Table of Contents

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

FORM 10-K

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

For the fiscal year ended December 31, 2025

or

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

For the transition period from _____ to _____

Commission File Number: 001-37846

QUOIN PHARMACEUTICALS LTD.

(Exact name of registrant as specified in its charter)

State of Israel	**92-2593104**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

42127 Pleasant Forest Court
Ashburn, VA 20148-7349
(Address of principal executive offices; Zip Code)

Registrant's telephone number, including area code: (703) 980-4182

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing thirty - five (35) Ordinary Shares, no par value per share	QNRX	The Nasdaq Stock Market LLC
Ordinary Shares, no par value per share*		N/A

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

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's voting equity held by non-affiliates, computed by reference to the closing price at which the American Depositary Shares ("ADS") were last sold on The Nasdaq Stock Market LLC as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $5.4 million. The registrant has no non-voting common equity.

As of March 23, 2026, the registrant had 63,126,930 ordinary shares, no par value per share, outstanding, and 1,803,626 ADSs outstanding (assuming all ordinary shares are represented by ADSs), with each ADS representing thirty - five (35) ordinary shares.

GENERAL INFORMATION

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

Effective April 9, 2025, the ratio of American Depositary Shares ("ADSs") evidencing our ordinary shares, no par value per share ("Ordinary Shares"), changed from 1 ADS representing one (1) Ordinary Share to 1 ADS representing thirty - five (35) Ordinary Shares (the "Ratio Change"), which resulted in a 1 - for - 35 reverse split of the issued and outstanding ADSs (the "Reverse Split"). Our Ordinary Shares were not affected by this adjustment. Except as specifically provided, ADSs and related option, warrant, purchase price and exercise price information presented in this Annual Report, including our consolidated financial statements and the related notes, has been retroactively adjusted to reflect the Ratio Change and the Reverse Split.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

- our limited operating history and the difficulties encountered by a small developing company;
- our history of losses and inability to fund our business from operations may require us in the future to obtain additional capital the terms of which may not be on acceptable terms, or at all;
- we must raise additional capital to fund our operations in order to continue as a going concern;
- our lack of revenue and potential inability to be profitable;
- uncertainties of cash flows and inability to meet working capital needs;
- the terms of our October 2025 private placement may make it difficult for us to procure additional financing;
- our ability to obtain regulatory approvals;
- our ability to generate favorable pre-clinical and clinical trial results;
- our ability to identify and develop potential product candidates;
- additional costs or delays associated with unsuccessful clinical trials;

- the inability to predict the timing of revenue from sales of a future product;
- the extensive regulatory requirements and future developmental and regulatory challenges we will still face even if we obtain approval for a product candidate;
- our ability to maintain orphan drug designation or obtain orphan drug exclusivity for our product candidates;
- the potential oversight of programs or product candidates that may be more profitable or more successful;
- our manufacturing processes may not be validated and our methodology may not be accepted by the scientific community;
- the ability to conduct clinical trials, because of difficulties enrolling patients or other reasons;
- the costs and demands of being a publicly traded company may harm our business;
- potential adverse effects resulting from failure to maintain effective internal controls;
- our ability to comply with the applicable continued listing requirements of Nasdaq;
- the potential negative impact on our securities price and trading volume if securities or industry analysts do not publish reports about us or if they adversely change their recommendations about our business;
- the potential volatility of the market price for our ADSs;
- the potential dilution of our shareholders' potential ownership due to future issuances of share capital;
- the requirement for holders of ADSs to act through the depositary to exercise their rights;
- the potential limitations on ADS holders with respect to the transfer of their ADSs;
- the risks of securities class action litigation; and
- other risks and uncertainties, including those listed under Part I, Item 1A of this Annual Report titled "Risk Factors."

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

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

In addition, certain sections of this Annual Report contain information obtained from independent industry sources and other sources that we have not independently verified.

SUMMARY OF RISK FACTORS

An investment in our Company is subject to a number of risks. Set forth below is a high-level summary of some, but not all, of these risks. You should review and consider carefully the risks and uncertainties described in more detail in "Part I, Item 1A. Risk Factors" of this Annual Report, which includes a more complete discussion of the risks summarized below as well as a discussion of other risks related to our business and an investment in our securities.

Risks Related to Our Financial Position and Capital Requirements

- We have a limited operating history that you can use to evaluate us, and the likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company.
- We must raise additional capital to fund our operations in order to continue as a going concern.
- We have incurred significant losses since our inception and have limited cash available for our operations.
- We have never generated any revenue from product sales or any other sources since inception and may never be profitable.
- We expect that we will need to raise additional capital, which may not be available on acceptable terms, or at all.
- The terms of our October 2025 private placement may make it difficult for us to procure additional financing.

Risks Related to the Discovery and Development of Product Candidates

- Pre - clinical and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from pre - clinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed.
- We may not be successful in our efforts to identify or develop potential product candidates.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Any of our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.
- Even if we complete the necessary pre - clinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a future product.
- Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements, and our products may face future development and regulatory challenges.
- We may not be able to maintain orphan drug designation or obtain orphan drug exclusivity for our product candidates.
- Our Rare Pediatric Disease designation from the FDA does not guarantee that the NDA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process or increase the likelihood that any of our product candidates will receive marketing approval.
- We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.
- We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.
- If we obtain approval to commercialize any approved products outside of the United States, Europe and Japan, a variety of risks associated with international operations could materially adversely affect our business.
- Coverage and adequate reimbursement may not be available for our product candidates, if approved, which could make it difficult for us to sell products profitably.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to conduct some aspects of our compound formulation, research and pre - clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such formulation, research or testing.
- We rely, or will rely, on third-party manufacturers to produce the supply of our pre - clinical product, clinical product candidates and commercial supplies of any approved product candidates.
- We rely on limited sources of supply for the drug substance of product candidates and any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.
- Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.
- We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

Risks Related to Our Intellectual Property

- If we are unable to obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.
- Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.
- If we fail to obtain licenses or comply with our obligations in these agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

Other Risks Related to Our Business Operations and Industry

- The pausing or termination of government grants by the United States government could have a major effect on the pharmaceutical industry, and as a result, our operations and prospects.
- Inadequate funding, government shutdowns, workforce reductions or other policy changes affecting the FDA, the SEC or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.
- Our future success depends on our ability to attract and retain key executives and to attract, retain and motivate qualified personnel.
- We may need to expand our organization and may experience difficulties in managing our growth, which could disrupt our operations.
- Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

- Future relationships with customers and third - party payors as well as certain of our business operations may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.
- Our operations may be impacted from changes to current regulations and future legislation.
- We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.
- Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in damage to our reputation and/or subject us to costs, fines or lawsuits.
- We have been, and may in the future be, adversely affected by health epidemics and pandemics which may significantly harm our business, prospects, financial condition and operating results.
- Business interruptions could delay us in the process of developing our future products.

Risks Related to Being an Israeli Company

- Shareholders may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us or our executive officers and directors, or asserting U.S. securities laws claims in Israel.
- The rights and responsibilities of our shareholders are governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.
- Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Risks Related to Ownership of Our ADSs and Ordinary Shares

- We do not know whether a market for our securities will be sustained and as a result it may be difficult for shareholders to sell our securities.
- We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which may harm our business
- Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.
- Our failure to meet the continued listing requirements of the Nasdaq Capital Market could result in a delisting of our ADSs.
- The market price for our ADSs may be volatile.
- We may be at risk of securities class action litigation.
- Substantial future sales or perceived potential sales of our ADSs in the public market could cause the price of our ADSs decline.
- Our shareholders may experience substantial dilution as a result of future issuances of our equity securities.
- We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.
- If we pay dividends or other distributions, an ADS holder may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, an ADS holder may not receive dividends or other distributions on our ordinary shares and an ADS holder may not receive any value for them, if it is illegal or impractical to make them available to such ADS holder.
- Holders of ADSs must act through the depositary to exercise their rights.
- Holders of ADSs may be subject to limitations on the transfer of their ADSs.

