$ —	$ —	$ 7,190,138

December 31, 2023	Level 1	Level 2	Level 3	Total
US Treasury Bills and Notes	$ 8,293,663	$ —	$ —	$ 8,293,663
Total US Treasury Bills amd Notes Asset	$ 8,293,663	$ —	$ —	$ 8,293,663

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, which 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 2,147,412 ordinary shares represented by 2,147,412 ADSs as of September 30, 2024. Under the Amended Plan, the Company may grant options to its directors, officers, employees, consultants, advisers and service providers. As of September 30, 2024, 1,869,401 shares remained available for issuance.

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, 2023	**278,011**	**$ 25.34**	**9.68**
Granted	—	—	
Forfeited/Cancelled	—	—	
Outstanding at September 30, 2024	**278,011**	**$ 25.34**	**8.93**
Exercisable options at September 30, 2024	14,407	$ 210.00	7.60

The intrinsic value of outstanding options at September 30, 2024 was $0.

Stock based compensation expense was approximately $313,000 ($68,000 included in research and development expense and $245,000 included in general and administrative expenses) in the three months ended September 30, 2024 and approximately $933,000 ($186,000 included in research and development expense and $747,000 included in general and administrative expenses) in the nine months ended September 30, 2024.

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.

At September 30, 2024, the total unrecognized compensation expense related to non-vested options was approximately $2.1 million and is expected to be recognized over the remaining weighted average service period of approximately 2.98 years.

NOTE 7 – PREPAID EXPENSES

Prepaid expenses are as follows:

	September 30, 2024	December 31, 2023
Prepaid R&D costs	$ 398,920	$ 447,979
Prepaid insurance	45,586	401,972
Prepaid expense	21,322	8,500
Deferred offering costs (note 13)	108,103	32,583
Total	$ 573,931	$ 891,034
Less: Short-term portion	(190,541)	(591,034)
Long-term portion	**$ 383,390**	**$ 300,000**

NOTE 8 - ACCRUED EXPENSES

Accrued expenses are as follows:

	September 30, 2024	December 31, 2023
Research contract expenses (note 12)	$ 417,461	$ 358,287
Payroll (note 11)	859,447	804,156
Payroll taxes (note 11)	79,948	93,989
Professional fees	94,952	50,534
Other expenses	53,044	1,740
Total	**$ 1,504,852**	**$ 1,308,706**

NOTE 9 – IN-LICENSED TECHNOLOGY

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 sublicenses 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, 2024 and December 31, 2023.

NOTE 10 - INTANGIBLE ASSETS

Intangible assets are as follows:

	September 30, 2024	December 31, 2023
Technology license – Skinvisible	$ 1,000,000	$ 1,000,000
Total cost	1,000,000	1,000,000
Accumulated amortization	(491,666)	(416,666)
Net book value	**$ 508,334**	**$ 583,334**

The Company recorded amortization expense of approximately $25,000 and $26,000 in the three months ended September 30, 2024 and 2023, respectively. The Company recorded amortization expense of approximately $75,000 and $78,000 in the nine months ended September 30, 2024 and 2023, respectively. The annual amortization expense expected to be recorded for existing intangible assets for the remaining of 2024 through 2027, and thereafter, is approximately $25,000, $100,000, $100,000, $100,000 and $183,000, respectively.

NOTE 11 - RELATED PARTY TRANSACTIONS

Employment Agreements and 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 by Dr. Myers and Ms. Carter to third parties on behalf of Quoin Inc., were not paid by Quoin Inc. to Dr. Myers and Ms. Carter, and 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 $75,000 and $200,000 to Ms. Carter in the three months ended September 30, 2024 and 2023, 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, 2024 and 2023, respectively.

As of September 30, 2024, approximately $1.7 million and $1.3 million of such indebtedness was outstanding to Dr. Myers and Ms. Carter, respectively.

Amounts due to officers at September 30, 2024 and December 31, 2023 consisted of the following:

	September 30, 2024	December 31, 2023
Salaries and other compensation	$ 3,073,733	$ 3,523,733
Less: Short-term portion	(600,000)	(600,000)
Long-term portion	**$ 2,473,733**	**$ 2,923,733**

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 with Therapeutics Inc. for the management of the preclinical and clinical development of QRX003 for Netherton Syndrome. The initial term of the agreement was three years with automatic one year extensions, and 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. An additional work order was entered into in December 2022 for a second QRX003 clinical study at an expected estimated cost of approximately $830,000. For the three and nine months ended September 30, 2024 and 2023, the Company incurred a research and development expense under these agreements of approximately $275,000 and $926,000 and $155,000 and $1,113,000 respectively.

