
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of November 2022 (No. 2)

Commission File Number 001-37846

QUOIN PHARMACEUTICALS LTD.

(Translation of registrant's name into English)

Azrieli Center, Round Tower, 30th Floor
132 Menachem Begin Blvd
Tel Aviv, 6701101

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

EXPLANATORY NOTE

Unaudited Interim Financial Statements as of, and for the period ended, September 30, 2022, and Related Management's Discussion and Analysis of Financial Condition and Results of Operations

On November 10, 2022, Quoin Pharmaceuticals Ltd. (the "Company") issued unaudited interim financial statements as of, and for the period ended, September 30, 2022, together with the related Management's Discussion and Analysis of Financial Condition and Results of Operations, attached hereto as Exhibits 99.1 and 99.2, respectively, and incorporated by reference herein.

The information in this Form 6-K, including the exhibits hereto, shall be incorporated by reference into the Company's registration statements on Form S-8 (Registration Nos. 333-214817, 333-220015, 333-225003 and 333-232230,) and on Form F-3 (Registration Nos. 333-219614 and 333-229083).

Exhibit

No.

Exhibit

99.1

[Unaudited Interim Financial Statements as of, and for the period ended, September 30, 2022](#)

99.2

[Management's Discussion and Analysis of Financial Condition and Results of Operations as of, and for the period ended, September 30, 2022](#)

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Information formatted in Extensible Business Reporting Language (XBRL): (i) Unaudited Consolidated Balance Sheets, (ii) Unaudited Consolidated Statements of Operations, (iii) Unaudited Consolidated Statements of Shareholders' Deficit, (iv) Unaudited Consolidated Statements of Cash Flows, and (v) Notes to Unaudited Consolidated Financial Statements.

SIGNATURE

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.

Date: November 10, 2022

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

QUOIN PHARMACEUTICALS LTD.

Condensed Consolidated Financial
Statements as of September 30, 2022
and December 31, 2021 and for the
three and nine months ended September 30,
2022 and 2021 (unaudited)

QUOIN PHARMACEUTICALS LTD.

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QUOIN PHARMACEUTICALS LTD.**Consolidated Balance Sheets**

| | September 30, 2022 | December 31, 2021 |
|---|-------------------------------|------------------------------|
| | (Unaudited) | (Audited) |
| ASSETS | | |
| Current assets: | | |
| Cash | \$ 5,249,832 | \$ 7,482,773 |
| Investments | 9,911,200 | — |
| Prepaid expenses | 496,686 | 1,015,474 |
| Total current assets | <u>15,657,718</u> | <u>8,498,247</u> |
| Intangible assets, net | 730,572 | 808,604 |
| Deferred loan costs | 50,000 | 50,000 |
| Total assets | <u>\$ 16,438,290</u> | <u>\$ 9,356,851</u> |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 280,698 | \$ 923,239 |
| Accrued expenses | 1,569,920 | 1,685,409 |
| Accrued license acquisition | — | 250,000 |
| Accrued interest and financing expense | 1,146,251 | 743,840 |
| Due to officers – short term | 600,000 | 600,000 |
| Warrant liability | — | 373,599 |
| Total current liabilities | <u>3,596,869</u> | <u>4,576,087</u> |
| Due to officers – long term | 3,673,733 | 4,123,732 |
| Total liabilities | <u>\$ 7,270,602</u> | <u>\$ 8,699,819</u> |
| Commitments and contingencies | | |
| Shareholders' equity: | | |
| Ordinary shares, no par value per share, 50,000,000,000 ordinary shares authorized – 24,233,024,799 (4,846,605 ADS's) ordinary shares issued and outstanding at September 30, 2022 and 3,354,650,799 (670,930 ADS's) at December 31, 2021 | \$ — | \$ — |
| Treasury Stock, 2,641,693 ordinary shares | (2,932,000) | (2,932,000) |
| Additional paid in capital | 47,615,475 | 31,659,017 |
| Accumulated deficit | (35,515,787) | (28,069,985) |
| Total shareholders' equity | <u>9,167,688</u> | <u>657,032</u> |
| Total liabilities and shareholders' equity | <u>\$ 16,438,290</u> | <u>\$ 9,356,851</u> |

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

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

| | Nine months ended September 30, | | Three months ended September 30, | |
|---|--|-----------------------|---|-----------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses | | | | |
| General and administrative | \$ 5,112,002 | \$ 2,525,366 | \$ 1,582,059 | \$ 1,042,783 |
| Research and development | 2,059,769 | 556,064 | 745,506 | 259,996 |
| Total operating expenses | <u>7,171,771</u> | <u>3,081,430</u> | <u>2,327,565</u> | <u>1,302,779</u> |
| Other (income) and expenses | | | | |
| Forgiveness of accounts payable | (416,000) | — | — | — |
| Fair value adjustment to convertible notes payable | — | 1,250,000 | — | — |
| Change in fair value of warrant liability | (77,237) | 4,522,844 | — | (146,808) |
| Financing expense | — | 275,000 | — | — |
| Unrealized loss | 3,053 | — | 3,053 | — |
| Interest income | (15,132) | — | (15,132) | — |
| Interest and financing expense | 714,081 | 516,276 | 714,081 | 248,165 |
| Total other expense | <u>208,765</u> | <u>6,564,120</u> | <u>702,002</u> | <u>101,357</u> |
| Net loss | <u>\$ (7,380,536)</u> | <u>\$ (9,645,550)</u> | <u>\$ (3,029,567)</u> | <u>\$ (1,404,136)</u> |
| Deemed dividend on warrant modification | (65,266) | — | (65,266) | — |
| Net loss attributable to shareholders | <u>\$ (7,445,802)</u> | <u>\$ (9,645,550)</u> | <u>\$ (3,094,833)</u> | <u>\$ (1,404,136)</u> |
| Loss per ADS | | | | |
| Loss per ADS | | | | |
| Basic | \$ (4.65) | \$ (40.14) | \$ (0.94) | \$ (5.84) |
| Fully-diluted | \$ (4.65) | \$ (40.14) | \$ (0.94) | \$ (5.84) |
| Weighted average number of ADS's outstanding | | | | |
| Basic | 1,601,396 | 240,292 | 3,291,806 | 240,292 |
| Fully-diluted | 1,601,396 | 240,292 | 3,291,806 | 240,292 |

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

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Shareholders' Equity (Unaudited)

Three and Nine months ended September 30, 2021

| | Ordinary Shares | ADS's | No Par Value | Treasury Stock | Additional Paid in Capital | Accumulated Deficit | Total |
|--------------------------------------|--------------------|---------|--------------------|-------------------|----------------------------------|------------------------|-----------------|
| Balance at December 31, 2020 | 1,201,460,800 | 240,292 | — | \$ — | \$ 100 | \$ (6,607,397) | \$ (6,607,297) |
| Net loss | — | — | — | — | — | (3,903,871) | (3,903,871) |
| Balance at March 31, 2021 | 1,201,460,800 | 240,292 | — | \$ — | \$ 100 | \$ (10,511,268) | \$ (10,511,168) |
| Net loss | — | — | — | — | — | (4,337,543) | (4,337,543) |
| Balance at June 30, 2021 | 1,201,460,800 | 240,292 | — | \$ — | \$ 100 | \$ (14,848,811) | \$ (14,848,711) |
| Net loss | — | — | — | — | — | (1,404,136) | (1,404,136) |
| Balance at September 30, 2021 | 1,201,460,800 | 240,292 | — | \$ — | \$ 100 | \$ (16,252,947) | \$ (16,252,847) |

Three and Nine months ended September 30, 2022

| | Ordinary Shares | ADS's | No Par Value | Treasury Stock | Additional Paid in Capital | Accumulated Deficit | Total |
|---|--------------------|-----------|--------------------|-------------------|----------------------------------|------------------------|----------------|
| Balance at December 31, 2021 | 3,354,650,799 | 670,930 | — | \$ (2,932,000) | \$ 31,659,017 | \$ (28,069,985) | \$ 657,032 |
| Net loss | — | — | — | — | — | (1,682,802) | (1,682,802) |
| Cashless exercise of warrants | 3,200 | 1 | — | — | — | — | — |
| Reclassification of warrant liability upon issuance of Exchange warrant | — | — | — | — | 296,362 | — | 296,362 |
| Balance at March 31, 2022 | 3,354,653,999 | 670,931 | — | \$ (2,932,000) | \$ 31,955,379 | \$ (29,752,787) | \$ (729,408) |
| Net loss | — | — | — | — | — | (2,668,167) | (2,668,167) |
| Stock based compensation | — | — | — | — | 229,441 | — | 229,441 |
| Cashless exercise of warrants | 1,710,500,800 | 342,100 | — | — | — | — | — |
| Balance at June 30, 2022 | 5,065,154,799 | 1,013,031 | — | \$ (2,932,000) | \$ 32,184,820 | \$ (32,420,954) | \$ (3,168,134) |
| Net loss | — | — | — | — | — | (3,029,567) | (3,029,567) |
| Stock based compensation | — | — | — | — | 267,283 | — | 267,283 |
| Issuance of ADS and Pre-Funded Warrants, net | 16,800,000,000 | 3,360,000 | — | — | 14,904,569 | — | 14,904,569 |
| Cashless exercise of warrants | 2,146,935,000 | 429,387 | — | — | — | — | — |
| Settlement of accrued expenses | 220,935,000 | 44,187 | — | — | 193,537 | — | 193,537 |
| Deemed dividend on warrant modification | — | — | — | — | 65,266 | (65,266) | — |
| Balance at September 30, 2022 | 24,233,024,799 | 4,846,605 | — | \$ (2,932,000) | \$ 47,615,475 | \$ (35,515,787) | \$ 9,167,688 |

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

QUOIN PHARMACEUTICALS LTD.