Table of Contents

PART I

Item 1. Business

Company Overview

We are a late-stage clinical specialty pharmaceutical company focused on the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently either no approved or very limited treatments or cures. Our lead product, QRX003, is under clinical development as a potential treatment for Netherton Syndrome ("NS"), a rare hereditary genetic disease. QRX003 is entering pivotal registrational clinical testing under an open Investigational New Drug ("IND") application with the Food and Drug Administration ("FDA"). We have opened six clinical sites in the United States ("U.S.") along with international sites that are being opened in the UK, Spain, France and the Netherlands. QRX003 is currently being tested in seven pediatric NS patients in investigator-initiated studies in Ireland, Austria, the Netherlands and New Zealand. QRX003 is also being developed as a potential treatment for Peeling Skin Syndrome with the first subject being treated in New Zealand. We are in the process of expanding this study to include up to an additional five pediatric subjects. We entered into a Research Agreement with the Queensland University of Technology ("QUT") in Australia, under which we have obtained an option for a global license to QRX008 for the potential treatment of scleroderma, as well as a Research Agreement with The School of Pharmacy at University College Cork ("UCC") for the development of novel topical formulations of rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are either limited or no approved therapies or cures, including microcystic lymphatic malformations, venous malformations and angiofibromas among others. We have also entered into 9 commercial partnerships for QRX003 spanning 61 countries outside of our core commercial territories of the U.S., Western Europe and Japan. These partnership countries include Canada, Australia, New Zealand, the Middle East, China, Taiwan, Hong Kong Singapore, Israel, Central and Eastern Europe, Turkey as well as several countries in Latin America.

Our mission is to develop and commercialize proprietary therapeutic drug products that treat rare and orphan diseases, particularly for those diseases where no approved treatment currently exists. To achieve this, we plan to:

- complete the late-stage clinical testing of QRX003 in NS and, if successful, submit for marketing approval in the United States, Europe, Japan and the other territories for which we have commercial agreements in place;
- prepare to commercialize QRX003 by (i) establishing our own sales infrastructure in the U.S., Europe and Japan and (ii) work with our distribution partners to commercialize the product in Canada, Australia/New Zealand, the Middle East, China, Hong Kong, Taiwan, Latin America, Central and Eastern Europe, Turkey and Singapore;
- continue the development of QRX003 for Peeling Skin Syndrome and related rare, genetic skin diseases;
- commence clinical testing of one or more selected formulations of topical rapamycin; 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.

To date, no products have been commercialized and no revenue has been generated.

Our Product Candidates

QRX003

QRX003 is a topical lotion being developed for the treatment of a number of rare genetic skin diseases. Our most advanced program is for NS. The active ingredient in QRX003 is a broad-spectrum serine protease inhibitor whose mechanism of action is to target the kallikreins responsible for the process of skin shedding. Due to the genetic mutation of the SPINK5 gene, which results in the absence of the kallikreins that regulate Lympho-epithelial Kazal-type-related inhibitor ("LEKTI") protein, a large, 15-domain serine protease inhibitor expressed in epithelial tissues, crucial for regulating skin barrier function and desquamation, these kallikreins go unregulated and become hyperactive resulting in the uncontrolled desquamation that leads to the highly defective skin barrier in NS patients. When applied to the skin, QRX003 is designed to perform the function of the missing LEKTI protein and down regulate, but not completely

stop, the activity of kallikreins, leading to a more normalized skin shedding process and the formation of a stronger and more effective skin barrier.

While several other companies are pursuing the development of products to treat NS, we believe, to date we are the only company that is actively dosing subjects in multiple NS clinical studies under an open IND with the FDA.

In light of the expected near-term completion of the QRX003 clinical program for NS, in July 2025 Quoin announced that it has discontinued the development of QRX007 for NS. QRX007 was being developed through Quoin's research agreement with QUT.

QRX003 is also being developed as a potential treatment for Peeling Skin Syndrome, a rare genetic skin disease for which there is no approved treatment or cure. In addition, we are planning to pursue the development of QRX003 as a potential treatment for a number of Ichthyosis related disorders and SAM Syndrome potentially putting the product in position to become the first approved for four genetic skin diseases.

QRX008

In May 2022, we entered into a Research Agreement with QUT, pursuant to which we have an option for up to six months after the project completion to in-license a small molecule VLA - 4 inhibitor, the QRX008 product. QRX008 is a potential treatment for scleroderma, a rare autoimmune disease for which there is currently no approved treatment, and it is under early-stage development by QUT. We are planning to schedule a meeting with QUT to discuss the future direction of the research program.

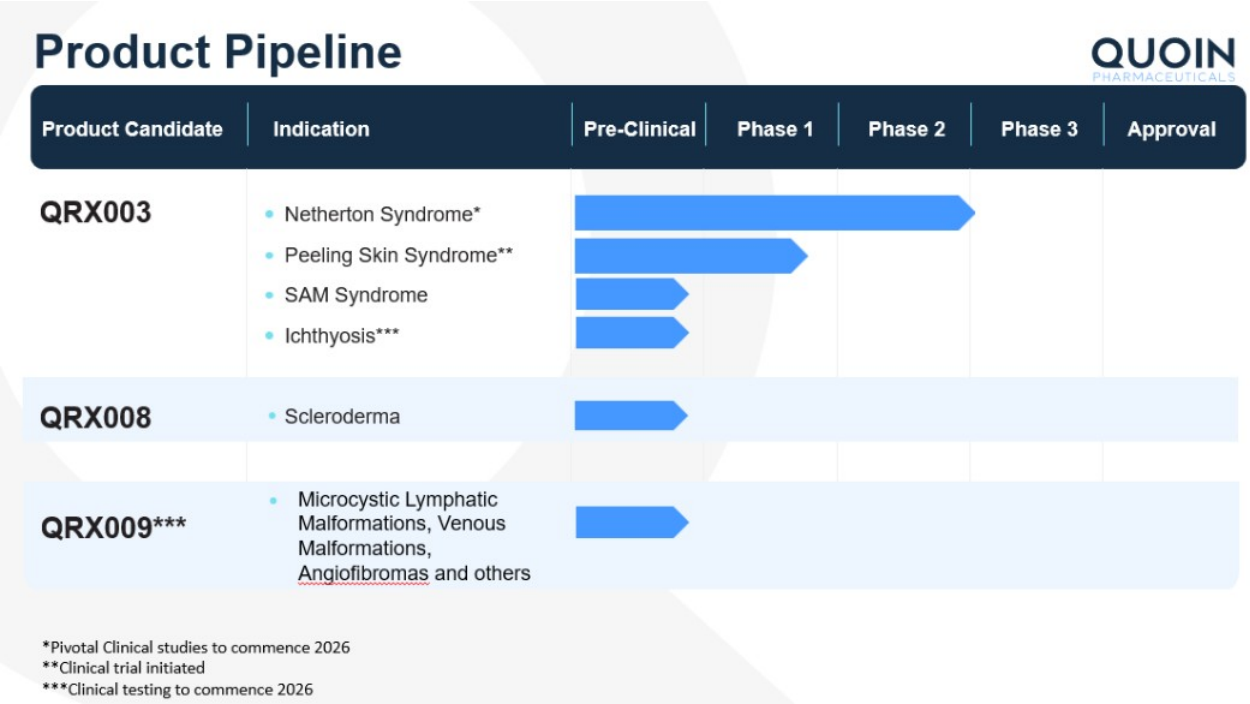
QRX009

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

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

On November 11, 2025 we announced that the target loading concentrations for two topical rapamycin delivery technologies have been successfully achieved. Specifically, a rapamycin loading concentration of 4% w/w has been achieved for our proprietary topical formulation while an even higher rapamycin concentration of 5% w/w has been formulated in a proprietary dermal patch system. We plan to move forward with the manufacture of clinical trial and stability batches from at least one of the delivery technologies with a view to commencing clinical testing in the second half of 2026.

Our Current Product Pipeline



Netherton Syndrome

NS is a rare autosomal recessive genetic disease affecting an estimated 6,000 – 8,000 patients combined in the U.S. and Europe. NS is caused by a mutation in the SPINK5 gene and has an incidence of approximately 1/200,000 births. Under normal circumstances, the SPINK5 gene encodes a protein, called lympho-epithelial kazal type related inhibitor ("LEKTI") that serves as a brake system on the activity of certain proteases (enzymes that digest proteins) in the skin called Kallikreins. The absence of the LEKTI protein, as a result of the genetic defect that causes NS, leads to unregulated protease activity in the skin by the Kallikreins, resulting in too few layers of the outer skin (stratum corneum), thereby leading to a highly defective and compromised skin barrier. As a result, patients with NS suffer from a variety of medical issues including regular, severe infections, skin cancer, chronic pruritus, asthma, and allergies among others.