In November 2021, the Company entered into a research agreement with Queensland University of Technology (QUT) for a pre-clinical research program for the development of a product to treat Netherton Syndrome of approximately $250,000. In May 2022, the Company entered into a second research agreement with QUT for the development of a product to treat Scleroderma of approximately $610,000. Each agreement remains in place until the completion of the research program, which in each case was initially anticipated to be 18 months from execution. For the three and nine months ended September 30, 2024 and 2023, the Company incurred research and development costs related to these agreements of approximately $0 and $0, and $85,000 and $361,000, respectively.

On June 10, 2024, the Company signed a research agreement with The School of Pharmacy at UCC. The scope of the agreement encompasses the development of novel topical formulations of rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are currently no approved therapies or cures. Under the terms of the agreement, based on the achievement of certain milestones, the Company will fund up to approximately €567,000 ($608,000) plus VAT over an anticipated 2-1/2 year period to support UCC research program to investigate the development of a number of topical rapamycin formulations for future development as potential treatments for several rare and orphan diseases. Following completion of the research program, the Company will have the option to advance the clinical development of rapamycin formulations developed by UCC. The Company incurred no costs related to this agreement in the three and nine months ended September 30, 2024.

Performance milestones and Royalties

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

NOTE 13 – SHAREHOLDERS' EQUITY

Alumni Equity Line and Purchase Agreement

On January 25, 2024, the Company entered into a purchase agreement (the "Alumni Purchase Agreement") with Alumni Capital LP ("Alumni"). Pursuant to the Alumni Purchase Agreement, the Company has the right to sell to Alumni up to $8,000,000 (the "Commitment Amount") of newly issued ordinary shares that are represented by ADS, subject to certain conditions and limitations, from time to time during the term of the Alumni Purchase Agreement.

The Company does not have the right to commence any sales of ordinary shares represented by ADSs to Alumni under the Alumni Purchase Agreement until the date, which the Company refers to as the Commencement Date, that all of the conditions set forth in the Alumni Purchase Agreement have been satisfied, including that the registration statement the Company agreed to file with the SEC pursuant to the Alumni Purchase Agreement is declared effective by the SEC, and the Company's shareholders have approved of the issuance of ADSs under the Alumni Purchase Agreement, which approval was obtained on April 5, 2024.

From and after the Commencement Date, the Company may, from time to time and at the Company's sole discretion for a period of three months, which the Company at its sole discretion may increase by an additional three months (such period, including any extension, the "Commitment Period"), on any business day that the Company may select, direct Alumni to purchase ordinary shares represented by ADSs. The purchase price for the ordinary shares represented by ADSs the Company may sell to Alumni will be based upon formulas set forth in the Alumni Purchase Agreement based on the then current market price of the ADSs as computed under the Alumni Purchase Agreement and will depend on the type of purchase notice the Company submits to Alumni from time to time. There is no upper limit on the price per share that Alumni could be obligated to pay for the ADSs under the Alumni Purchase Agreement; provided, however at no time can the purchase price be below a floor price of $1.00 per share (subject to adjustment). The Company agreed to issue purchase notices for an aggregate of at least $4,000,000 of the Commitment Amount prior to the end of the Commitment Period.

As consideration for Alumni's irrevocable commitment to purchase ADSs under the Alumni Purchase Agreement, the Company agreed to issue to Alumni, at the times set forth in the Alumni Purchase Agreement beginning with the trading day after the Commencement Date, a number of ADSs with a value at the time of issuance not to exceed $240,000 in the aggregate (the "Commitment Securities"). The Company may pay cash in lieu of issuing all or any portion of the Commitment Securities.

As of September 30, 2024 the Company has not filed the required registration statement or sold any ADSs to Alumni under the Alumni Purchase Agreement.

Public Offering

On March 7, 2024, (the "2024 Closing Date") the Company completed an offering (the "2024 Offering") of the following securities (i) 811,250 ordinary shares represented by ADSs, (ii) 4,062,500 Series D warrants (the "Series D Warrants") to purchase 4,062,500 ordinary shares represented by ADSs, (iii) 4,062,500 Series E warrants (the "Series E Warrants" and together with the Series D Warrants, the "2024 Warrants") to purchase 4,062,500 ordinary shares represented by ADSs, and (iv) 3,251,250 pre-funded warrants (the "2024 Pre-Funded Warrants") to purchase 3,251,250 ordinary shares represented by ADSs for aggregate gross proceeds of approximately $6.5 million, resulting in net proceeds of approximately $5.5 million, after deducting the placement agent's fees and offering expenses paid by the Company. Each ADS (or 2024 Pre-Funded Warrant to purchase one ADS in lieu thereof) was sold together with a Series D Warrant to purchase one ADS and a Series E Warrant to purchase one ADS. The ADSs and accompanying 2024 Warrants were sold at a combined public offering price of $1.60 and the 2024 Pre-Funded Warrants and accompanying 2024 Warrants were sold at a combined public offering price of $1.5999, which is equal to the combined purchase price per ADS and accompanying 2024 Warrants, minus the exercise price of each 2024 Pre-Funded Warrant of $0.0001. As of September 30, 2024, all 2024 Pre - Funded Warrants have been exercised and are included in issued and outstanding ADSs. The Series D and Series E warrants have an exercise price of $1.60 per share, were exercisable immediately following the 2024 Closing Date and expire in two years and five years, respectively, from the closing of the 2024 Offering.