Quoin Pharmaceuticals Ltd

Consolidated Statements of Cash Flows (unaudited)

Nine months ended September 30,

| | 2022 | 2021 |
|--|-----------------|----------------|
| Cash flows provided by (used in) operating activities | | |
| Net loss | \$ (7,380,536) | \$ (9,645,550) |
| Fair value adjustment to convertible notes payable | — | 1,250,000 |
| Change in fair value of warrant liability | (77,237) | 4,522,844 |
| Stock based compensation | 496,724 | — |
| Forgiveness of trade payable | (416,000) | — |
| Financing expense | — | 275,000 |
| Amortization of intangibles | 78,032 | 78,032 |
| Increase in accrued interest and financing expense | 402,411 | 516,276 |
| Unrealized gain on investments | (12,079) | — |
| Changes in assets and liabilities: | | |
| Increase (decrease) in accounts payable and accrued expenses | (148,493) | 462,117 |
| Decrease in prepaid expenses | 518,788 | — |
| Net cash used in operating activities | \$ (6,538,390) | \$ (2,541,281) |
| Cash flows used in investing activities | | |
| Purchase of investments | (9,899,121) | — |
| Payment for license acquisition | (250,000) | (375,000) |
| Net cash used in investing activities | \$ (10,149,121) | \$ (375,000) |
| Cash flows provided by financing activities: | | |
| Payments of offering costs | — | (164,578) |
| Payments of deferred loan costs | — | (50,000) |
| Increase in due to officers | — | 139,285 |
| Payment of amounts due to officers | (449,999) | (154,466) |
| Proceeds from issuance of “Bridge Notes”, net | — | 3,475,000 |
| Proceeds from sale of equity securities, net | 14,904,569 | — |
| Net cash provided by financing activities | \$ 14,454,570 | \$ 3,245,241 |
| Net change in cash | (2,232,941) | 328,960 |
| Cash - beginning of period | 7,482,773 | 323,832 |
| Cash - end of period | \$ 5,249,832 | \$ 652,792 |
| Supplemental information - Non cash items: | | |
| Reclassification of warrant liability to equity upon issuance of “Exchange warrants” | \$ 296,362 | \$ — |
| Deemed dividend on warrant modification | \$ 65,266 | \$ — |
| Offering expenses associated with warrant modification | \$ 491,601 | \$ — |
| Settlement of accrued expenses | \$ 193,537 | \$ — |

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

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2022 and 2021

NOTE 1 – ORGANIZATION AND BUSINESS

Quoin Pharmaceuticals Ltd. (“Quoin Ltd.,” or the “Company”), formerly known as Collect Biotechnology Ltd. (“Collect”), is the holding company for Quoin Pharmaceuticals, Inc., a Delaware corporation (“Quoin Inc.”). On October 28, 2021, Collect completed the business combination with Quoin Inc., in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021 (the “Merger Agreement”), by and among Collect, Quoin Inc. and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Collect (“Merger Sub”), pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Collect (the “Merger”). Immediately after completion of the Merger, Collect changed its name to “Quoin Pharmaceuticals Ltd.” Because Quoin Inc. was the accounting acquirer, its historical financial statements became the Company’s historical financial statements and such assets and liabilities continued to be recorded at their historical carrying values. The impact of the recapitalization has been retroactively applied to all periods presented.

Effective August 1, 2022, the ratio of American Depositary Shares (“ADSs”) evidencing ordinary shares changed from 1 ADS representing four hundred (400) ordinary shares to 1 ADS representing five thousand (5,000) ordinary shares, which resulted in a one for 12.5 reverse split of the issued and outstanding ADSs (the “Ratio Change”). All ADSs and related option and warrant information presented in these financial statements and accompanying footnotes has been retroactively adjusted to reflect the reduced number of ADSs resulting from the Ratio Change.

Quoin Inc. was incorporated in Delaware on March 5, 2018. Quoin Inc. is a specialty pharmaceutical company focused on developing and commercializing therapeutic products that treat rare and orphan diseases. The first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome (NS). QRX003, is currently in clinical development in the United States under an open IND application with the U.S. Food and Drug Administration (“FDA”). The ongoing study is a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in NS patients. The Company commenced opening of clinical sites in July 2022. In addition, the Company intends to pursue the clinical development of QRX003 in additional rare dermatological diseases, including Peeling Skin Syndrome, SAM Syndrome and Palmoplantar Keratoderma. To date, no products have been commercialized and revenue has not been generated.

NOTE 2 - LIQUIDITY RISKS AND OTHER UNCERTAINTIES

The Company has incurred net losses every year since inception and has an accumulated deficit of approximately \$35.5 million at September 30, 2022. The Company has historically funded its operations through debt and equity financings. On August 9, 2022, the Company completed an offering (the “Offering”) of ordinary shares represented by ADSs and pre-funded warrants to purchase ordinary shares represented by ADSs with each ADS and pre-funded warrant accompanied by an ordinary warrant, for aggregate gross proceeds of \$16.8 million, resulting in net proceeds of approximately \$14.9 million (see Note 14). As a result of the completion of the Offering, the Company believes that it has sufficient resources 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.

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2022 and 2021

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 single-source suppliers which include the supplier of the active pharmaceutical ingredient (API), as well as the contract manufacturer of the drug substance for the expected clinical development.

Coronavirus ("COVID-19") created a global pandemic, which commenced in 2020. The Company's operations, to date, have not been dramatically affected by COVID-19. However, the extent of any future impact on the Company's operational and financial performance will depend on the possibility of a resurgence and resulting severity with respect to the Company's access to API and drug product for clinical testing, as well as the Company's ability to safely and efficiently conduct planned clinical trials.

Nasdaq Listing

On April 22, 2022, the Company received a letter from the Listing Qualifications staff (the "Staff") of The Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that it is no longer in compliance with Nasdaq Listing Rule 5550(b)(1) requiring minimum stockholders' equity of at least \$2.5 million for continued listing on The Nasdaq Capital Market. Based on the Company's Form 6-K, dated August 10, 2022, the Staff has determined that the Company complies with the minimum stockholder's equity requirement, and the Company evidences continued compliance with these financial statements for the quarter ended September 30, 2022.

On June 10, 2022, the Company received a letter from the Staff notifying the Company that the closing bid price per ADS was below the required minimum of \$1.00 for a period of 30 consecutive business days and that the Company did not meet the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2). Since then, the Staff has determined that the closing bid price of the Company's ADSs has been at \$1.00 per ADS or greater, and the Company has regained compliance with the minimum bid price requirement.

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

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("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, reflecting the operations of Quoin Inc. since inception and include the accounts of Quoin Ltd. since the date of the Merger. In the opinion of management, such statements

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2022 and 2021

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, 2022 and for the three and nine months then ended. The results of operations for the three and nine months ended September 30, 2022 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, 2021 and for the year then ended which are included in the Company's Annual Report on Form 20-F, filed with the SEC on April 14, 2022, as updated in the Company's Form 6-K furnished to the SEC on August 11, 2022. The Company operates in one segment.

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 selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. In addition, other factors may affect estimates, 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.

Reclassification:

Certain 2021 amounts were reclassified to conform to the current year presentation. The amount reclassified included the short term portion from long term portion due to officers.

Cash and cash equivalents:

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

Warrants:

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

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

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2022 and 2021

Investments:

Investments as of September 30, 2022 consist of U.S. Treasury Bills, which are classified as trading securities, totaling \$9.9 million. 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 mature within the subsequent six months from the date of purchase. As of September 30, 2022, the carrying value of the Company's U.S. Treasury Bills 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 the Company considers 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 the Company's 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, 2022 and 2021, 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 expense in future periods as the related services are rendered.

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
September 30, 2022 and 2021

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 to employees, non-employees and directors 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.

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

Fair value of financial instruments:

The Company considers its cash, investments, accounts payable, and accrued expenses to meet the definition of financial instruments. The carrying amounts of the remaining 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.

Earnings (loss) per share:

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

For the three and nine months ended September 30, 2022, the number of shares excluded from the diluted net earnings (loss) per share included outstanding options and warrants to purchase 309,114 ADSs and 3,368,820 ADSs, respectively. For the three and nine months ended September 30, 2021, the 5,183 ADS's issuable upon the conversion of both the Convertible Notes Payable (as defined below) and the 40,247 ADSs issuable upon conversion of the Bridge Notes (as defined below) as well as the warrants issued in connection with both of these convertible instruments are not included in the denominator since their inclusion would be anti-dilutive.