Newborns with NS have reddened skin (erythroderma) and sometimes a thick parchment-like covering of skin (collodion membrane). The skin is red and scaly all over. Hair shafts are fragile and break easily due to trichorrhexis or "bamboo hair," resulting in short sparse hair. In older children and adults, the scaling may have a distinctive circular pattern (ichthyosis linearis circumflexa). Babies with NS may be born prematurely. Trouble gaining weight in infancy and childhood is common and can be severe. Infants may also have recurrent skin infections and septicemia. They may develop hypernatremia (elevated sodium levels in the blood) due to excessive loss of fluid from the skin surface. Because hairs may not be affected at birth and then may be sparse in all babies in the first months of life, the characteristic hair defect that is diagnostic of NS may not be detected initially. Infants with NS may be misdiagnosed as having congenital ichthyosiform erythroderma, atopic dermatitis or psoriasis. Atopic dermatitis (red, itchy patches of skin) may be present, and a cradle cap-like scale and redness may appear on the face, scalp and eyebrows.

There are currently no approved therapies to treat NS. In the absence of an approved therapeutic product, patients can only obtain minor symptomatic relief, generally by the regular use of emollients and moisturizing creams and lotions. Other topical agents must be used with caution because the highly compromised skin in NS patients may allow ingredients from some topically applied medications to be excessively absorbed into the bloodstream, which may pose a danger to the patient. Use of topical keratolytic agents, such as urea or lactic acid derivatives, may be limited by skin irritation and is generally reserved for older children or adults. Base line treatment may

also include oral antihistamines, which can help to control the itchy, eczematous component, and topical or systemic antibiotics as needed. Oral and topical steroids and systemic biologics may be beneficial in reducing inflammation and the eczematous component of the disease. However, the well-documented side effects of long-term steroid use need to be carefully considered. There is a critical need for a new and effective treatment for NS.

Clinical and Regulatory Status of QRX003 for the Treatment of NS

Our lead asset, QRX003, is currently in late-stage clinical development in the U.S. under an open IND application with the FDA. We submitted an IND in March 2022 to the FDA to initiate a clinical study of QRX003 in adult NS patients. We received a 'Study May Proceed' notification from the FDA on June 13, 2022, for Study CL-QRX003-001.

Table 1 lists all completed, current and planned clinical studies for QRX003 in NS.

Study Number	Study Stage	Status	Number of Patients	Design
CL-QRX003-001**	POC-Monotherapy	Completed	13	Vehicle controlled*
CL-QRX003-002A/B**	POC-Adjuvant Therapy	Completed	8	Open Label, Baseline Controlled
CL-QRX003-002C CL-QRX003-003	P2-Adjuvant P2-Mono/Adjuvant	Ongoing Ongoing	8 8	Open Label, Baseline Controlled Open Label, Baseline Controlled
CL-QRX003-004	P2-Monotherapy	Ongoing	8	Open Label, Baseline Controlled
NA	Pediatric Investigator Study	Ongoing	7	Open Label, Baseline Controlled
CL-QRX003-005	Pivotal-Monotherapy	To commence 2026	16	TBD
CL-QRX003-006	Long Term Extension	To commence 2026	TBD	NA

*Still blinded.
**Partial Body Dosing. All others Whole Body Dosing.

Study CL-QRX003-001 is a randomized vehicle controlled study. In Part A of the study, which recruited 11 subjects, two doses of QRX003 were tested against a vehicle control. In this part of the study a low potency cosmetic grade of the active ingredient was used. The test articles were applied once-daily to approximately 20% of the subject's body surface area ("BSA") over a 12 week period. In Part B of the study, which recruited 2 subjects, participants either received QRX003 containing 4% GMP grade DPHP or a vehicle control. The test articles were applied twice-daily to approximately 20% of BSA. Recruitment into this study has been completed and the data has not been unblinded as of yet.

In November 2022, we submitted a protocol for Study CL-QRX003-002 in NS patients to the FDA under our open IND and the study initiated in December 2022. In Part A of this study, which recruited 7 subjects, all participants received the low potency cosmetic grade DPHP once daily on approximately 20% BSA. All participants in this study had been receiving off-label systemic therapy prior to entry into the study and remained on that treatment throughout the duration of the study. Endpoints evaluated in Part A at Week 12 included change from baseline on the Investigator's Global Assessment ("IGA") scale (0-5), change from baseline on the Worst Itch-

Numeric Rating Scale ("WI-NRS"), a scale for the evaluation of pruritus or itch (0-10) and change from baseline on the Modified Ichthyosis Area Severity Index ("M-IASI"), which assesses the severity and extent of skin symptoms associated with ichthyosis (0-48).

The following Figure 1 outlines initial clinical data obtained from the first seven evaluable subjects from Part A of this study

FIGURE 1

Data:

IGA: (Scale 0-4)

- 2 of 7 had a minimum of 1 grade improvement from baseline

Pruritus

- 5 of 7 had a two-point improvement **(nominal p-value of 0.001)**
- 3 of 5 had a four-point improvement **(nominal p-value of 0.0579)**
- Mean change from baseline score -2.9 **(nominal p-value of 0.0327)**

Despite being treated once daily with low potency cosmetic grade DPHP, two of the 7 subjects achieved a one grade improvement from baseline for the IGA (scale of 0-4) at Week 12. In addition, five of the 7 subjects had a two-grade improvement from baseline for the WI-NRS (scale of 0-10) at Week 12. Although not powered for statistical significance, this result was nominally statistically significant with a p-value of 0.001. Furthermore, of the 5 subjects, whose WI-NRS was 4 or higher at baseline, three achieved a 4-grade improvement at Week 12 with 12 weeks once-daily application of cosmetic grade DPHP with a nominal p-value of 0.0579. The mean change in WI-NRS from baseline was -2.89, which was also nominally statistically significant.

In Part B of Study CL-QRX003-002, a single subject was tested with QRX003 containing 4% GMP grade DPHP twice-daily over a 12-week period on 20% BSA. The endpoints for Part B of the study were the same as those in Part A. The clinical data from this portion of the study are outlined in Table 2.

TABLE 2

End Point	Baseline	6 weeks (Treatment period midpoint)	12 weeks (End of treatment period)
M-IASI*	18	4	3
WI-NRS**	7	4	2
IGA***	3 (Moderate)	2 (Mild)	1 (Almost Clear)

**M-IASI: Modified Ichthyosis Area of Severity Index, a score used to assess the severity and extent of skin symptoms associated with ichthyosis. Lower scores indicate improvement.*
***WI-NRS: Worst Itch Numeric Rating Scale, which measures the severity of itch on an 11-point scale (0 = no itch, 10 = worst imaginable itch).*
****IGA: Investigator's Global Assessment, which uses descriptive categories (e.g., clear, almost clear, mild, moderate, severe) to evaluate the overall severity of Netherton Syndrome symptoms.*

At baseline, the subject had an IGA of 3 (moderate) which improved to 1 (almost clear) following twice daily treatment with QRX003, while the subject's WI-NRS improved significantly a highly intrusive score of 7 to a very tolerable score of 2. Furthermore, for the M-IASI, the baseline score of 18 had significantly improved to 3 after 12 weeks of QRX003 treatment. The subject returned to

the clinical site at week 16 for final evaluation after treatment with QRX003 had been discontinued for 4 weeks. As outlined in Table 3, all assessed endpoints had returned to, or were worse than, baseline levels after treatment with QRX003 had been removed for 4 weeks.

TABLE 3

End Point	Baseline	6 weeks (Treatment period midpoint)	12 weeks (End of treatment period)	4 weeks post discontinuation of treatment
M-IASI*	18	4	3	18
WI-NRS**	7	4	2	8
IGA***	3 (Moderate)	(2) Mild	(1) Almost Clear	(3) Moderate

**M-IASI: Modified Ichthyosis Area of Severity Index, a score used to assess the severity and extent of skin symptoms associated with ichthyosis. Lower scores indicate improvement.*
***WI-NRS: Worst Itch Numeric Rating Scale, which measures the severity of itch on an 11-point scale (0 = no itch, 10 = worst imaginable itch).*
****IGA: Investigator's Global Assessment, which uses descriptive categories (e.g., clear, almost clear, mild, moderate, severe) to evaluate the overall severity of Netherton Syndrome symptoms.*

Following review of these clinical data, Study CL-QRX003-002 was converted to a 'whole-body' protocol Phase 2 study (Part C) where QRX003 is applied twice-daily over a 12-week period to approximately 80% BSA. This portion of the study is currently recruiting up to 8 evaluable subjects, and no data has been reported yet.