In connection with the 2024 Offering, the Company entered into a Securities Purchase Agreement (the "2024 Purchase Agreement") dated March 4, 2024, with certain institutional investors signatory thereto, pursuant to which the Company agreed to issue and sell to such investors, certain of the ADSs, 2024 Pre-Funded Warrants and 2024 Warrants sold in the 2024 Offering. Pursuant to the terms of the 2024 Purchase Agreement, the Company agreed, subject to certain exceptions, (i) to not enter into variable rate financings for a period of 180 days following the closing of the 2024 Offering, and (ii) to not enter into any equity financings for 90 days from closing of the 2024 Offering.

On March 7, 2024, the Company also entered into privately negotiated agreements with the holders of certain existing outstanding warrants to purchase up to 638,834 ADSs, 207,499 of which were warrants issued in the Company's 2022 public offering and 431,335 of which were warrants issued in the Company's 2023 public offering (collectively, the "Prior Warrants") to, among other things, reduce the exercise price of such Prior Warrants to $1.60 and to extend the current expiration date of the Prior Warrants until March 7, 2029. The incremental fair value of the modified warrants was approximately $209,000, which was accounted for as an offering expense in connection with the 2024 Offering.

Warrants

The following table summarizes warrant activities during the nine months ended September 30, 2024:

	ADSs Underlying Warrants	Weighted Average Exercise Price Per ADS
Outstanding and exercisable at December 31, 2023	864,081	$ 16.13 *
Granted Common Warrants	8,125,000	1.60
Granted Pre-Funded Warrants	3,251,250	—
Exercised Pre-Funded Warrants	(3,251,250)	—
Terminated	(735)	1,650.00
Outstanding and exercisable at September 30, 2024	8,988,346	$ 2.10

As of September 30, 2024, outstanding common warrants expire in 2026, 2027 and 2029, and have an intrinsic value of $0.

* Note that the exercise price of certain existing outstanding warrants to purchase up to 638,834 ADSs was reduced from $12.00 and $13.20 to $1.60 on March 7, 2024, 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 unaudited condensed consolidated financial statements.

NOTE 15 – LICENSE AGREEMENTS

As of September 30, 2024, the Company had nine commercial license and supply agreements outstanding, whereby the Company will receive a royalty or other proceeds from the specified product revenues from the licensor, if and when the underlying products are approved and commercialized or sold via compassionate use or early access programs. No royalty revenues have been received through September 30, 2024 from any of these agreements.

NOTE 16 – SUBSEQUENT EVENTS

As previously disclosed, on April 29, 2024, the Company received a deficiency letter from the Listing Qualifications Department of Nasdaq notifying the Company that it was no longer in compliance with the minimum bid price requirement, and that, pursuant to Nasdaq Rule 5810(c)(3)(A), the Company had an initial period of one hundred eighty (180) calendar days, or until October 28, 2024 to regain compliance with the minimum bid price requirement. See Note 2. On October 16, 2024, the Company submitted a letter to Nasdaq requesting an additional 180-day grace period to regain compliance with the minimum bid price requirement.

On October 29, 2024, the Company received a letter from the Listing Qualifications Department of Nasdaq notifying the Company that Nasdaq has granted the Company an additional 180 calendar days, or until April 28, 2025, to regain compliance with the minimum bid price requirement. The Staff's determination in granting the Company the extension was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market with the exception of the minimum bid price requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse split, if necessary. Accordingly, there is no immediate effect on the listing or trading of the Company's ADS on the Nasdaq Capital Market under the symbol "QNRX."

Compliance may be achieved without further action if the closing bid price of the Company's ADS is at or above $1.00 for a minimum of ten consecutive business days at any time during the second 180-day compliance period, in which case Nasdaq will notify the Company if it determines the Company is in compliance and the matter will be closed; however Nasdaq may require the closing bid price to equal or to exceed the $1.00 minimum bid price requirement for more than 10 consecutive business days before determining that the Company complies. If compliance cannot be demonstrated by April 28, 2025, the Staff will provide written notification that the Company's securities will be delisted. At that time, the Company may appeal the Staff's determination to a Hearings Panel (the "Panel"). If the Company appeals it will be asked to provide a plan to regain compliance to the Panel. Historically, Panels have generally viewed a near-term reverse split as the only definitive plan acceptable to resolve a minimum bid price deficiency.