NOTE 4 – CONVERTIBLE NOTES AND WARRANTS

On October 2, 2020, Quoin Inc. commenced an offering of promissory notes (the "2020 Notes" or "Convertible Notes Payable") and warrants. Based upon the terms agreed to in March 2021 in the Primary Financing (see Note 5), the 2020 Notes were mandatorily convertible into 5,183 ADSs in the Primary Financing, subject to adjustment.

The holders of the 2020 Notes (the "2020 Noteholders") also received warrants exercisable at any time after the issuance date for 29,388 ADSs at an initial exercise price of \$49.75 per ADS. At the time of grant, the Company determined that these warrants met the criteria to be recorded as a liability instrument. Effective March 13, 2022, each holder agreed to exchange these warrants for warrants on the substantially same terms as the Investor Exchange Warrants (See Note 5) with the same number of shares issuable upon the exercise of an Exchange Warrant as upon the exercise of the original warrant and the same exercise price with a contractual term of 5 years (the "Noteholder Warrants").

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The Noteholder Warrants have been determined to have equity classification. The change in the fair value of the warrants through the exchange date was included in other income (expense) in the accompanying statement of operations, and then reclassified from liability to additional paid in capital. On July 14, 2022, as a result of the Altium Agreement (see Note 5), the exercise price of the Noteholder Warrants was reduced to \$0 and the 2020 Noteholders subsequently exercised all of their warrants. The change in the exercise price of the Noteholder Warrants resulted in a deemed dividend of approximately \$65,000 recorded during the three and nine months ended September 30, 2022.

The ADSs issued to the 2020 Noteholders did not account for accrued interest which was estimated to be approximately \$744,000 at December 31, 2021, and included in accrued interest and financing expense in the accompanying consolidated balance sheet. Approximately \$312,000 was paid to two of the five 2020 Noteholders during the nine months ended September 30, 2022. Based on the terms of the cash settlement with these two 2020 Noteholders, the Company's estimate of the liability to the remaining three 2020 Noteholders was increased to \$1,146,000 as of September 30, 2022. The Company expects to settle the remaining liability in 2022 or early 2023.

NOTE 5 – BRIDGE FINANCING AND PRIMARY FINANCING

Bridge Financing

In connection with the Merger Agreement and the Securities Purchase Agreement (described below), Quoin Inc. entered into a "Bridge Purchase Agreement" on March 24, 2021 with the Investor, pursuant to which the Investor agreed to purchase notes (the "Bridge Notes") in the aggregate principal amount of up to \$5,000,000 in exchange for an aggregate purchase price of up to \$3,800,000 together with warrants. The Bridge Notes were purchased in three closings: (i) the first purchase of \$2,000,000 on March 25, 2021 (proceeds of \$1,500,000); (ii) the second purchase of \$1,700,000 in April 2021 (proceeds of \$1,250,000); and (iii) a third purchase of \$1,300,000 in May 2021 (proceeds of \$1,000,000).

The Bridge Notes were issued with a 25% original issue discount, at an interest rate of 15% per annum and had a maturity date of the earliest to occur of: (i) December 25, 2021, (ii) the date on which Quoin Inc.'s equity is registered under the Exchange Act or is exchanged for equity so registered or (iii) immediately prior to the closing of the Merger.

The Investor and Quoin Inc. agreed that if the Primary Financing is consummated, the Investor may, at its election, offset the purchase price related to the Primary Financing, by an amount equal to the outstanding amount under this Bridge Note, and, upon such set-off, the portion of this Bridge Note shall be deemed to have been paid in its entirety and all obligations thereunder shall be deemed to be fully satisfied.

The Bridge Notes were offset against the purchase price under the Securities Purchase Agreement related to the Primary Financing and converted into 100,618 ADSs upon the closing of the Primary Financing in October 2021. Interest expense, at the stated interest rate, recognized in the three and nine months ended September 30, 2022 and 2021 was \$0 and \$187,000 and \$0 and \$334,000, respectively.

Bridge Warrants

Upon the funding of each Bridge Note tranches described above, the Investor received warrants (the "Bridge Warrants") to purchase a number of shares of Quoin Inc.'s common stock equal to the aggregate principal amount of the Bridge Notes. The Bridge Warrants had a term of five years from the date all of the shares underlying the Bridge Warrants are freely tradable. Quoin Inc. issued a total of 99,074 Bridge Warrants in the year ended December 31, 2021.

Following the closing date of the Merger, on each of the tenth trading day, the forty-fifth day, the ninetieth day, and the one hundred thirty-fifth day thereafter (each, a "Reset Date"), if the initial exercise price of the Bridge Warrants is greater than the arithmetic average of 85% of the three lowest weighted average prices of the post-Merger ordinary shares of the combined company during the ten trading day period immediately preceding the applicable Reset Date (the "Reset Price"), the exercise price of the Bridge Warrants will be reset

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to the Reset Price. Furthermore, the number of shares underlying Bridge Warrants will be adjusted such that the aggregate number of shares of common stock of Quoin Inc. issuable to the Investor reflects the Reset Price instead of the initial exercise price. Adjustments to the exercise price and number of warrant shares are available to the Investor until the second anniversary of the Registration Date, as defined in the Bridge Warrants. Upon the occurrence of a Fundamental transaction, as defined in the Bridge Warrants, the warrant holder has the right to elect a cash settlement for the value of the warrant based on the Black Scholes options pricing model.

The Company determined that the warrants met the criteria to be recorded as a liability instrument through the exchange date on the closing of the Primary Financing. The fair value of warrants was determined by a MonteCarlo simulation model to be approximately \$1.6 million at the date of issuance of the 39,630 warrants in connection with the first closing and \$2.2 million at the date of issuance of the 59,444 warrants in connection with the second and third closing of the Bridge Notes.

Upon the closing of the Primary Financing, the Bridge Warrants were exchanged for warrants to purchase 99,074 ADSs at a fixed per share exercise price of \$49.75 (“Investor Exchange Warrants”), as amended, which replaced the reset provisions and modified the fundamental transaction requirements of the Bridge Warrants. On July 14, 2022, the Company and the Investor entered into an agreement amending the terms of the Investor Exchange Warrants, see below agreements with Altium Growth Fund, LP and Warrant Exercises.

Primary Financing

On October 28, 2021, the Company completed the private placement transaction with the Investor for an aggregate purchase price of approximately \$17.0 million (comprised of the set off of approximately \$5.0 million of Bridge Notes, and approximately \$12.0 million in cash) (the “Primary Financing”), which resulted in the net proceeds of approximately \$10.1 million. The Company issued 342,100 ADSs to the Investor.

Quoin Ltd. also was required to issue to the Investor, effective as of March 13, 2022, the 136th day following the consummation of the Merger (i) Series A Warrant to purchase 342,100 ADSs (the “Series A Warrant”) (ii) Series B Warrant to purchase 342,100 ADSs (the “Series B Warrant”) and (iii) Series C Warrant to purchase 191,174 ADSs (“Series C Warrant” and, together with the Series A Warrant and Series B Warrant, the “Investor Warrants”). The exercise price for the Investor Warrants is \$49.75 per ADS, with Series A Warrant having a five-year maturity, and Series B Warrant and Series C Warrant having a two-year maturity.

The Company had the right to require the mandatory exercise of the Series C Warrant, subject to an effective registration statement being in place for the resale of the shares underlying such warrants and the satisfaction of equity market conditions, as defined in the Series C Warrant. On April 22, 2022, a registration statement for the resale of the shares underlying Investor Warrants was declared effective by the Securities and Exchange Commission. In the period from April 22, 2022 to June 30, 2022, the Investor exercised the Series B Warrant in full pursuant to the alternate cashless exercise rights of such warrant, which gives the Investor the sole option as elected by the Investor to receive 1.0 ADS for each warrant ADS underlying such warrant, resulting in the issuance of a total of 342,100 ADSs to the Investor. The market related conditions to require the mandatory exercise of the Series C Warrant were not met during the period up to July 14, 2022.

Agreements with Altium Growth Fund, LP and Warrant Exercises

On July 14, 2022, the Company, Quoin Inc. and Altium entered into an agreement (the “Altium Agreement”), pursuant to which the parties agreed to, among other things, (i) amend certain terms of the Series A Warrant and Investor Exchange Warrants previously issued to Altium to reduce the exercise price to \$0.00 per ADS with respect to a total of 399,999 ADSs, (ii) cancel the Series C Warrant and the remaining portion of the Series A Warrant previously issued to Altium, and (iii) terminate the Purchase Agreements, pursuant to which the warrants were previously issued to Altium. The incremental fair value of the modified warrants was approximately \$491,000, which was accounted for as an offering expense as part of the Offering (see Note 14) as the modification was done in contemplation of the Offering. As of August 2, 2022, Altium exercised all of its outstanding warrants to purchase ADSs at \$0.00 per ADS exercise price and the Company issued a total of 399,999 ADSs to Altium.

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The exercise price of the Noteholder Warrants was also reduced to \$0.00 as of July 14, 2022 as a result of the Altium Agreement. The change in the exercise price of the Noteholder Warrants resulted in a deemed dividend of approximately \$65,000 recorded during the three and nine months ended September 30, 2022. From July to September 2022, the 2020 Noteholders exercised all their warrants to purchase ADSs at \$0.00 per ADS exercise price, and the Company issued a total of 29,388 ADSs to such noteholders.

NOTE 6 - 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.