Study CL-QRX003-003 is a Phase 2 study that is being conducted by Dr. Amy Paller at Northwestern University. This study will recruit up to 8 evaluable subjects who will be treated twice-daily over a 12-week period with QRX003 on greater than 80% BSA. Unlike Study CL-QRX003-002, a majority of subjects in this study will not receive ongoing concurrent off-label systemic therapy. This study is currently recruiting and no data has been reported yet. Study CL-QRX003-004 is also a Phase 2 open-label study that will recruit up to 8 evaluable subjects, all of whom will fully wash out of any ongoing off-label systemic therapy prior to participation in the study. Participants will receive QRX003 twice-daily on greater than 80% BSA over a twelve-week period. Subjects are currently being screened for participation in the study and dosing has not been initiated as of yet.

Studies CL-QRX003-005 and CL-QRX003-006 are planned Phase 3 and 12-month Long Term Extension studies, respectively, which have not started yet.

In addition to the above studies, we are conducting an investigator-initiated clinical study of QRX003 in pediatric NS patients. The study is being conducted in Ireland, Austria, the Netherlands and New Zealand. Seven pediatric NS patients are currently being treated in the study. Table 4 outlines results for the one pediatric subject for which data are currently available.

TABLE 4

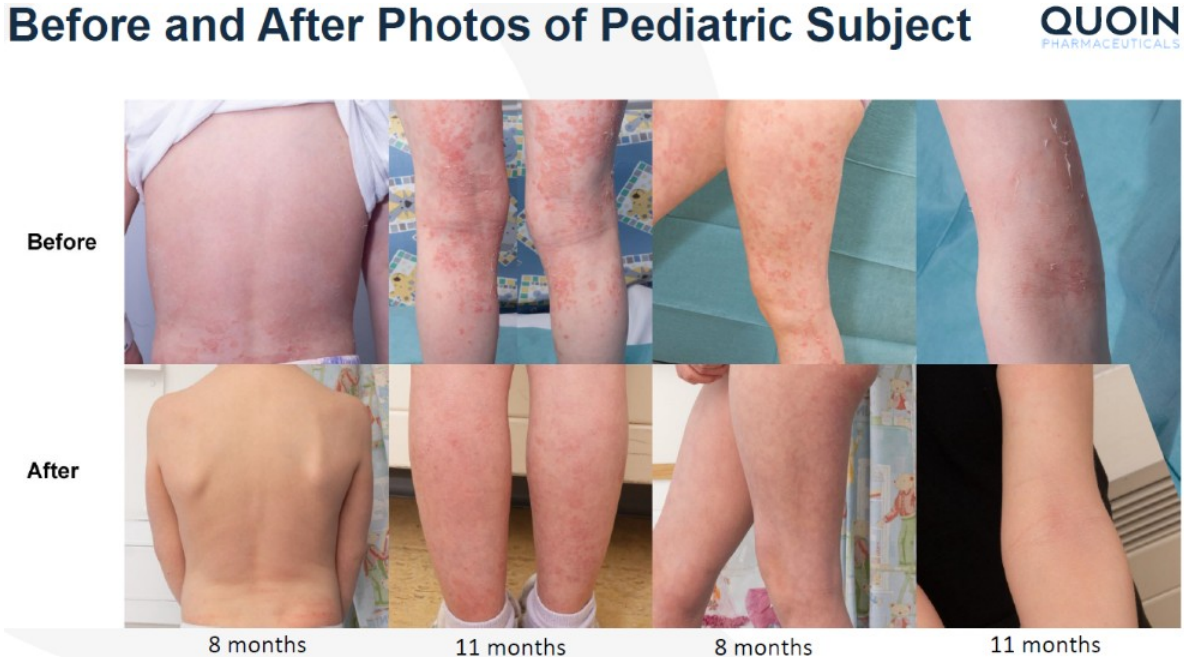
Endpoint*	Baseline	12 Month
Investigator Global Assessment	4 (Severe)	0 (Clear)
Pruritus	5	0

* IGA scale 0-4, Pruritus scale 0-10.

After 12 months of treatment with QRX003, the subject's skin was adjudicated to be clear by the clinical assessor and their pruritus was rated as "no itch", with both endpoints being scored at 0. In addition, the subject is experiencing zero nightly sleep disturbance and

has not required antibiotic, antiviral, antihistamine or glucocorticoid medication. Baseline and 12 month photos of the subject's skin are illustrated in Figure 2 below. The subject continues to be treated with QRX003 and has experienced no treatment related adverse events.

FIGURE 2



We have received Orphan Drug Designation from the European Medicines Agency for QRX003, which would result in 10 years of market exclusivity in Europe upon approval. This designation offers benefits like scientific advice on study protocols and fee reductions.

The FDA has granted Rare Pediatric Disease Designation to QRX003 for the treatment of Netherton Syndrome, enabling potential Priority Review Voucher eligibility upon marketing approval for the treatment of NS. The FDA has also granted Orphan Drug Designation to QRX003 for the treatment of Netherton Syndrome. Furthermore, the FDA has granted Fast Track Designation to QRX003 for the treatment of NS.

On January 20, 2026, we announced that we had filed an application for Breakthrough Medicine Designation with the Saudi Food and Drug Authority ("SFDA") for QRX003. The SFDA's Breakthrough Medicine Designation program is designed to expedite the development, review, and potential availability of medicines that address serious or life-threatening conditions with high unmet medical need and which meet SFDA eligibility requirements. If granted, the designation will allow for accelerated regulatory review and could enable earlier patient access in Saudi Arabia.

On January 27, 2026, we announced that we had submitted an application to the Japanese Ministry of Health, Labour and Welfare ("MHLW") for Orphan Drug Designation ("ODD") for QRX003 for the treatment of Netherton Syndrome. The MHLW's Orphan Drug Designation program provides orphan status to therapies intended for the treatment, diagnosis, or prevention of rare diseases that affect fewer than 50,000 people in Japan. This designation provides certain benefits, including R&D subsidies, tax credits for qualified clinical testing, reduction of MHLW application fees, priority review and ten years of market exclusivity, if approved.

On March 25, 2026, we provided a clinical and regulatory update from our constructive Type C meeting with U.S. FDA for QRX003 in NS. We reported that the FDA indicated that a single Phase 3 study may be sufficient to support marketing approval in the US and expressed openness to an alternative study design for Phase 3 that would likely not include a traditional upfront vehicle or placebo control (the "March Type C Meeting Minutes"). See Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments – Public and Private Offerings – October 2025 Private Placement" for a description of

the March Type C Meeting Minutes' affect on the exercise period of the Series H Warrants issued in connection with the Company's October 2025 private placement transaction.

Clinical and Regulatory Status of QRX003 for the Treatment of Peeling Skin Syndrome

On August 6, 2024, we announced the planned initiation of an investigator-led clinical study in New Zealand for QRX003 in pediatric patients with Peeling Skin Syndrome. This rare genetic condition currently has no approved treatments or cures. The first clinical site opened in and dosing of the patient commenced in December 2024. Quoin is actively evaluating additional clinical sites in other countries. Table 5 below outlines clinical results for the first pediatric patient for whom data is available

TABLE 5

End Point	Baseline	12 weeks
M-IASI*	36	12
IGA**	4 (Severe)	2 (Mild)
CDQLI***	19	11

**M-IASI: Modified Ichthyosis Area of Severity Index, a score used to assess the severity and extent of skin symptoms associated with ichthyosis. Lower scores indicate improvement.*

***IGA: Investigator's Global Assessment, which uses descriptive categories (e.g., clear, mild, moderate, severe) to evaluate the overall severity of disease symptoms.*

****The CDQLI is a validated clinical tool designed for children aged 4-15 that is used to measure the impact of their skin disease on a child's quality of life in terms of symptoms, leisure activities, sleep, school, personal relationship and treatment. The scale for the CDQLI is 0-30.*

After 12 weeks of treatment with QRX003, improvement was observed across all evaluated endpoints. The subject has now been treated with QRX003 for over one-year with continued improvement in skin appearance and texture. In addition, the subject's pruritus has diminished significantly leading to markedly improved sleep function. Quoin is actively working to recruit up to an additional 5 pediatric subjects into this study.