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 unaudited condensed consolidated financial statements and related notes thereto included in Part I-Item 1 of this Form 10-Q. 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, and with the University College Cork ("UCC") for the development of novel topical formulations of Rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are currently no approved therapies or cures.

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 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, we 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. Except as specifically provided, ordinary share, ADS and related option and warrant information presented herein, including our unaudited condensed consolidated 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.

Recent Developments

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 our initial study, patients are actively being screened and recruited into the study and dosing commenced in December 2022. This study originally was designed as a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in 18 adult 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. This study originally was designed to be conducted in ten adult NS patients who are currently receiving, and will continue to do so throughout the study, off-label systemic therapy, primarily systemic biologic therapy. This is an open-label study with no placebo control. Both of our NS clinical studies are running concurrently and utilize the same clinical trial sites and investigators.

On October 24, 2023, we released positive initial clinical results obtained from the first six evaluable subjects in our open-label study. As a result of this positive initial data and the absence of any safety concerns from both studies, on November 8, 2023 we submitted a number of protocol amendments to the FDA, under our open IND, with a view to optimizing both studies and potentially leading to even better clinical outcomes and a more rapid regulatory approval. These protocol amendments included eliminating the lower dose from the double-blinded study, modifying the dosing frequency from once-daily to twice-daily and increasing the number of subjects from 18 to 30. For the open-label study, the number of subjects was increased from 10 to 20 and dosing was modified from once-daily to twice-daily. On December 13, 2023, we announced that we were cleared by the FDA to implement these protocol amendments. In February 2024 we submitted a further protocol amendment to the FDA requesting permission to lower the age of eligibility for participation in both studies to 14 years and older from 18 years and older. On March 4, 2024 we announced that we were cleared to implement this protocol amendment. All protocol amendments have now been implemented and going forward participants in both studies will be dosed twice-daily with those enrolled in the blinded study receiving either a 4% dose of QRX003 or a placebo, while subjects in the open-label will receive a 4% dose of QRX003 only.

On June 27, 2024 we announced that we will expand our ongoing Netherton Syndrome clinical studies to include international sites. The first international site will be opened at a research hospital in Saudi Arabia. This hospital is currently treating a number of Netherton patients who will now become eligible for recruitment into our studies. An experienced Clinical Research Organization has been engaged to manage the study locally.

On August 6, 2024, we announced the planned initiation of an investigator-led clinical study in New Zealand for QRX003 in pediatric patients with Peeling Skin Syndrome. This rare genetic condition currently has no approved treatments or cures. The first clinical site and patient have been identified, and Quoin is actively evaluating additional clinical sites in other countries.

On October 22, 2024 we announced the further expansion of our ongoing Netherton Syndrome clinical studies to include to include two additional international sites in the United Kingdom (UK). These sites, Great Ormond Street Hospital and St. Thomas' Hospital, both in London, are recognized centers of excellence for treating Netherton Syndrome patients in the UK. Both sites have available cohorts of patients potentially eligible to participate in Quoin's studies. A Principal Investigator for the UK studies has been appointed and a Clinical Research Organization has been engaged.

The UK and Saudi Arabia sites will operate under the auspices of Quoin's open Investigational New Drug (IND) application with the US Food and Drug Administration. Quoin is also in advanced stage of preparation for the opening of additional sites in several other Western European countries and is concluding a feasibility study in multiple Eastern European countries with both territories having available cohorts of patients with Netherton Syndrome.

Research Agreement with University College Cork

On June 10, 2024 we signed a research agreement with The School of Pharmacy at UCC. The scope of the agreement encompasses the development of novel topical formulations of rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are currently no approved therapies or cures. UCC will apply its proprietary dissolvable microneedle delivery technology along with other formulation approaches to optimize the local delivery of rapamycin and potentially enhance its therapeutic effectiveness as a potential treatment for several pre-identified clinical targets.

Under the terms of the agreement, we will fund a research program at UCC over an anticipated 2-1/2 year period to investigate the development of a number of topical rapamycin formulations for future development as potential treatments for several rare and orphan diseases, where it is believed that the drug's mechanism of action may provide for clinical efficacy in these settings. Following completion of the research program, we will have the option to advance the clinical development of rapamycin formulations developed by UCC. The terms of the agreement do not require us to pay any upfront license or milestone fees or any royalties based on future product sales.