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 tables present the Company's assets and liabilities that are measured at fair value on a recurring basis by fair value hierarchy at December 31, 2021 and September 30, 2022:

| December 31, 2021 | Level 1 | Level 2 | Level 3 | Total |
|-------------------------------|----------------|----------------|----------------|--------------|
| 2020 Notes warrants | \$ — | \$ — | \$ 373,599 | \$ 373,599 |
| Total Warrant Liability | \$ — | \$ — | \$ 373,599 | \$ 373,599 |
| September 30, 2022 | Level 1 | Level 2 | Level 3 | Total |
| US Treasury Bills | \$ 9,911,200 | \$ — | \$ — | \$ 9,911,200 |
| Total US Treasury Bills Asset | \$ 9,911,200 | \$ — | \$ — | \$ 9,911,200 |

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The following shows the movement of the warrant liability balance during 2021 and the nine months ended September 30, 2022.

| | Bridge Financing Warrants | 2020 Note Warrants |
|---|---------------------------------|-----------------------|
| Beginning Balance January 1, 2021 | \$ — | \$ — |
| Warrant value at issuance (recorded as warrant liability expense) | 3,783,079 | 894,113 |
| Change in fair value of warrants | 8,627,651 | (520,514) |
| Reclassification of warrant liability to an equity instrument | (12,410,730) | — |
| Ending balance December 31, 2021 | <u>\$ —</u> | <u>\$ 373,599</u> |
| Change in fair value of warrants | — | (77,237) |
| Reclassification of warrant liability to an equity instrument | — | (296,362) |
| Ending balance September 30, 2022 | <u>\$ —</u> | <u>\$ —</u> |

The Investor Exchange Warrant issued to the Investor on the Merger date was determined to be an equity-classified instrument, and accordingly the warrant liability on such date of approximately \$12.4 million was reclassified to additional paid in capital. The Exchange Warrants issued to the 2020 Noteholders effective as of March 13, 2022 were determined to be an equity-classified instrument, and accordingly the warrant liability on such date of \$296,362 was reclassified to additional paid in capital on that date.

NOTE 7 – 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 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 1,826,991,617 ordinary shares, represented by 365,398 ADSs as of September 30, 2022. Under the Amended Plan, the Company may grant options to its directors, officers, employees, consultants, advisers and service providers. The Amended Plan was approved by the shareholders at the Company’s Annual General Meeting of Shareholders held on April 12, 2022.

On April 12, 2022, the Company granted options to acquire 1,535,714,000 ordinary shares, represented by 307,142 ADSs, at \$17.50 per share to management, directors and employees and 58,255 shares remained available for issuance. Such options vest over a three or four year period. There were no grants during the three months ended September 30, 2022.

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, 2021 | 5,744 | \$ 636.74 | 0.33 |
| Granted | 307,142 | \$ 17.50 | |
| Forfeited/Cancelled | (3,772) | \$ 792.05 | |
| Outstanding at September 30, 2022 | 309,114 | \$ 19.56 | 9.53 |
| Exercisable options at September 30, 2022 | 1,972 | \$ 339.80 | 0.08 |

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The intrinsic value of outstanding options at September 30, 2022 was \$0.

Stock options granted during the nine months ended September 30, 2022 were valued using the Black-Scholes option-pricing model with the following weighted average assumptions:

| | <u>September 30,</u> <u>2022</u> |
|-----------------------------------|-------------------------------------|
| Expected volatility | 106.0 % |
| Risk-free interest rate | 2.7 % |
| Expected dividend yield | 0.0 % |
| Expected life of options in years | 6.9 |
| Exercise Price | \$ 17.50 |
| Fair value of ADS | \$ 15.38 |
| Estimated fair value of option | \$ 12.92 |

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

At September 30, 2022, the total unrecognized compensation expense related to non-vested options was approximately \$3,472,529 and is expected to be recognized over the remaining weighted average service period of approximately 3.32 years.

NOTE 8 – PREPAID EXPENSES

Prepaid expenses are as follows:

| | <u>September 30,</u> <u>2022</u> | <u>December 31,</u> <u>2021</u> |
|-------------------|-------------------------------------|------------------------------------|
| Prepaid R&D costs | \$ 414,061 | \$ 329,033 |
| Prepaid insurance | 74,017 | 684,191 |
| Prepaid expense | 8,608 | 2,250 |
| Total | <u>\$ 496,686</u> | <u>\$ 1,015,474</u> |

NOTE 9 - ACCRUED EXPENSES

Accrued expenses are as follows:

| | <u>September 30,</u> <u>2022</u> | <u>December 31,</u> <u>2021</u> |
|---------------------------------------|-------------------------------------|------------------------------------|
| Research contract expenses (note 13) | \$ 381,862 | \$ 193,537 |
| Payroll (note 12) | 759,833 | 557,937 |
| Payroll taxes (note 12) | 153,552 | 199,582 |
| Investor Relation firm fees (note 13) | 98,000 | 584,000 |
| Professional fees | 115,451 | 144,377 |
| Other Expenses | 61,222 | 5,976 |
| Total | <u>\$ 1,569,920</u> | <u>\$ 1,685,409</u> |

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NOTE 10 – IN-LICENSED TECHNOLOGY**Polytherapeutics:**

On March 24, 2018, Quoin Inc. entered into a securities purchase agreement (the “Acquisition Agreement”), in which it agreed to acquire all of the equity interests in Polytherapeutics, Inc. (the “Seller” or “Polytherapeutics”) for \$40,833 and future royalties provided Quoin Inc. commercializes products using the technology developed by the Seller. The terms of any royalty payments to the Seller are 4.0% of the net revenue of royalty products, as defined in the Acquisition Agreement during the ten (10) year period commencing from the date of first sale of a royalty product. If a generic product is introduced by a third party to the market, during the royalty period, the royalty fees shall be reduced from 4% to 2%. If, during the royalty period, two or more generic products are introduced, the royalty fees shall be reduced from 2% to 0%.

Quoin Inc. also entered into a research and consulting agreement which committed Quoin Inc. to pay the Seller for additional research and development consulting services (See Notes 13 and 15).

Skinvisible:

On October 17, 2019, Quoin Inc. entered into an exclusive license agreement with Skinvisible Inc. (“Skinvisible”), pursuant to which Skinvisible granted a license to use certain patented technology for the development of products for commercial sale in the orphan rare skin disease field, and for the use of a proprietary polymer deliver system technology. This technology is currently being used in the development of QRX003. In exchange for the license, Quoin Inc. agreed to pay Skinvisible \$1,000,000, as well as development and sales milestone payments and a single digit royalty on all net sales, as defined.

The development milestones originally required payments upon achieving development milestones for the first Rare Skin Disease drug product developed using the licensed technology and the first two Ketamine products, as defined. On January 27, 2021, Quoin Inc. and Skinvisible entered into an amendment which modified the clinical milestone payment requirements such that \$750,000 would be payable to Skinvisible upon achievement of specified clinical milestones, and \$21.75 million upon regulatory approval in the U.S. and EU respectively.

The license fee was originally due in two equal installments of \$500,000 payable no later than December 31, 2019 and June 30, 2020, which were not paid. The agreement was subsequently amended several times to extend the payment due dates. On June 21, 2021, the parties entered into the most recent amendment which modified the payment terms and eliminated the \$750,000 clinical milestone payments, reduced the milestone payment upon regulatory approval of the product containing the Skinvisible technology in either the U.S. or E.U., whichever happens first to a total of \$5,000,000.

NOTE 11 - INTANGIBLE ASSETS

Intangible assets are as follows:

| | September 30, 2022 | December 31, 2021 |
|--|-----------------------|----------------------|
| Acquired technology – Polytherapeutics | \$ 40,433 | \$ 40,433 |
| Technology license – Skinvisible | 1,000,000 | 1,000,000 |
| Total cost | 1,040,433 | 1,040,433 |
| Accumulated amortization | (309,861) | (231,829) |
| Net book value | \$ 730,572 | \$ 808,604 |

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The Company recorded amortization expense of approximately \$78,000 for the nine months ended September 30, 2022 and 2021. The Company recorded amortization expense of approximately \$26,000 for the three months ended September 30, 2022 and 2021. The annual amortization expense expected to be recorded for existing intangible assets for the years 2022 through 2026, and thereafter, is approximately \$26,000, \$104,000, \$104,000, \$104,000, \$104,000, and \$288,000, respectively.

NOTE 12 - RELATED PARTY TRANSACTIONS**Employment Agreements and Due to Officers/Founders:**

In March 2018, Quoin Inc. executed employment agreements with both of its officers who are also co-founders of Quoin Inc. The employment agreements for both officers/founders allow for a onetime expense that covers the salaries they would have otherwise been paid for efforts they undertook in the periods since inception. The salaries and benefits allowances provided for under the employment agreements began to accrue as the services were being provided by the officers/founders and are included in Due to Officers on the accompanying balance sheet.

Since the Merger closing, the Company is approved to pay and has been repaying amounts due to officers/founders at a rate of \$25,000 each per month.