Clinical and Regulatory Status of QRX009

Quoin is targeting submitting a pre-IND meeting request to the FDA for QRX009 before the end of Q2 of 2026 and to initiate clinical testing in one or more Proof of Concept ("POC") studies before the end of 2026. The initial target indications for those POC clinical studies will be selected from Microcystic Lymphatic Malformations, Venous Malformations, Gorlin Syndrome, Epidermolysis Bullosa and Pachyonychia Congenita In addition, Quoin is planning to initiate a pharmacokinetic study for QRX009 in healthy volunteers in Q2 of 2026.

Commercial Strategy

QRX003 has the potential to become the first approved treatment for NS globally to reach the market and may therefore capture significant market share based on our own commercial infrastructure which we plan to establish in the U.S., Western Europe and Japan as well as from our commercial partnerships. We currently anticipate that QRX003, if approved, would be applied once or twice daily over the patient's entire body. Because NS is a chronic disease and does not spontaneously resolve, we believe there is an opportunity for the product, should it be approved, for long-term chronic use.

We intend to self-commercialize QRX003, and other rare disease products the company may develop, if approved, in both the U.S. and Europe. We are also in the process of initiating the establishment of a Japanese subsidiary to facilitate the self-commercialization of QRX003 in Japan. Because of the very low number of patients and the fact that diagnosis and treatment are generally provided by a relatively small number of board-certified dermatologists in major urban areas, we believe this concentration of care will enable us to market QRX003 with a small, dedicated salesforce to target patients and caregivers in the U.S, Europe and Japan. Outside of these territories, we have currently established nine separate marketing partnerships for QRX003 that cover 61 different countries including Australia, New Zealand, the Middle East, Central and Eastern Europe, Turkey, Canada, China, Taiwan, Hong Kong, Singapore and the major countries in Latin America.

Once the commercial infrastructure has been established for QRX003 for NS, the subsequent approval and addition of new rare disease indications or products is not expected to result in a significant increase in the size of that infrastructure. In particular, we believe it is highly likely that physicians who treat patients with NS would also treat patients with Peeling Skin Syndrome, SAM Syndrome and other Ichthyosis related disorders, enabling our sales personnel to discuss several products, once approved, with each treating physician.

A key element of our commercial strategy will be to add new products to our portfolio beyond those which we develop ourselves. This will be achieved through in-licensing, acquisition or the establishment of research partnerships with universities or other institutions. While it is intended that these products will treat rare and orphan diseases, we may widen our scope of interest beyond rare skin diseases as we believe this will not add significant incremental burden to an already established commercial infrastructure.

Pricing

We have not concluded a formal pricing analysis of QRX003 in NS. We anticipate that pricing at launch may be influenced by the product label negotiated with the FDA, by pharmacoeconomic data developed to support pricing and the potential for greater sales under negotiated government contracts.

Competition

The clinical biotechnology industry is a competitive industry characterized by technological innovation and growth. Our competitors include other biotechnology and pharmaceutical companies, academic institutions, and public and private research institutions. These entities engage in efforts to research, discover and develop new medicines and treatments for substance use. These entities also seek patent protection and licensing revenues for their research results and may compete with us in recruiting skilled talent. Some of these entities are larger and better funded than us. Our management can make no assurances that we can effectively compete with these competitors. We also may be unable to keep pace with technological developments and other market factors. Currently, there are no approved products to treat NS. However, to our knowledge, there are a number of therapeutic products at various stages of development for the treatment of NS, including candidates from LifeMax Laboratories, Inc., Sixera Pharmaceuticals, ResVita Bio, BioCryst and Azitra Inc. As of now, to the best of our knowledge, only Azitra and BioCryst are actively dosing subjects in clinical studies of NS patients under an open IND.

Manufacturing

Our manufacturing strategy is to contract with third parties to manufacture our clinical and commercial active pharmaceutical ingredient (API) and drug product supplies. The formulation and processes used to manufacture our products are proprietary, and we have agreements with various third-party manufacturers and suppliers, such as Ferndale Contract Manufacturing and TopChem Pharmaceuticals Limited, that are intended to restrict these manufacturers from using or revealing any unpublished proprietary information.

Intellectual Property

Patents and Trademarks

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to develop and manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain.

The following table lists patents and trademarks that we use in our business.

Patents	Trademarks
Patent applications directed to adjunctive therapy for NS with QRX003 filed by Quoin Pharmaceuticals Inc. in the U.S., Australia, Canada, China, Europe, Japan, Korea, and Mexico.	U.S. Trademark Registration No. 6918421 for word mark "RARE DISEASES ARE ONLY RARE IF YOU DON'T LIVE WITH ONE" filed by Quoin Pharmaceuticals, Inc.
U.S. patent application for high purity active ingredient for QRX003.	U.S. Trademark Registration No. 7071539 for design and words "Quoin Pharmaceuticals" filed by Quoin Pharmaceuticals, Inc.
	U.S. Trademark Application No. 98/184,357 for word mark "QELTIQ" filed by Quoin Pharmaceuticals, Inc.
U.S. provisional patent application directed to rapamycin formulation for treatment of particular skin disorders	U.S. Trademark Application No. 98/850,670 for word mark "NETHERTON NOW: BECAUSE EVERYONE DESERVES TO FEEL COMFORTABLE IN THEIR OWN SKIN" filed by Quoin Pharmaceuticals, Inc.
U.S. provisional patent application directed to use of QRX003 according to a new dosage and for particular skin disorders. PCT Application directed to adjunctive therapy for NS with QRX003 filed by Quoin Pharmaceuticals Inc.	U.S. Trademark Application No. 98/850,671 for word mark "NETHERTON NOW" filed by Quoin Pharmaceuticals, Inc.

License Agreement with Skinvisible

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

Trade Secrets

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, including processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although each of our employees agrees to assign their inventions to us through an employee inventions agreement, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology are required to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Regulatory

General

Government authorities in the United States and other countries extensively regulate, among other things, the pre-clinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of pharmaceutical products. In the United States, pharmaceutical products are subject to rigorous review under the Federal Food, Drug, and Cosmetic Act, and other federal statutes and regulations.

FDA Approval Process

To obtain approval of our product candidates from the FDA, we must, among other requirements, demonstrate in pre - clinical studies and well-controlled clinical trials that the product is safe and effective for its intended use and that the manufacturing facilities,

processes and controls are adequate to preserve the drug's identity, strength, quality and purity. The drug approval process generally includes:

- pre - clinical laboratory tests, *in vitro* and *in vivo* pre - clinical studies and formulation and stability studies;
- the submission to the FDA of an application for human clinical testing, which is known as an IND application;
- adequate and well-controlled human clinical trials to demonstrate the safety and effectiveness of the drug;
- the submission to the FDA of a new drug application ("NDA") for a drug; and
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current GMP ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- the approval by the FDA of an NDA.

Pre - clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Pre - clinical trials must also be conducted in accordance with FDA and comparable foreign authorities' legal requirements, regulations or guidelines, including Good Laboratory Practice. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. Before human clinical testing can begin, a sponsor must submit the results of the pre - clinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND, a request for authorization from the FDA to administer an investigational new drug product to humans.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practices ("GCP"), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Clinical trials must be conducted under the supervision of one or more qualified investigators pursuant to protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. For each institution where a clinical trial will be conducted, an institutional review board ("IRB") must review and approve the clinical trial protocol and informed consent form required to be provided to each trial subject or his or her legal representative prior to a clinical trial commencing, and conduct on-going monitoring of the study until completed or termination to assure that appropriate steps are taken to protect the human subjects participating in the research.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1: In Phase 1 studies, the product candidate is initially introduced into healthy human volunteers and tested for safety, dosage and tolerability, absorption, distribution, metabolism and excretion and, effect on the body.

Phase 2: Phase 2 studies are conducted in a limited patient population. These studies continue to evaluate safety while gathering preliminary data on effectiveness in patients with the targeted disease or condition.