Public Offering

On March 7, 2024, (the "2024 Closing Date") we completed an offering (the "2024 Offering") of the following securities (i) 811,250 ordinary shares represented by ADSs, (ii) 4,062,500 Series D warrants (the "Series D Warrants") to purchase 4,062,500 ordinary shares represented by ADSs, (iii) 4,062,500 Series E warrants (the "Series E Warrants" and together with the Series D Warrants, the "2024 Warrants") to purchase 4,062,500 ordinary shares represented by ADSs, and (iv) 3,251,250 pre-funded warrants (the "2024 Pre-Funded Warrants") to purchase 3,251,250 ordinary shares represented by ADSs for aggregate gross proceeds of approximately $6.5 million, resulting in net proceeds of approximately $5.5 million, after deducting the placement agent's fees and offering expenses paid by us. Each ADS (or 2024 Pre-Funded Warrant to purchase one ADS in lieu thereof) was sold together with a Series D Warrant to purchase one ADS and a Series E Warrant to purchase one ADS. The ADSs and accompanying 2024 Warrants were sold at a combined public offering price of $1.60 and the 2024 Pre-Funded Warrants and accompanying 2024 Warrants were sold at a combined public offering price of $1.5999, which is equal to the combined purchase price per ADS and accompanying 2024 Warrants, minus the exercise price of each 2024 Pre-Funded Warrant of $0.0001. As of September 30, 2024 all 2024 Pre-Funded Warrants have been exercised and are included in issued and outstanding ADSs. The Series D Warrants and the Series E Warrants have an exercise price of $1.60 per share, were exercisable immediately following the closing of the 2024 Offering and expire in two years and five years, respectively, from the closing of the 2024 Offering.

In connection with the 2024 Offering, we entered into a Securities Purchase Agreement (the "2024 Purchase Agreement") dated March 4, 2024, with certain institutional investors signatory thereto, pursuant to which we agreed to issue and sell to such investors, certain of the ADSs, 2024 Pre-Funded Warrants and 2024 Warrants sold in the 2024 Offering. Pursuant to the terms of the 2024 Purchase Agreement, we agreed, subject to certain exceptions, (i) to not enter into variable rate financings for a period of 180 days following the closing of the 2024 Offering, and (ii) to not enter into any equity financings for 90 days from the closing of the 2024 Offering.

On March 7, 2024, we also entered into privately negotiated agreements with the holders of certain existing outstanding warrants to purchase up to 638,834 ADSs (the "Prior Warrants") to, among other things, reduce the exercise price of such Prior Warrants to $1.60 and to extend the current expiration date of the Prior Warrants until March 7, 2029. The incremental fair value of the modified warrants was approximately $209,000, which was accounted for as an offering expense in connection with the 2024 Offering.

Alumni Equity Line and Purchase Agreement

On January 25, 2024, we entered into a Purchase Agreement (the "Alumni Purchase Agreement") with Alumni Capital LP ("Alumni"). Pursuant to the Alumni Purchase Agreement, we have the right to sell to Alumni up to $8,000,000 (the "Commitment Amount") of newly issued ordinary shares that are represented by ADS (the "Purchase Notice Securities"), subject to certain conditions and limitations, from time to time during the term of the Alumni Purchase Agreement.

We do not have the right to commence any sales of ordinary shares represented by ADSs to Alumni under the Alumni Purchase Agreement until the date, which we refer to as the Commencement Date, that all of the conditions set forth in the Alumni Purchase Agreement have been satisfied, including that the registration statement we agreed to file with the SEC pursuant to the Alumni Purchase Agreement is declared effective by the SEC, and our shareholders have approved of the issuance of ADSs under the Alumni Purchase Agreement, which approval was obtained on April 5, 2024.

From and after the Commencement Date, we may, from time to time and at our sole discretion for a period of three months, which we at our sole discretion may increase by an additional three months (such period, including any extension, the "Commitment Period"), on any business day that we select, direct Alumni to purchase ordinary shares represented by ADSs. The purchase price for the ordinary shares represented by ADSs we may sell to Alumni will be based upon formulas set forth in the Alumni Purchase Agreement based on the then current market price of the ADSs as computed under the Alumni Purchase Agreement and will depend on the type of purchase notice we submit to Alumni from time to time. There is no upper limit on the price per share that Alumni could be obligated to pay for the ADSs under the Alumni Purchase Agreement; provided, however at no time can the purchase price be below a floor price of $1.00 per share (subject to adjustment). We agreed to issue purchase notices for an aggregate of at least $4,000,000 of the Commitment Amount prior to the end of the Commitment Period.

As consideration for Alumni's irrevocable commitment to purchase ADSs under the Alumni Purchase Agreement, we agreed to issue to Alumni, at the times set forth in the Alumni Purchase Agreement beginning with the trading day after the Commencement Date, a number of ADSs with a value at the time of issuance not to exceed $240,000 in the aggregate (the "Commitment Securities"). The ADSs to be issued will be valued at the average of the closing prices of the ADSs on Nasdaq for the five trading days immediately prior to the date such ADSs are issued. We may pay cash in lieu of issuing all or any portion of the Commitment Securities.