Amounts due to officers at September 30, 2022 and December 31, 2021 consisted of the following:

| | September 30, 2022 | December 31, 2021 |
|--|-------------------------------|------------------------------|
| Salaries and other compensation | \$ 4,108,500 | \$ 4,108,500 |
| Invoices paid on behalf of the Company | 165,233 | 615,232 |
| Total | <u>4,273,733</u> | <u>4,723,732</u> |
| Less: Short-term portion | (600,000) | (600,000) |
| Long-term portion | <u>\$ 3,673,733</u> | <u>\$ 4,123,732</u> |

Expenses:

Research and development expense to a related party, incurred in the three and nine months ended September 30, 2022 and 2021 was approximately \$12,000 and \$0 and \$36,000 and \$0, respectively.

For the nine months ended September 30, 2021, the Company paid a consulting fee of \$100,000 to a board member.

NOTE 13 – RESEARCH, CONSULTING AND OTHER COMMITMENTS**Research and consulting agreement:**

Quoin Inc. entered into a research and consulting agreement which commits it to pay the former owner of Polytherapeutics (the “Consultant” or “Seller”) to transfer the technical know-how of Polytherapeutics with respect to (i) good manufacturing practices (“GMP”), clinical and commercial manufacturing of the Company’s PolyDur polymer and (ii) formulation development of products utilizing the Company’s PharmaDur polymer. The agreement required monthly consulting payments of \$20,833 beginning on July 31, 2018 and ending February 28, 2021 (the “Post-Closing Period”) for a total of \$666,667 over the consulting period. Pursuant to an amendment, the Post-Closing Period was revised to terminate on December 31, 2020.

Through September 30, 2022 and the financial statement issuance date, the Company has not made any payments, the Consultant has not performed any services and the Company has not incurred or accrued for any expenses. See Note 15 for Consultant’s notification of breach of contract.

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Other research consulting agreements:

Quoin Inc. entered into three consulting agreements with Axella Research LLC (“Axella”) to provide regulatory and pre-clinical/clinical services to the Company with respect to QRX003 and QRX004. The combined fees of the three agreements are approximately \$270,000, payable as milestones were met. The Company incurred accrued expenses of approximately \$194,000 in relation to Axella consulting agreements as of December 31, 2021. In September 2022 the Company issued 44,187 ADS’s to one of Axella’s principals to settle the outstanding liability in full. The Company incurred no research and development expenses in connection with these agreements, for both of the three and nine months ended September 30, 2022 and 2021, as no services were provided.

In November 2020, Quoin Inc. entered into a Master Service Agreement for an initial term of three years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. The latest work order was entered into in June 2022 for a clinical study at an expected estimated cost of approximately \$4.4 million through the second quarter of 2024. For the three and nine months ended September 30, 2022 and 2021, the Company incurred a research and development expense under this agreement of approximately \$423,000 and \$904,000, and \$88,000 and \$232,000 respectively.

In November 2021, the Company entered into a commitment with Queensland University of Technology for research related services associated with Netherton Syndrome of approximately \$250,000 for an expected period of eighteen months. For the three and nine months ended September 30, 2022, the Company incurred research and development costs related to this agreement of approximately \$35,000 and \$112,000, respectively.

In May 2022, the Company entered into a commitment with Queensland University of Technology for research related services associated with Scleroderma of approximately \$610,000 for an expected period of eighteen months. The Company incurred research and development expenses of approximately \$138,000 for the three and nine months ended September 30, 2022. As of September 30, 2022, the Company recorded prepaid research and development costs related to this agreement of approximately \$85,000.

Consulting agreement:

Quoin Inc. entered into a consulting agreement with an Investor Relations (IR) firm, which provides for a monthly fee of \$14,000. The agreement had an automatic annual renewal clause and has been in effect since November 2017. The Company owed the IR firm \$584,000 as of December 31, 2021, which was included in accrued expenses in the accompanying balance sheet. In March 2022, the Company entered into a settlement agreement with the IR firm reducing the liability to \$168,000, and recognized \$416,000 as other income in the accompanying consolidated statement of operations. As of September 30, 2022, the balance of this liability is \$98,000. For the three and nine months ended September 30, 2021, the Company incurred expenses of \$42,000 and \$42,000, respectively. For the three and nine months ended September 30, 2022, the Company incurred expenses of \$42,000 and \$70,000, respectively.

Performance milestones and royalties:

See Note 10 for asset and in-licensed technology commitments.

Merger agreement commitment:

In consideration for the Share Transfer disclosed in Note 1, the pre-closing Collect shareholders received a contingent value right (“CVR”) entitling the holders to earnouts during the Payment Period (as such term is defined in the Share Transfer Agreement), comprised mainly of payments upon sale, milestone payments, license fees and exit fees realized by EnCellX. In order to secure such right, shares constituting 40% of EnCellX share capital are held in escrow.

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In connection with the Share Transfer, Collect entered into a CVR Agreement with Mr. Eyal Leibovitz, in the capacity of Representative for the holders of CVRs, and Computershare Trust Company, N.A., a federally chartered trust company (the “Rights Agent”). Under the terms of the CVR Agreement, the holders of the Collect ADSs immediately prior to the Merger had the right to receive, through their ownership of CVRs, their pro-rata share of the net Share Transfer consideration, making such holders of CVRs the indirect beneficiaries of the net payments under the Share Transfer. CVRs were recorded in a register administered by the Rights Agent but were not certificated. Since the Company will not receive any net proceeds from the CVR’s, there is no asset or liability recorded in the consolidated financial statements.

NOTE 14 – SHAREHOLDERS’ EQUITY

The Company held a Special General Meeting on February 28, 2022, at which the Company’s shareholders adopted the Amended and Restated Articles of Association of the Company. The Company held its Annual General Meeting on April 12, 2022, at which the Company’s shareholders approved an increase to the authorized share capital to 50,000,000,000 ordinary shares from 12,500,000,000, no par value. The Company held a further Annual General Meeting on November 3, 2022, at which the Company’s shareholders approved an increase to the authorized share capital to 500,000,000,000 ordinary shares from 50,000,000,000, no par value (see Note 17). These ordinary shares are not redeemable and do not have any preemptive rights.

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

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

The Bank of New York Mellon, as depository, has registered and delivered American Depositary Shares, also referred to as ADSs. Following an ADS ratio adjustment effective August 1, 2022, each ADS represents five thousand (5,000) ordinary shares (or a right to receive five thousand (5,000) ordinary shares). Each ADS will also represent any other securities, cash or other property which may be held by the depository. ADSs may be held either (a) directly (1) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs or (2) by having uncertificated ADSs, or (b) indirectly by holding a security entitlement in ADSs through a broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC.

On August 9, 2022 the Company completed an offering (the “Offering”) of 11,050,000,000 ordinary shares represented by 2,210,000 ADSs at a purchase price of \$5.00 per ADS and pre-funded warrants (the “Pre-Funded Warrants”) to purchase 5,750,000,000 ordinary shares represented by 1,150,000 ADSs at a per pre-funded warrant price of \$4.9999, with each ADS and Pre-Funded Warrant accompanied by an ordinary warrant (the “Common Warrant”), for aggregate gross proceeds of \$16.8 million, resulting in net proceeds of approximately \$14.9 million. Each Common Warrant has an exercise price of \$5.00 per ADS and expires on the fifth anniversary of the Closing Date. On the Closing Date, the holder of Pre-Funded Warrants sold in the Offering exercised its Pre-Funded Warrants in full.

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In connection with the Offering, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain institutional investors. The Purchase Agreement provided that for a period of 180 days following the closing of the Offering, the Company will not effect or enter into an agreement to effect a “variable rate transaction” as defined in the Purchase Agreement. Further, the Company has agreed in the Purchase Agreement not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs or ordinary shares or their equivalents, subject to certain exceptions, for a period of 90 days after the closing of the Offering. The Purchase Agreement also contained representations, warranties, indemnification and other provisions customary for transactions of this nature.

Warrants

The following table summarizes warrant activities during the year ended December 31, 2021 and the nine months ended September 30, 2022:

| | ADSs Underlying Warrants | Weighted Average Exercise Price Per Share |
|---|--------------------------------|--|
| Outstanding at December 31, 2021 | 137,282 | \$ 55.39 |
| Granted | 5,385,374 | 11.21 |
| Terminated | (232,349) | 49.75 |
| Exercised – Cashless and Pre Funded Warrants | (1,921,487) | — |
| Outstanding and exercisable at September 30, 2022 | 3,368,820 | \$ 5.35 |

As of September 30, 2022, outstanding warrants expire in 2024 and 2027, and have an intrinsic value of \$0.

NOTE 15 – CONTINGENCIES

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

In February 2020, the Seller of the equity interests in Polytherapeutics and party to the Research Agreement communicated with Quoin Inc. threatening litigation for non-payment and related breach of contract and immediate payment of all monthly payments in the amount of \$666,667. See Notes 10 and 13. The Consultant has not provided any services and has not complied with other technical requirements under the Research Agreement, and therefore is considered to be in breach of contract. The Company and the Consultant have had communications with respect to the duration, commencement date and payment of the consulting services, but a revised agreement has not been reached. No lawsuits have been filed as of the financial statement issuance date. Should a formal claim or lawsuit be filed, the Company believes it has meritorious defenses.