Phase 3: Phase 3 trials further evaluate efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate

and provide, if appropriate, an adequate basis for product labeling. In many cases, particularly for prevalent diseases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In many other diseases, such as rare diseases, a single Phase 3 trial may be sufficient when supported by confirmatory evidence In other cases, though less common, a single Phase 3 trial may be sufficient when the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

Post-approval studies: sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These studies are used to gather additional information about a product's safety and/or efficacy in patients affected by the therapeutic indication.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the United States. The NDA must include the results of all pre-clinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The submission of most NDAs is subject to the payment of a substantial application user fee. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. An NDA for a drug that has been designated as an orphan drug is not subject to an application fee, unless the NDA includes an indication for other than a rare disease or condition.

Pursuant to the current Prescription Drug User Fee Act ("PDUFA") goals, FDA's goal for acting on the submission of an NDA for a new molecular entity is ten months from the date the FDA files the NDA. The FDA conducts a preliminary review of an NDA within 60 days after submission to determine whether it is sufficiently complete to permit substantive review, before determining whether to file the NDA. This two-month preliminary review effectively extends the typical NDA review period to twelve months. In rare cases, the FDA may request additional information rather than file an NDA. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA files it.

The FDA may also refer applications for novel pharmaceutical products, as well as pharmaceutical products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee, typically a panel that includes clinicians, statisticians and other experts, for review, evaluation, and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee but generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the pharmaceutical product is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the respective claimed indication.

Following the FDA's evaluation of an NDA, it will issue an approval letter or a complete response letter ("CRL"). An approval letter authorizes the sponsor to begin commercial marketing of the drug for specific indications. A CRL means that the review cycle of the application is complete and the application will not be approved in its present form. A CRL describes the specific deficiencies in the NDA identified by the FDA and may recommend actions that the applicant might take, including providing additional clinical data, such as an additional Phase 3 trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing, to resolve the deficiencies. If a CRL is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter, or withdraw the application. Even if the sponsor submits the recommended data and information, the FDA may decide that the NDA does not satisfy the criteria for approval.

As condition to a product's regulatory approval, the FDA may require a sponsor to conduct Phase 4 studies designed to further assess the drug's safety and effectiveness after NDA approval, or may require other testing and surveillance programs to monitor the safety of the approved product. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. A REMS could include medication guides, communication plans to healthcare professionals or other elements to assure safe use, such as provider certification or training, restricted distribution methods, and patient registries.

There are a variety of regulations governing clinical trials and requirements for obtaining marketing approval for pharmaceutical products outside the United States. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries and regions must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from one regulatory authority to another and the time may be longer or shorter than that required for FDA approval. In the EU, Canada and Australia, regulatory requirements and approval processes are similar, in principle, to those in the United States.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs and biologic products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by the FDA to be substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act ("BPCA") provides a six-month extension of any patent or non-patent exclusivity for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Expedited Programs

The FDA is required to facilitate the development, and expedite the review, of drug products that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and pre - clinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

The FDA is also required to expedite the development and review of applications for approval of products that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the product candidate. The FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Orphan Drug Designation

Pursuant to the Orphan Drug Act, the FDA may grant special status, or orphan designation, to a drug intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States, or there is no reasonable expectation that the sales of the product will offset the cost of developing and making the drug available in the United States. A request for orphan drug designation must be submitted before the NDA is submitted. Following the grant of orphan designation, the FDA will publicly disclose the identity of the therapeutic drug candidate and its potential orphan use. Orphan designation does not shorten the duration of the regulatory review and approval process.

If a drug candidate with orphan designation subsequently receives the first FDA approval for the disease or condition for which it has orphan designation, the drug is entitled to a seven-year period of market exclusivity subject to certain exceptions (e.g., clinical superiority of a subsequent product). This means that the FDA may not approve another drug application authorizing another manufacturer to market the same drug for the same indication for seven years. This does not preclude competitors from receiving approval of the same product that has orphan exclusivity for a different indication or a different product for the same indication for which the orphan product has exclusivity. The orphan designation of a drug also provides the sponsor with certain financial incentives including tax credits and waiver of PDUFA fees.

The granting of an orphan drug designation does not shorten the duration of the regulatory review and approval process nor does it guarantee regulatory approval. The first applicant of a new drug application, or NDA, to receive FDA, approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven - year exclusive marketing period in the United States for that product for that indication.

Rare Pediatric Disease Priority Review Voucher Program

Under the Rare Pediatric Disease Priority Review Voucher program, the FDA may award a priority review voucher to the sponsor of an approved marketing application for a product that treats or prevents a rare pediatric disease. The voucher entitles the sponsor to priority review of one subsequent marketing application.

A voucher may be awarded only for an approved rare pediatric disease product application. A rare pediatric disease product application is an NDA for a product that treats or prevents a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years; in general, the disease must affect fewer than 200,000 such individuals in the U.S.; the NDA must be deemed eligible for priority review; the NDA must not seek approval for a different adult indication (i.e., for a different disease/condition); the product must not contain an active ingredient that has been previously approved by the FDA; and the NDA must rely on clinical data derived from studies examining a pediatric population such that the approved product can be adequately labeled for the pediatric population. Before NDA approval, the FDA may designate a product in development as a product for a rare pediatric disease, but such designation is not required to receive a voucher.

To receive a rare pediatric disease priority review voucher, a sponsor must notify the FDA, upon submission of the NDA, of its intent to request a voucher. If the FDA determines that the NDA is a rare pediatric disease product application and grants priority review, and if the NDA is approved, the FDA will award the sponsor of the NDA a voucher upon approval of the NDA. The FDA may revoke a rare pediatric disease priority review voucher if the product for which it was awarded is not marketed in the U.S. within 365 days of the product's approval.

The voucher, which is transferable to another sponsor, may be submitted with a subsequent NDA or biologics license application ("BLA") and entitles the holder to priority review of the accompanying NDA or BLA. The sponsor submitting the priority review voucher must notify the FDA of its intent to submit the voucher with the NDA or BLA at least 90 days prior to submission of the NDA or BLA and must pay a priority review user fee in addition to any other required user fee. The FDA must take action on an NDA or BLA under priority review within six months of receipt of the NDA or BLA.

The Rare Pediatric Disease Priority Review Voucher program was reauthorized in February 2026. Under the current statutory sunset provisions, the FDA may only award a priority review voucher for a rare pediatric disease application approved by September 30, 2029 unless the program is extended.

Post-Marketing Obligations

All approved drug products are subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the product, sampling and distribution requirements, notifying the FDA and gaining approval for certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action, criminal prosecution, or civil penalties.

The FDA may require post-marketing studies or clinical trials to develop additional information regarding the safety of a product. These studies or trials may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side-effects associated with long-term use. The FDA may require post-marketing studies or trials

to investigate known serious risks or signals of serious risks or identify unexpected serious risks and may require periodic status reports if new safety information develops. Failure to conduct these studies in a timely manner may result in substantial civil fines.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the United States and abroad in order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other federal, foreign, state or local agencies. In complying with the cGMP regulations, manufacturers must continue to assure that the product meets applicable specifications, regulations and other post-marketing requirements. Any third-party manufacturers must also maintain compliance with all applicable regulations and requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product.

Also, newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional pre-clinical or clinical studies, or even in some instances, revocation or withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's withdrawal of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the NDA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product or NDA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development, or affect the conditions under which approved products are marketed.

Data Privacy

We are subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal information. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. Certain privacy and data protection laws, such as the Health Insurance Portability and Accountability Act (HIPAA) and the California Consumer Privacy Act (CCPA), may not apply to us directly at this time, but those laws may apply to the investigators, health care professionals, third party payors, and business partners with whom we have relationships and so may apply to our processing of personal information that we receive from or share with such third parties. We may also engage service providers, such as contract research organizations, to process personal information on our behalf. We cannot ensure that all our contractors, vendors, licensees, business partners or collaborators will comply with all applicable privacy and data protection laws and regulations. The failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations.

Pricing and Reimbursement

In both the United States and foreign markets, the ability to successfully commercialize product candidates that have obtained regulatory approval by the FDA or other governmental authorities depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the U.S., governmental payors such as Medicare and Medicaid, managed care organizations, and private commercial health insurers. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services ("CMS"). Private payors tend to follow CMS to a substantial degree. However, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In addition, direct or indirect governmental price regulation may affect the prices that we may charge for product candidates. For example, in the United States and some foreign jurisdictions, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect the pharmaceutical industry, including the Patient Protection and Affordable Care Act of 2010 and the Inflation Reduction Act of 2022. We anticipate that in the U.S., Congress, state legislatures, and private sector entities will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs.