In connection with the 2024 Offering, we agreed not to sell any ADS to Alumni under the Alumni Purchase agreement for a period of 180 days from the 2024 Closing Date. As of September 30, 2024 we have not filed the required registration statement or sold any ADS to Alumni under the Alumni Purchase Agreement.

Nasdaq Listing

On April 29, 2024, we received a letter from the Listing Qualifications Department of Nasdaq (notifying us that the closing bid price per ADS of the Company was below the required minimum of $1.00 for a period of 31 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 28, 2024, to regain compliance with Nasdaq's minimum bid price requirement. On October 16, 2024, the Company submitted a letter to Nasdaq requesting an additional 180-day grace period to regain compliance with the minimum bid price requirement. On October 29, 2024, the Company received a letter from the Listing Qualifications Department of Nasdaq granting the Company an additional 180 calendar day grace period, or until April 28, 2025, to regain compliance. The Staff's determination in granting the Company the extension was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market with the exception of the minimum bid price requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse split, if necessary. Accordingly, there is no immediate effect on the listing or trading of the Company's ADS on the Nasdaq Capital Market under the symbol "QNRX."

Compliance may be achieved without further action if the closing bid price of the Company's ADS is at or above $1.00 for a minimum of ten consecutive business days at any time during the second compliance period, in which case Nasdaq will notify the Company if it determines the Company is in compliance and the matter will be closed; however Nasdaq could require the closing bid price to equal or to exceed the $1.00 minimum bid price requirement for more than 10 consecutive business days before determining that the Company complies. If compliance cannot be demonstrated by April 28, 2025, the Staff will provide written notification that the Company's securities will be delisted. At that time, the Company may appeal the Staff's determination to a Hearings Panel. If the Company appeals it will be asked to provide a plan to regain compliance to the Panel. Historically, Panels have generally viewed a near-term reverse split as the only definitive plan acceptable to resolve a minimum bid price deficiency.

The Company intends to actively monitor the bid price of its ADSs and will consider available options to regain compliance with Nasdaq's listing requirements.

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 product candidates we may choose to develop; and
- costs for sponsored research.

Research and development activities will continue to be central to our business plan. Product candidates 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 candidate.

The duration, costs and timing of clinical trials of QRX003 and any other future product candidate 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 will increase in the future to support our continued research and development activities. These increases will likely 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 interest income and unrealized loss (gain) on investments.

Results of Operations – Three months ended September 30, 2024 compared to the three months ended September 30, 2023

The following table sets forth our results of operations for the three months ended September 30, 2024, compared to the three months ended September 30, 2023:

	Three months September 30,		
	2024	2023	Change
Operating Expenses			
General and administrative	$ 1,357,715	$ 1,366,464	$ (8,749)
Research and development	1,170,287	758,759	411,528
Total operating expenses	2,528,002	2,125,223	402,779
Other (income) and expenses			
Unrealized gain	(31,729)	(2,119)	(29,610)
Realized and accrued interest income	(146,388)	(196,425)	50,037
Total other income	(178,117)	(198,544)	20,427
Net loss	$ (2,349,885)	$ (1,926,679)	$ (423,206)

General and Administrative Expenses

General and administrative expenses were approximately $1,358,000 and $1,366,000, in the three months ended September 30, 2024 and 2023, respectively, representing a decrease of $9,000, or approximately 1%. The decrease is primarily due to a decreases in legal and professional fees of $59,000, travel related expenses of $91,000 and insurance costs of $31,000, offset by increases in public company costs of $100,000, compensation and benefits of $54,000, and non-cash stock-based compensation expense of $10,000.

Research and Development Expenses

Research and development expenses were approximately $1,170,000 and $759,000, in the three months ended September 30, 2024 and 2023, respectively, representing an increase of $412,000, or approximately 54%. The increase was primarily due to $380,000 in increased expenditures on our development programs, including work related to the clinical studies for the development of QRX003, and a increase of $34,000 of non-cash stock-based compensation. 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. Amortization of intangible assets was approximately $25,000 and $26,000 in each of the three month periods ended September 30, 2024 and 2023.

Other (Income) and Expenses:

We earned approximately $32,000 in unrealized gain and $146,000 in realized and accrued interest income, and approximately $2,000 in unrealized gain and $196,000 in realized and accrued interest income, in the three months ended September 30, 2024 and September 30, 2023 respectively, from our cash and cash equivalents and investments in marketable debt securities.