NOTE 16 – LICENSE AGREEMENTS

In November and December 2021, the Company entered into three license and supply agreements, whereby the Company is entitled to a royalty or other proceeds from the specified product revenues in select non-US markets from the licensee, if and when the underlying products are approved and commercialized. During nine months ended September 30, 2022, the Company entered into six license and supply agreements, whereby the Company will receive a royalty or other proceeds from the specified product revenues in select non-US markets from the licensor, if and when the underlying products are approved and commercialized. No royalty revenues have been received through September 30, 2022 under any of these agreements.

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
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NOTE 17 - SUBSEQUENT EVENTS

On November 3, 2022, the Company held its Annual General Meeting of Shareholders, at which the Company's shareholders approved an increase to the authorized share capital to 500,000,000,000 ordinary shares from 50,000,000,000, no par value.

**MANAGEMENT’S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes, which are included elsewhere in this Form 6-K, and our audited consolidated financial statements and related notes for the year ended December 31, 2021 included in our Form 20-F filed with the U.S. Securities and Exchange Commission (the “SEC”) on April 14, 2022, as updated in our Form 6-K furnished to the SEC on August 11, 2022. Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“GAAP”), reflect the operations of Quoin Pharmaceuticals Inc. (“Quoin Inc.”) since inception and include the accounts of Quoin Ltd. since the closing of the Merger (as defined below). Unless context indicates or suggests otherwise, “we”, “our”, “us”, “Quoin Ltd.” and the “Company” in this section refers to the consolidated operations of Quoin Pharmaceuticals Ltd.

Forward-Looking Statements

Certain information included in this discussion and analysis of our financial condition and results of operations 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 history of losses and needs for additional capital to fund our operations and our expected use of net proceeds of the Offering (as defined below);
- our limited operating history and the difficulties encountered by a small developing company;
- 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 comply with the applicable continued listing requirements of Nasdaq;
- our ability to obtain regulatory approvals;
- our ability to obtain 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 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 exclusivity for our product candidates;
- our ability to obtain Rare Pediatric Disease designation for our product candidates;
- the potential oversight of programs or product candidates that may be more profitable or more successful;
- our technology may not be validated and our methods 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 publicly traded may strain our resources;
- potential adverse effects resulting from failure to maintain effective internal controls;

- our obligations and governance practices as a “foreign private issuer” being different from those of U.S. domestic reporting companies may result in less protection for investors;
- 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;
- the potential volatility of the market price for our ADSs (as defined below);
- the potential dilution of our shareholders’ potential ownership due to the Offering and future issuances of share capital;
- the requirement for holders of ADSs to act through the depository 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 factors referred to in section “Risk Factors” in the “Risk Factors” section in Item 3.D. of our Form 20-F and our other filings with the SEC.

All forward-looking statements contained herein speak only as of the date of this Form 6-K and are expressly qualified in their entirety by the cautionary statements included in this section. We do not undertake to update or revise forward-looking statements to reflect events or circumstances that arise after the date on which such statements are made or to reflect the occurrence of unanticipated events, except as required by law. In evaluating forward-looking statements, you should consider these risks and uncertainties and not place undue reliance on our forward-looking statements.

Operating Results

Overview

We are a clinical stage, emerging specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that help 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 technology, that could help address rare skin diseases for which there are currently no approved treatments or cures. Our first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome (NS).

Clinical testing of QRX003 is currently in clinical development in the United States under an open IND application with the U.S. Food and Drug Administration (“FDA”). The ongoing study is a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in NS patients. The trial will be conducted in up to six clinical sites in the United States. The first clinical site was opened in July 2022 and a majority of sites have now been opened as of the financial statement date, with the remainder expected to open in the fourth quarter of 2022. Patient recruitment is actively underway and dosing is anticipated to commence in the fourth quarter of 2022. On October 18, 2022, Quoin Ltd. announced that it plans to run a second clinical study in Netherton patients, under its currently open IND submission with the FDA. The second study will be an open label study testing QRX003 in approximately ten Netherton patients who are currently receiving systemic therapy, primarily biologic therapy. It is anticipated that this open label study will run concurrently with Quoin Ltd.’s other study. In addition, the Company intends to pursue the clinical development of QRX003 in additional rare dermatological diseases, including Peeling Skin Syndrome, SAM Syndrome and Palmoplantar Keratoderma. To date, no products have been commercialized and revenue has not been generated.

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:

- seek the necessary regulatory approvals to complete the clinical development 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
- pursue business development activities by seeking partnering, licensing, merger and acquisition opportunities or other transactions to further expand our pipeline and drug-development capabilities and which take advantage of our financial resources for the benefit of increasing stockholder value.

COVID-19 created a global pandemic, which commenced in 2020. Our operations, to date, have not been dramatically affected by COVID-19. However, the extent of any future impact on our operational and financial performance will depend on the possibility of a resurgence and resulting severity of COVID-19 impact with respect to our access to API and drug product for clinical testing, as well as our ability to safely and efficiently conduct planned clinical trials.

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”.

Key Recent Events and Developments

Merger

On October 28, 2021, Collect completed the business combination with Quoin Inc. in accordance with the terms of the Merger Agreement, by and among Collect, Quoin Inc. and Merger Sub, which was a wholly-owned subsidiary of Collect, pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Collect (the “Merger”). Immediately after completion of the Merger, Collect changed its name to “Quoin Pharmaceuticals, Ltd.”

We have accounted for the transaction as a reverse recapitalization with Quoin Inc. as the accounting acquirer. Because Quoin Inc. is the accounting acquirer, its historical financial statements became our historical financial statements and such assets and liabilities continued to be recorded at their historical carrying values. The impact of the recapitalization has been retroactively applied to all periods presented.

In addition, on October 28, 2021, Collect sold the entire share capital of its subsidiary, Collect Biotherapeutics Ltd., which essentially included all of Collect’s then existing net assets, to EnCellX Inc. (“EnCellX”), a newly formed U.S. privately held company based in San Diego, CA (the “Share Transfer”), pursuant to an Amended and Restated Share Transfer Agreement. We have no interests in EnCellX subsequent to the closing of the Merger.

ADS Ratio Change

Effective August 1, 2022, the ratio of American Depositary Shares (“ADSs”) evidencing ordinary shares changed from 1 ADS representing four hundred (400) ordinary shares to 1 ADS representing five thousand (5,000) ordinary shares, which resulted in a one for 12.5 reverse split of the issued and outstanding ADSs (the “Ratio Change”). All ADS and related option and warrant information presented herein and our financial statements and accompanying footnotes, has been retroactively adjusted to reflect the reduced number of ADSs resulting from the Ratio Change.

Nasdaq Listing

On April 22, 2022, we received a letter from the Listing Qualifications staff (the “Staff”) of The Nasdaq Stock Market, LLC (“Nasdaq”) notifying us that we are no longer in compliance with Nasdaq Listing Rule 5550(b)(1) requiring minimum stockholders’ equity of at least \$2.5 million for continued listing on The Nasdaq Capital Market. Based on our Form 6-K, dated August 10, 2022, the Staff has determined that we comply with the minimum stockholder’s equity requirement, and we evidence continued compliance with our financial statements for the quarter ended September 30, 2022.

On June 10, 2022, we received a letter from the Staff notifying us that the closing bid price per ADS was below the required minimum of \$1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq

Listing Rule 5550(a)(2). Since then, the Staff has determined that the closing bid price of our ADSs has been at \$1.00 per ADS or greater, and we have regained compliance with the minimum bid price requirement.

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

Agreements with Altium Growth Fund, LP and Warrant Exercises

On October 28, 2021, we completed the private placement transaction with Altium Growth Fund, LP ("Altium" or the "Investor") for an aggregate purchase price of approximately \$17.0 million (comprised of the set off of approximately \$5.0 million of Bridge Notes, and approximately \$12.0 million in cash) (the "Primary Financing"), which resulted in the net proceeds of approximately \$10.1 million. We issued 342,100 ADSs to the Investor.

We also issued to the Investor, effective as of March 13, 2022, the 136th day following the consummation of the Merger (i) Series A Warrant to purchase 342,100 ADSs (the "Series A Warrant") (ii) Series B Warrant to purchase 342,100 ADSs (the "Series B Warrant") and (iii) Series C Warrant to purchase 191,174 ADSs ("Series C Warrant" and, together with the Series A Warrant and Series B Warrant, the "Investor Warrants"). The exercise price for the Investor Warrants is \$49.75 per ADS, with Series A Warrant having a five-year maturity, and Series B Warrant and Series C Warrant having a two-year maturity.

We had the right to require the mandatory exercise of the Series C Warrant, subject to an effective registration statement being in place for the resale of the shares underlying such warrant and the satisfaction of equity market conditions, as defined in the Series C Warrant. On April 22, 2022, a registration statement for the resale of the shares underlying Investor Warrants was declared effective by the Securities and Exchange Commission. In the period from April 22, 2022 to June 30, 2022, the Investor exercised the Series B Warrant in full pursuant to the alternate cashless exercise rights of such warrant, which gives the Investor the sole option as elected by the Investor to receive 1.0 ADS for each warrant ADS underlying such warrant, resulting in the issuance of a total of 342,100 ADSs to the Investor. The market related conditions to require the mandatory exercise of the Series C Warrant were not met during the period up to July 14, 2022.