Healthcare Reform

In the United States, there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices.

For example, several healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act ("IRA") in August 2022, which, among other things, requires the U.S. Department of Health and Human Services ("HHS") to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs, which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. Currently, a drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but loses that exclusion if it has designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. However, as a result of a statutory amendment enacted in July 2025, beginning with the 2028 negotiated price applicability year, a drug may be designated for more than one rare disease or condition and still be excluded from price negotiation, as long as the only approved indications are for such rare diseases or conditions. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions have been and may continue to be subject to legal challenges. It is unclear what policies will be advanced with respect to IRA implementation and other drug pricing proposals.

In addition, in May 2025, the administration published an executive order regarding most favored nation ("MFN") drug pricing, which is sometimes referred to as international reference pricing. This executive order directs HHS to communicate MFN price targets to pharmaceutical manufacturers, and if significant progress towards MFN pricing is not delivered, to propose a rule making plan to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to mandate reduced prices of at least some drugs in the United States, if they are also sold in comparator countries.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. It is unclear to what extent additional statutory, regulatory, and administrative initiatives will be enacted and implemented.

Regulatory Authorities Outside the United States

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may be marketed only once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the role of the National Institute for Health and Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

Environmental and Safety Laws

We do not use, handle, store, or dispose of hazardous materials and our operations do not produce hazardous waste. Accordingly, we are not subject to federal, state and local regulations relating to the use, handling, storage and disposal of hazardous materials. Any waste generated is non-hazardous and is disposed of by third party contractors. Likewise, given that we have less than 10 employees, we are not subject to the recordkeeping requirements under the Occupational Safety and Health Administration ("OSHA") although other OSHA regulations may apply. OSHA and/or the Environmental Protection Agency may promulgate regulations that may affect our research and development programs.

We are also subject to various laws and regulations governing laboratory practices and the experimental use of animals.

Human Capital

As of December 31, 2025, we had four full-time employees and two part-time employees. Our employees are not represented by any collective bargaining agreements, and we have never experienced an organized work stoppage.

Enforceability of Civil Liabilities

To the extent any of our shareholders may seek to enforce a U.S. judgment in Israel against us or our executive officers and directors, or to assert U.S. securities law claims in Israel, shareholders may have difficulties enforcing such a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, in Israel.

We have been informed by our legal counsel in Israel that it may be difficult to assert U.S. securities laws claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact which can be a time-consuming and costly process. Matters of procedure will also be governed by Israeli law.

We have irrevocably appointed Quoin Pharmaceuticals, Inc., as our agent to receive service of process in any action against us in any U.S. federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering. Subject to specified time limitations and legal procedures, Israeli courts may enforce a U.S. judgment in a civil matter which is non-appealable, including a judgment based upon the civil liability provisions of the Securities Act or the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that, among other things:

- the judgment was rendered by a court of competent jurisdiction, according to the laws of the state in which the judgment is given;
- the judgment is enforceable according to the laws of Israel and according to the law of the foreign state in which the relief was granted; and
- the judgment is not contrary to public policy of Israel.

Even if such conditions are met, an Israeli court may not declare a foreign civil judgment enforceable if:

- the prevailing law of the foreign state in which the judgment is rendered does not allow for the enforcement of judgments of Israeli courts (subject to exceptional cases);
- the defendant did not have a reasonable opportunity to be heard and to present his or her evidence, in the opinion of the Israeli court;
- the enforcement of the civil liabilities set forth in the judgment is likely to impair the security or sovereignty of Israel;
- the judgment was obtained by fraud;
- the judgment was rendered by a court not competent to render it according to the rules of private international law prevailing in Israel;

- the judgment conflicts with any other valid judgment in the same matter between the same parties; or
- an action between the same parties in the same matter was pending in any Israeli court or tribunal at the time at which the lawsuit was instituted in the foreign court.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

Company Information

We were incorporated under the laws of the State of Israel in 1986 under the name Montiger Ltd. Between 1986 and 2021, we underwent several name changes, including the name change to Cellect Biotechnology Ltd. ("Cellect"). On October 28, 2021, Cellect completed the business combination with Quoin Pharmaceuticals, Inc., a Delaware corporation ("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 Cellect, Quoin Inc. and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Cellect ("Merger Sub"), pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Cellect (the "Merger"). Immediately after completion of the Merger, Cellect changed its name to "Quoin Pharmaceuticals Ltd."

Prior to January 1, 2023, we qualified as a "foreign private issuer" as such term is defined in Rule 405 under the Securities Act. Since January 1, 2023, we have been obligated to file or furnish reports, proxy statements, and other information on U.S. domestic issuer forms with the Securities and Exchange Commission (the "SEC"), which are more detailed and extensive in certain respects, and which must be filed more promptly, than the forms available to a foreign private issuer.

The address of our executive corporate offices is 42127 Pleasant Forest Ct., Ashburn, VA 20148, and our telephone number is (703) 980-4182. Our website is *www.quoinpharma.com*. Information contained on or accessible through this website is not incorporated by reference in, or otherwise a part of, this Annual Report, and any references to this website are intended to be inactive textual references only.

Available Information

We are subject to the informational requirements of the Exchange Act and in accordance therewith, we file reports, proxy and information statements and other information with the SEC. You can read our SEC filings over the Internet at the SEC's website at www.sec.gov. Our filings with the SEC are also available free of charge on the investors section of our website at www.quoinpharma.com. Our filings are available free of charge as soon as reasonably practicable after we electronically file them with, or furnish them to, the SEC. From time to time, we also use multiple social media channels to communicate with the public about Quoin and its products. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage you to review the information we post on such social media channels as our LinkedIn page (https://www.linkedin.com/company/quoin-pharmaceuticals/) and our Twitter account (@Quoinpharma). This list may be updated from time to time on our investor relations website.

Information contained on or accessible through the websites and social media channels referred to above is not incorporated by reference in, or otherwise a part of, this Annual Report, and any references to these websites and social media channels are intended to be inactive textual references only.

Smaller Reporting Company

We are a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"). As a result, we may take advantage of certain reduced disclosure obligations available to smaller reporting companies, including reduced disclosure about our executive compensation arrangements and the requirements to provide only two years of audited financial statements in our annual reports and registration statements. We will continue to be a "smaller reporting company" as long as (1) we have a public float (i.e., the market value of our ADSs held by non-affiliates) less than $250 million calculated as of the last business

day of our most recently completed second fiscal quarter, or (2) our annual revenues are less than $100 million for our previous fiscal year and we have either no public float or a public float of less than $700 million as of the end of that fiscal year's second fiscal quarter. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our results of operations and financial prospects.

Item 1A. Risk Factors

This section describes the material risks to our business, which should be considered carefully in addition to the other information in this Annual Report and our other filings with the SEC. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future. Additionally, our business is subject to general risks applicable to any company, such as economic conditions, geopolitical events, extreme weather and natural disasters. If known or unknown risks or uncertainties materialize, our business operations, financial condition, results of operations and prospects could be adversely affected now and in the future, potentially in a material way. The following discussion of risk factors contains forward-looking statements, as discussed in the "Cautionary Note Regarding Forward-Looking Statements and Summary of Risk Factors" section on page 1.

Risks Related to Our Financial Position and Capital Requirements

We have a limited operating history that you can use to evaluate us, and the likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company.

Our wholly owned subsidiary, Quoin Inc., commenced operations in 2018. As such, we have a limited operating history and our operations are subject to all of the risks inherent in the establishment of a new business enterprise, including a lack of operating history. Since inception, our operations have been primarily limited to acquiring and licensing intellectual property rights, undertaking research and conducting pre-clinical and clinical studies for our initial programs and negotiating and executing the Merger and financings. We have not yet obtained regulatory approval for any product candidates. Consequently, any predictions about our future success or viability, or any evaluation of our business and prospects, may not be accurate. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company starting a new business enterprise and the highly competitive environment in which we will operate. Since we have a limited operating history, we cannot assure you that our business will be profitable or that we will ever generate sufficient revenues to meet our expenses and support our anticipated activities. In addition, there is no guarantee that any of our product candidates will ever receive approval from the FDA. We cannot be certain that our business strategy will be successful or that we will be solvent at any particular time. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with the early stages of the development of any company. If we fail to address any of these risks or difficulties adequately, our business will likely suffer. Because of the numerous risks and uncertainties associated with developing and commercializing our products, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and investors may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of products in the medical and pharmaceutical industries. We may never successfully commercialize our products and our business may fail.