Results of Operations – Nine months ended September 30, 2024 compared to the nine months ended September 30, 2023

The following table sets forth our results of operations for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023:

	Nine months ended September 30,		
	2024	2023	Change
Operating Expenses			
General and administrative	$ 4,590,936	$ 4,685,241	$ (94,305)
Research and development	2,532,468	2,475,596	56,872
Total operating expenses	7,123,404	7,160,837	(37,433)
Other (income) and expenses			
Unrealized (gain) loss	(23,043)	11,926	(34,969)
Realized and accrued interest income	(449,163)	(536,068)	86,905
Total other income	(472,206)	(524,142)	51,936
Net loss	$ (6,651,198)	$ (6,636,695)	$ (14,503)

General and Administrative Expenses

General and administrative expenses were approximately $4,591,000 and $4,685,000, in the nine months ended September 30, 2024 and 2023, respectively, representing a decrease of $94,000, or approximately 2%. The decrease was primarily due to decreases in legal and professional fees of $211,000, travel related expenses of $105,000 and insurance costs of $95,000, offset by increases in compensation and benefits of $155,000, public company costs of $107,000 and non-cash stock-based compensation expense of $56,000.

Research and Development Expenses

Research and development expenses were approximately $2,532,000 and $2,476,000, in the nine months ended September 30, 2024 and 2023, respectively, representing an increase of $57,000, or approximately 2%. The increase was primarily due to $83,000 of non-cash stock-based compensation expense allocated to research and development expenses. This is offset by a decrease of $22,000 in 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. 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. Amortization of intangible assets was approximately $75,000 and $78,000 in each of the nine month periods ended September 30, 2024 and 2023.

Other (Income) and Expenses:

We earned approximately $23,000 in unrealized gain and $449,000 in realized and accrued interest income in the nine months ended September 30, 2024 and we earned approximately $536,000 in realized and accrued interest income and incurred approximately $12,000 in unrealized loss in the nine months ended September 30, 2023, from our cash and cash equivalents and investments in marketable debt securities.

Liquidity and Capital Resources

We have incurred net losses every year since inception and had an accumulated deficit of approximately $52.9 million at September 30, 2024. We have a limited operating history and have historically funded our operations through debt and equity financings. We incurred net losses of approximately $6.7 million and negative cash flows from operations of $5.6 million for the nine months ended September 30, 2024. At September 30, 2024, we had cash and cash equivalent balances totaling $3.1 million and investments of $7.2 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 are subject to risks common to development stage biopharmaceutical companies including, but not limited to, unanticipated clinical trial costs and the ability to estimate such occurrences, if any, on our cash, liquidity, additional financing requirements, and availability. Accordingly, we may need to raise additional funds sooner than planned. 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.

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 candidate, 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 the warrants issued to investors in 2022, 2023 and 2024 public offerings, 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, 2024, we had approximately $10,307,000 in cash and cash equivalents and investments in marketable securities. The table below presents our cash flows for the nine month periods ended September 30, 2024 and 2023:

	Nine months ended September 30,	
	2024	2023
Net cash used in operating activities	$ (5,620,790)	$ (4,640,784)
Net cash provided (used) in investing activities	1,290,037	(455,684)
Net cash provided by financing activities	5,046,305	5,399,266
Net change in cash and cash equivalents	$ 715,552	$ 302,798

Operating Activities

Net cash used in operating activities was approximately $5,621,000 and $4,641,000 in the nine months ended September 30, 2024 and 2023, respectively. The increase in 2024 was mostly due to decreases in accounts payable and accrued expenses, partially offset by a decrease in net loss adjusted for non-cash income and expenses.

Investing Activities

Net cash provided (used) in investing activities was approximately $1,290,000 and ($456,000) in the nine months ended September 30, 2024 and 2023, respectively, consisting of net proceeds from maturity and purchases of short maturity US Treasury Bills and Notes.

Financing Activities

Net cash provided by financing activities was approximately $5,046,000 for the nine months ended September 30, 2024, consisting of the receipt of approximately $5.5 million in net proceeds from the 2024 Offering partially offset by repayments of amounts due to officers of $450,000. Net cash provided by financing activities was approximately $5,399,000 for the nine months ended September 30, 2023, consisting of the receipt of $5.8 million in net proceeds from the of our public offering in February 2023 (the “2023 Offering”), partially 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 with Therapeutics Inc. for the management of the preclinical and clinical development of QRX003 for Netherton Syndrome. The initial term of the agreement was three years with automatic one year extensions, and 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. An additional work order was entered into in December 2022 for a second QRX003 clinical study at an expected estimated cost of approximately $830,000. For the three and nine months ended September 30, 2024 and 2023, we incurred research and development expenses under these agreements of approximately $275,000 and $926,000, and $155,000 and $1,113,000, respectively.

In November 2021, we entered into a research agreement with Queensland University of Technology ("QUT") for a pre-clinical research program for the development of a product to treat Netherton Syndrome of approximately $250,000. In May 2022, we entered into a second research agreement with QUT for the development of a product to treat Scleroderma of approximately $610,000. Each agreement remains in place until the completion of the research program. For the three and nine months ended September 30, 2024 and 2023, we incurred research and development costs related to these agreements of approximately $0 and $0, and $85,000 and $361,000 respectively.