On July 14, 2022, we entered into an agreement with Quoin Inc. and Altium (the "Altium Agreement"), pursuant to which the parties agreed to, among other things, (i) amend certain terms of the Series A Warrant and Investor Exchange Warrants previously issued to Altium to reduce the exercise price to \$0.00 per ADS with respect to a total of 399,999 ADSs, (ii) cancel the Series C Warrant and the remaining portion of the Series A Warrant previously issued to Altium, and (iii) terminate the Purchase Agreements, pursuant to which the warrants were previously issued to Altium. The incremental fair value of the modified warrants was approximately \$491,000, which was charged against the gross proceeds of the Offering (see below). From July 15, 2022 to August 2, 2022, Altium exercised all of its Series A Warrant to purchase 300,925 ADSs and all of its Investor Exchange Warrants to purchase 99,074 ADSs at \$0.00 per ADS exercise price, and we issued a total of 399,999 ADSs.

Noteholder Warrant Exercises

Commencing in October 2020, Quoin Inc. issued promissory notes (the "2020 Notes") to five noteholders, including our directors, Messrs. Langer and Culverwell (collectively, "2020 Noteholders"). The 2020 Notes were issued at a 25% original issue discount with an aggregate face value of \$1,213,313 with an interest at a rate of 20% per annum. The 2020 Notes were mandatorily convertible into ADSs based on the valuation negotiated in the Primary Financing. The 2020 Noteholders also received warrants exercisable at any time after the issuance date for a number of shares of Quoin Inc.'s common stock equal to 100% of the "as if converted" shares as if the 2020 Notes principal and interest were convertible at the lowest price any securities are sold, convertible, or exercisable into in the Primary Financing or the next round of financing (whichever is lower). At the closing of the Merger, ADSs were issued to the 2020 Noteholders upon the conversion of the principal of the 2020 Notes. In addition, effective as of March 13, 2022, Quoin Ltd. exchanged Quoin Inc. warrants held by the 2020 Noteholders for warrants on substantially the same terms as the Investor Exchange Warrants, exercisable for 29,388 ADSs, in the aggregate, at the exercise price of \$49.75 per ADS (the "Noteholder Warrants"). The Noteholder Warrants became exercisable immediately upon issuance and expire five years from March 13, 2022. The exercise price of the warrants held by the 2020 Noteholders was also reduced to \$0.00 as of July 14, 2022 as a result of the Altium Agreement. The change in the exercise price of the Noteholder Warrants resulted in a deemed dividend of approximately \$65,000. From July to September 2022, the 2020 Noteholders

exercised all their warrants to purchase ADSs at \$0.00 per ADS exercise price, and a total of 29,388 ADSs were issued to such noteholders.

Public Offering

On August 9, 2022 (the “Closing Date”), the Company completed an offering (the “Offering”) of 11,050,000,000 ordinary shares represented by 2,210,000 ADSs at a purchase price of \$5.00 per ADS and a pre-funded warrant (the “Pre-Funded Warrant”) to purchase 5,750,000,000 ordinary shares represented by 1,150,000 ADSs at a per pre-funded warrant price of \$4.9999, with each ADS and Pre-Funded Warrant accompanied by an ordinary warrant (the “Common Warrant”), for aggregate gross proceeds of \$16.8 million, resulting in net proceeds of approximately \$14.9 million, after deducting the placement agent’s fees and estimated offering expenses payable by the Company, and excluding the proceeds, if any, from the subsequent exercise of the Common Warrants. Each Common Warrant has an exercise price of \$5.00 per ADS and expires on the fifth anniversary of the Closing Date. On the Closing Date, the holder of the Pre-Funded Warrant sold in the Offering exercised its Pre-Funded Warrant in full.

In connection with the Offering, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain investors. The Purchase Agreement provided that for a period of 180 days following the closing of the Offering, the Company will not effect or enter into an agreement to effect a “variable rate transaction” as defined in the Purchase Agreement. Further, the Company has agreed in the Purchase Agreement not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs or ordinary shares or their equivalents, subject to certain exceptions, for a period of 90 days after the closing of the Offering. The Purchase Agreement also contained representations, warranties, indemnification and other provisions customary for transactions of this nature.

As a result of the Offering and warrant exercises, as of the financial statement date there were 24,233,024,799 ordinary shares outstanding, 99.99% of which are represented by 4,846,605 ADSs, and warrants outstanding exercisable into 16,844,100,000 ordinary shares represented by 3,368,820 ADSs.

License and Distribution Agreement and Supply Agreement

On July 14, 2022, Quoin Inc. entered into (i) a License and Distribution Agreement with Endo Ventures Limited (“Endo”), and (ii) a Supply Agreement with Endo. Under the terms of the License Agreement, Endo has the exclusive rights to commercialize, upon the receipt of applicable regulatory approvals, pharmaceutical product QRX003 (in finished dosage form for human use) in Canada. Under the terms of the Supply Agreement, Quoin agreed to manufacture and supply (or have manufactured and supplied) to Endo the foregoing pharmaceutical product QRX003 for sale in Canada.

Clinical Development

Quoin’s lead asset, QRX003, is currently in clinical development in the United States under an open IND application with the FDA. The ongoing study is a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in Netherton patients. The test materials will be 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.

The trial will be conducted in up to six clinical sites in the US. A majority of clinical sites have now been opened with the remainder expected to be opened in the quarter ending December 31, 2022. Quoin recently announced plans to initiate a second clinical study in Netherton patients who are currently receiving off-label systemic therapy, primarily systemic biologic therapy. This will be an open-label study in approximately ten patients with no placebo control.

Components of Our Results of Operations

Operating Expenses

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

Research and Development Expenses

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

Future research and development expenses may include:

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

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

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

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

- the timing and receipt of regulatory approvals; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for the founders and executive officers, professional fees and other corporate expenses, including significant costs incurred in 2021 in connection with the Merger and associated regulatory filings.

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 increased costs related to the hiring of personnel, including compensation and employee-related expenses, and fees to outside consultants, lawyers and accountants. Additionally, we anticipate increased costs associated with being a public company, including compliance with The Nasdaq Capital Market and SEC requirements, insurance and investor relations costs.

Other Expenses

Other expenses consist primarily of non-cash costs associated with the financing arrangements entered into during 2020 and 2021, including fair value adjustments to notes payable and warrants and interest expense associated with debt instruments. The majority of such expenses ceased upon conversion of the debt instruments and exchange of the warrants, most of which occurred at the Merger date.

Results of Operations – Three months ended September 30, 2022 compared to Three months ended September 30, 2021

The following table sets forth our results of operations for the three months ended September 30, 2022, compared to the three months ended September 30, 2021:

| | Three months ended September 30, | | Change |
|-------------------------------|---|-----------------------|-----------------------|
| | 2022 | 2021 | |
| Operating Expenses | | | |
| General and administrative | \$ 1,582,059 | \$ 1,042,783 | \$ 539,276 |
| Research and development | 745,506 | 259,996 | 485,510 |
| Total operating expenses | <u>2,327,565</u> | <u>1,302,779</u> | <u>1,024,786</u> |
| Other Expenses | | | |
| Warrant liability expense | — | (146,808) | 146,808 |
| Unrealized loss | 3,053 | — | 3,053 |
| Interest income | (15,132) | — | (15,132) |
| Interest expense | 714,081 | 248,165 | 465,916 |
| Total other expenses (income) | <u>702,002</u> | <u>101,357</u> | <u>600,645</u> |
| Net loss | <u>\$ (3,029,567)</u> | <u>\$ (1,404,136)</u> | <u>\$ (1,625,431)</u> |

General and Administrative Expenses

General and administrative expenses were approximately \$1,582,000 and \$1,043,000, in the three months ended September 30, 2022 and 2021, respectively, representing an increase of approximately \$539,000, or 52%. The increase was primarily due to the build-up of the company infrastructure post the Merger, \$305,000 of increased costs of becoming a public company related to insurance and filing costs and stock-based compensation expense of \$232,000 following the issuance of options under the Amended and Restated Equity Incentive Plan (the “Amended Plan”) in April 2022.

Research and Development Expenses

Our research and development expenses during the three months ended September 30, 2022 and 2021 were approximately \$746,000 and \$260,000, respectively, representing an increase of approximately \$486,000, or 187%. The increase was primary due to increased expenditures on our development programs following the completion of our financings in October 2021, including work related to

commencing the clinical studies for the development of QRX003 following the FDA clearance of our IND for QRX003 in April 2022. Also, included in the 2022 expenses were approximately \$115,000 of compensation costs related to managing the development programs. We expect to significantly increase our research and development efforts by conducting the remaining studies necessary for the development and approval of QRX003, see “Components of Our Results of Operations – Research and Development Expenses” above.

Other Expenses:

Interest and financing expense

In the fourth quarter of 2020, we issued convertible promissory notes in an initial bridge financing with an aggregate face value of \$1,213,333 (the “2020 Notes”) with a 20% coupon interest. In 2021, we issued additional convertible promissory notes in a subsequent Bridge Financing (the “Bridge Notes”) with an aggregate face value of \$5,000,000 with a 15% coupon interest.