On June 10, 2024, we entered into a research agreement with The School of Pharmacy at UCC. The scope of the agreement encompasses the development of novel topical formulations of Rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are currently no approved therapies or cures. Under the terms of the agreement, based on the achievement of certain milestones, we will fund up to approximately €567,000 ($608,000) plus VAT over an anticipated 2-1/2 year period to support UCC research program to investigate the development of a number of topical rapamycin formulations for future development as potential treatments for several rare and orphan diseases. Following completion of the research program, we will have the option to advance the clinical development of rapamycin formulations developed by UCC. For the three and nine months ended September 30, 2024 we did not incur any costs related to this agreement.

Critical Accounting Estimates

There have been no material changes to our critical accounting 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, 2023.

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 provide reasonable assurance 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. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation, as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15e under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2024, 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.

Except as set forth below, 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.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our ADSs.

Our ADSs are listed on the Nasdaq Capital Market, which imposes, among other requirements, a minimum bid requirement.

On April 29, 2024, we received a deficiency letter from the Listing Qualifications Department of Nasdaq notifying us that for the preceding 31 consecutive business days (March 14, 2024 through April 26, 2024), our ADSs did not maintain a minimum closing bid price of $1.00 ("Minimum Bid Price Requirement") per ADS as required by Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a compliance period of 180 calendar days, or until October 28, 2024, to regain compliance with Nasdaq Listing Rule 5550(a)(2). On October 16, 2024, the Company submitted a letter to Nasdaq requesting an additional 180-day grace period to regain compliance with the Minimum Bid Price Requirement. On October 29, 2024, the Company received a letter from the Listing Qualifications Department of Nasdaq granting the Company an additional 180 calendar day grace period, or until April 28, 2025, to regain compliance. The Staff's determination in granting the Company the extension was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market with the exception of the Minimum Bid Price Requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse split, if necessary. Compliance may be achieved without further action if the closing bid price of the Company's ADS is at or above $1.00 for a minimum of ten consecutive business days at any time during the second compliance period, in which case Nasdaq will notify the Company if it determines the Company is in compliance and the matter will be closed; however Nasdaq could require the closing bid price to equal or to exceed the $1.00 minimum bid price requirement for more than 10 consecutive business days before determining that the Company complies. If compliance cannot be demonstrated by April 28, 2025, the Staff will provide written notification that the Company's securities will be delisted. At that time, the Company may appeal the Staff's determination to a Hearings Panel.

If we cannot regain compliance with the Minimum Bid Price Requirement or if we otherwise fail to meet any of Nasdaq's listing standards, our ADSs will be subject to delisting. If that were to occur, our ADSs would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our ADSs. This would adversely affect the ability of investors to trade our ADSs and would adversely affect the value of our ADSs. Delisting from Nasdaq would cause us to pursue eligibility for trading of our ADSs on other markets or exchanges, or on an over-the-counter market. In such case, our stockholders' ability to trade or obtain quotations of the market value of our ADSs would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our ADSs, if delisted from the Nasdaq, would be listed on a national securities exchange, a national quotation service or the over-the-counter markets. Delisting from the Nasdaq could also result in negative publicity, adversely affect the market liquidity of our ADSs, decrease securities analysts' coverage of us or diminish investor, supplier and employee confidence.

The delisting of our ADSs from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future, or at all. Such a delisting would likely have a negative effect on the price of our ADSs and would impair your ability to sell or purchase our ADSs when you wish to do so. Further, if our ADSs were to be delisted from Nasdaq, our ADSs would cease to be recognized as a covered security, and we would be subject to additional regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the Nasdaq Minimum Bid Price Requirement would stabilize the market price or improve the liquidity of our ADSs, prevent our ADSs from falling below the Nasdaq minimum bid price required for continued listing again or prevent future non-compliance with other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our ADSs, our ADSs could be delisted.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the third quarter of 2024, none of our directors or executive officers adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as each term is defined in Item 408(a) of Registration S-K).

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).
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 7, 2024

By:/s/ Gordon Dunn

Name: Gordon Dunn
Title: Chief Financial Officer

Exhibit 31.1

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 7, 2024

Exhibit 31.2

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 7, 2024

Exhibit 32.1

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, 2024, 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 result of operations of the Company.

/s/ Dr. Michael Myers
Name: Dr. Michael Myers
Title: Chief Executive Officer
Date: November 7, 2024

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.

Exhibit 32.2

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, 2024, 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 result of operations of the Company.

/s/ Gordon Dunn
Name: Gordon Dunn
Title: Chief Financial Officer
Date: November 7, 2024

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.