Interest expense was \$714,000 and \$248,000 in the three months ended September 30, 2022 and 2021 respectively. Interest on the Bridge Notes was paid in October 2021 upon closing of the Primary Financing, and interest on the 2020 Notes did not accrue after October 2021 but remained unpaid and included as a liability on our consolidated balance sheet as of December 31, 2021. Approximately \$312,000 was paid to two of the five 2020 Noteholders during the nine months ended September 30, 2022. Based on the terms of the cash settlement with these two 2020 Noteholders, our estimate of the liability to the remaining three 2020 Noteholders was increased to \$1,146,000 as of September 30, 2022. We expect to settle the remaining liability in 2022 or early 2023.

Warrant liability expense

We determined our warrants required liability treatment at fair value, which was remeasured at each reporting period. The Bridge Note warrants which were exchanged for the Investor Exchange Warrants with a fixed exercise price of \$49.75 per ADS and reclassified as an equity instrument in October 2021 upon closing of the Primary Financing. The 2020 Note warrants were exchanged for warrants on the same terms as the Investor Exchange Warrants and reclassified as an equity instrument in March 2022. In the three months ended September 30, 2022, and September 30, 2021 we incurred a fair value gain or expense of \$0 and (\$147,000) respectively related to the warrants associated with the 2020 Notes and the Bridge Notes.

Results of Operations – Nine months ended September 30, 2022 compared to nine months ended September 30, 2021

The following table sets forth our results of operations for the nine months ended September 30, 2022, compared to the nine months ended September 30, 2021:

| | <u>Nine months ended September 30,</u> | | |
|--------------------------------|---|-----------------------|----------------------|
| | <u>2022</u> | <u>2021</u> | <u>Change</u> |
| Operating Expenses | | | |
| General and administrative | \$ 5,112,002 | \$ 2,525,366 | \$ 2,586,636 |
| Research and development | 2,059,769 | 556,064 | 1,503,705 |
| Total operating expenses | 7,171,771 | 3,081,430 | 4,090,341 |
| Other Expenses | | | |
| Forgiveness of trade payable | (416,000) | — | (416,000) |
| Fair value adjustments to debt | — | 1,250,000 | (1,250,000) |
| Warrant liability expense | (77,237) | 4,522,844 | (4,600,081) |
| Financing expense | — | 275,000 | (275,000) |
| Unrealized loss | 3,053 | — | 3,053 |
| Interest income | (15,132) | — | (15,132) |
| Interest expense | 714,081 | 516,276 | 197,805 |
| Total other expenses (income) | 208,765 | 6,564,120 | (6,355,355) |
| Net loss | \$ (7,380,536) | \$ (9,645,550) | \$ 2,265,014 |

General and Administrative Expenses

General and administrative expenses were approximately \$5,112,000 and \$2,525,000, in the nine months ended September 30, 2022 and 2021, respectively, representing an increase of \$2,587,000, or 102%. The increase was primarily due to the build-up of the company infrastructure post the Merger which included, \$1,248,000 in increased costs of becoming a public company related to professional services, filing and insurance costs, \$601,000 in increased salary and benefits expenses and stock-based compensation expense of \$432,000 following the issuance of options under the Amended and Restated Equity Incentive Plan (the “Amended Plan”) in April 2022.

Research and Development Expenses

Our research and development expenses during the nine months ended September 30, 2022 and 2021 were approximately \$2,060,000 and \$556,000, respectively, representing an increase of \$1,504,000, or approximately 270%. The increase was primary due to \$1,052,000 in increased expenditures on our development programs following the completion of our financings in October 2021, including work related to the filing of our IND for QRX003 in March 2022, work related to commencing the clinical studies for the development of QRX003 following the FDA clearance of our IND in April 2022. Also, included in the 2022 expenses were approximately \$353,000 of compensation costs related to managing the development programs. We expect to significantly increase our research and development efforts by conducting the remaining studies necessary for the development and approval of QRX003, see “Components of Our Results of Operations – Research and Development Expenses” above.

We amortize licensed or acquired intellectual property over its expected useful life, included in research and development expenses set out above. The license from Skinvisible was obtained in October 2019, see “Research and Development, Patents and Licenses.” Amortization of intangible assets was \$78,000 in each of the nine months ended September 30, 2022 and 2021.

Other Expenses:

Interest and financing expense

Interest expense on the 2020 Notes and Bridge Notes was \$714,000 and \$516,000 in the nine months ended September 30, 2022 and 2021 respectively. Interest on the Bridge Notes was paid in October 2021 upon closing of the Primary Financing, and interest on the 2020 Notes did not accrue after October 2021 but remained unpaid and included as a liability on our consolidated balance sheet as of December 31, 2021 a portion of which was paid in the nine months ended September 30, 2022. Approximately \$312,000 was paid to two of the five 2020 Noteholders during the nine months ended September 30, 2022. Based on the terms of the cash settlement with these two 2020 Noteholders, our estimate of the liability to the remaining three 2020 Noteholders was increased to \$1,146,000 as of September 30, 2022. We expect to settle the remaining liability in 2022 or early 2023.

Fair value adjustment to convertible notes payable

We elected to value the 2020 Notes and the Bridge Notes at fair value, which was remeasured at each reporting period. In the nine months ended September 30, 2021 we incurred a fair value adjustment of \$1,250,000 related to the Bridge Notes. The Bridge Notes and 2020 Notes were converted into equity in October 2021 on the closing of the Primary Financing.

Warrant liability expense

We determined our warrants required liability treatment at fair value, which was remeasured at each reporting period. In the nine months ended September 30, 2022, and September 30, 2021 we incurred a fair value gain of (\$77,000) related to the warrants associated with the 2020 Notes, and expense of \$4,523,000 related to the warrants associated with the 2020 Notes and the Bridge Notes, respectively. The Bridge Note warrants which were exchanged for the Investor Exchange Warrants with a fixed exercise price of \$49.74 per ADS and reclassified as an equity instrument in October 2021 upon closing of the Primary Financing. The 2020 Note warrants were exchanged for warrants on the same terms as the Investor Exchange Warrants and reclassified as an equity instrument in March 2022.

Forgiveness of Trade Payable

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

Liquidity and Capital Resources

We believe 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, unless one or more of our product candidates are accepted into Early Access Programs in certain countries, we do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will continue to increase substantially in 2022 as we advance the clinical development of QRX003.

Future Funding Requirements

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

- the scope, timing, rate of progress and costs of our drug development efforts, preclinical development activities, the timing of laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems; and
- the costs associated with being a public company.

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

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

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

Summary Statement of Cash Flows

As of September 30, 2022, we had approximately \$15,161,000 in cash and investments in marketable securities. The table below presents our cash flows for the nine months ended September 30, 2022 and 2021:

| | Nine months ended September 30, | |
|---|--|----------------|
| | 2022 | 2021 |
| Net cash used in operating activities | \$ (6,538,390) | \$ (2,541,281) |
| Net cash used in investing activities | (10,149,121) | (375,000) |
| Net cash provided by financing activities | 14,454,570 | 3,245,241 |
| Net increase (decrease) in cash | \$ (2,232,941) | \$ 328,960 |

Operating Activities

Net cash used in operating activities was approximately \$6,538,000 and \$2,541,000 for the nine months ended September 30, 2022 and 2021, respectively. The increase in 2022 was primarily due to the increase in research and development and general and administrative expenses, including significant expenses incurred in connection with becoming a public company and increased compensation costs, and partial pay-down of accrued interest on the 2020 Notes.

Investing Activities

Net cash used by investing activities was \$10,149,000 and \$375,000 in the nine months ended September 30, 2022 and 2021, respectively. The increase in cash used in investing activities for the nine months ended September 30, 2022 was primarily due to the purchases of short maturity US Treasury Bills from the proceeds of the recent public offering.

Financing Activities

Net cash provided by financing activities was \$14,545,000 for the nine months ended September 30, 2022. The net cash provided increased due to the receipt of \$14.9 million in net proceeds from the Offering partially offset by repayments of amounts due to officers at the aggregate rate of \$50,000 per month. Net cash from financing activities in the nine months ended September 30, 2021 was \$3,245,000, primarily representing net proceeds received from the issue of Bridge Notes.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments. However, our exposure to market risk for changes in interest rates is not significant

as we have no outstanding interest-bearing debt instruments, and we do not hold any interest-generating securities. See “Liquidity and Capital Resources” above.

Critical Accounting Policies and Use of Estimates

The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to accrued expenses, valuation allowance on deferred tax assets and valuation of intangible assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Results may differ from these estimates due to actual outcomes being different from those on which we based our assumptions. These estimates and judgments are regularly reviewed by management on an ongoing basis at the end of each quarter prior to the public release of our financial results.

Critical accounting policies are those that, in management’s view, are most important to the portrayal of a company’s financial condition and results of operations and most demanding on their calls on judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. We believe our most critical accounting policies and estimates relate to:

Use of estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. In addition, other factors may affect estimates, 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, fair value of debt instruments and warrants, research and development expense recognition, intangible asset estimated useful lives and impairment assessments, stock-based compensation, allowances of deferred tax assets, contingency recognition, and cash flow assumptions regarding going concern considerations.

Warrants:

We classify as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provide the us 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 our own stock. We classify 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 of our control) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

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

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 our use of the acquired assets or the strategy for our 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 nine months ended September 30, 2022 and 2021, 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 expense in future periods as the related services are rendered.