We must raise additional capital to fund our operations in order to continue as a going concern.

At December 31, 2025, we had an accumulated deficit of approximately $71.0 million, cash and cash equivalent balances totaling $3.8 million and investments of $14.9 million. Based on our current business plans and cash, cash equivalents and investments on hand, management has concluded that there is substantial doubt about our ability to continue as a going concern for a period of at least one year from the issuance of the audited consolidated financial statements included in this Annual Report. Our auditor also included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2025 with respect to this uncertainty. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks or uncertainties. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our shareholders. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. Any exercise of our outstanding warrants is at the discretion of the warrant holders and is dependent, in part, upon the market price of our ADSs. There can be no assurance that any of our outstanding warrants will ever be in-the-money prior to their expiration and, as such, our outstanding warrants may expire without being exercised. If we raise funds through collaborations and licensing arrangements, we might 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. Our outstanding warrants may not be exercised or may not be exercised in full. As such, we cannot conclude that funding will be available on acceptable terms on a timely basis, or at all. If we are unable to obtain additional funding when it becomes necessary, we may have to significantly limit our operations, 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.

The Company is subject to risks common to late-stage clinical specialty pharmaceutical companies including, but not limited to, unanticipated clinical trial costs and the ability to estimate such occurrences, if any, on our cash, liquidity, additional financing requirements, and availability. 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. If we are unable to improve our liquidity position, we may not be able to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to generate revenue and raise capital from financing transactions. There can be no assurance that we will be successful in accomplishing these objectives. Without such additional capital, we may be required to curtail or cease operations and be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment.

We have incurred significant losses since our inception and have limited cash available for our operations.

To date, we have not commercialized any products and have not generated any revenue. We have incurred net losses every year since inception and we have an accumulated deficit of approximately $71.0 million at December 31, 2025. We have historically funded our operations through our founders' funding expenditures and debt and equity financings. We have devoted a majority of our financial resources to research and development, including our pre-clinical and ongoing clinical development activities.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue and/or initiate clinical development of our product candidates, including—QRX003—a topical lotion comprised of a broad-spectrum serine protease inhibitor, which is under clinical development as a potential treatment for NS;
- further enhance our internal control systems;
- initiate the development of additional product candidates for other rare disease indications;
- acquire or in-license other products and technologies and advance those product candidates into clinical trials;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory, research, executive and administrative personnel; and
- create additional infrastructure to support our operations and our product development and planned future commercialization efforts.

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 or these candidates participate in early access or named patient programs, which is subject to significant uncertainty. Additional financing will be required to complete the research and development of our product candidates and to fund 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.

We have never generated any revenue from product sales or any other sources since inception, and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic alliance partners, to successfully complete the development of, obtain the necessary regulatory approvals for and commercialize our product candidates. We do not anticipate generating revenues from sales of our products until regulatory approval has been obtained, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing our research and pre - clinical development of product candidates;
- initiating and completing clinical trials for product candidates with favorable results;
- seeking, obtaining, and maintaining marketing approvals for product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing product candidates for which we may obtain marketing approval, with an alliance partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. In addition, our expenses could increase beyond expectations if we are required by the FDA or other foreign regulatory agencies to perform studies and trials in addition to those that we currently anticipate.

Even if one or more of the product candidates that we independently develop is approved for commercial sale, we may incur significant costs associated with commercializing any approved product. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We expect that we will need to raise additional capital, which may not be available on acceptable terms, or at all.

Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials, is expensive. We may need to raise additional capital to support our operations and such funding may not be available to us on acceptable terms, or at all. We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. For example, our pre-clinical or clinical trials may encounter technical difficulties or be subject to delays or other issues. Any of these events may increase our development costs more than we expect. In order to support our long-term plans, we may need to raise additional capital or otherwise obtain funding through additional strategic alliances if we choose to initiate pre-clinical or clinical trials for new product candidates other than programs currently partnered. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, future product candidates.

Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of any future product candidates;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

The terms of our October 2025 private placement may make it difficult for us to procure additional financing.

The securities purchase agreement, dated October 10, 2025, by and among us and the purchasers (the "October Purchasers") named therein (the "October 2025 Purchase Agreement"), that we entered into in connection with the October 2025 Private Placement (as defined herein) contains, among others, the following restrictive covenants: (i) we are prohibited from entering into variable rate financings until April 12, 2026; and (ii) we are prohibited from entering into any equity financings at an effective price per ADS or Ordinary Share that is less than the unit purchase price with respect to the October 2025 Private Placement until June 2, 2026. The October 2025 Purchase Agreement further provides that the purchasers thereunder have a right of participation in certain subsequent financings by us or any of our subsidiaries in an amount equal to up to an aggregate of 25% of such subsequent financings for 12 months following the date of the October 2025 Purchase Agreement.

To the extent we require additional funding, we will therefore be limited in the types of fundraising transactions that we are able to pursue in compliance with the October 2025 Purchase Agreement. If we require additional funding while these restrictive covenants remain in effect, we may be unable to effect a financing transaction on terms acceptable to us, or at all, while also remaining in compliance with the terms of the October 2025 Purchase Agreement, or we may be forced to seek a waiver from the October Purchasers, which such they are not obligated to grant to us. 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.

Risks Related to the Discovery and Development of Product Candidates

Pre-clinical and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from pre-clinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed.

We have no products approved for commercial marketing and most of our product candidates are in pre-clinical and clinical development as is the case with our lead asset for NS, which is currently being tested in four separate clinical studies in NS patients. Moreover, the clinical development process can take several years, and there is no assurance that our clinical trials will be successful or that we will obtain marketing approvals for any of our product candidates from the FDA or any foreign regulatory agencies, such as the EMA. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive pre-clinical tests and clinical trials to demonstrate the safety and efficacy of our product candidates.

The success of our product candidates will depend on several factors, including the following:

- successfully implementing pre - clinical studies which may be predictive of clinical outcomes;
- successful enrollment in clinical trials and completion of those trials with favorable results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection for current and future product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and
- successfully commercializing our products, if approved, including successfully establishing a sales force, marketing and distribution infrastructure, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete the development or commercialization of our product candidates, which would materially harm our business.

We may not be successful in our efforts to identify or develop potential product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our research methodology may be unsuccessful in identifying potential product candidates; or
- potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unsuitable for administration in patients in clinical trials, unlikely to receive marketing approval or unmarketable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results or planned interim analyses of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with the FDA or other regulatory authorities on final trial design, including selection of control dose and efficacy endpoints such as clinical outcome assessments
- delays in obtaining from the FDA, or comparable foreign regulatory authority, authorization to administer an investigational new drug product to humans through the submission or acceptance of an IND or similar foreign application;
- imposition of a clinical hold of clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- our inability to adhere to clinical trial requirements directly or with third parties such as CROs;
- clinical trial site or CRO non-compliance with good clinical practices (“GCPs”), good laboratory practices, or other regulatory requirements;
- inability or failure of clinical trial sites to adhere to the clinical trial protocol;
- delays in obtaining required IRB approval at each clinical trial site, or an IRB reversing such approval resulting in the suspension or termination of a trial at that site;
- delays in recruiting and retaining suitable patients to participate in a trial particularly for a rare disease such as NS;

- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to protocol procedures or requirements, product side effects or disease progression;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

Accordingly, we cannot be sure that we will submit INDs on our expected timelines and we cannot be certain the FDA or foreign regulatory agencies, such as the EMA, will allow us to progress into clinical trials based on the submission of any IND.

If we are required to conduct additional clinical trials or other testing of any product candidates beyond those that are currently contemplated, are unable to successfully complete clinical trials of any such product candidates or other testing, or if the results of these trials or tests are not positive, are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our future product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as originally intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales.

Any of our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity level and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment, the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, clinical trials by their nature test product candidates in only small samples of the potential patient populations. With a limited number of patients and limited duration of exposure in such trials, rare and potentially severe side effects of our product candidates may not be uncovered until a significantly larger number of patients are exposed to the product candidate.

If any of our product candidates receive marketing approval, and causes serious, unexpected, or undesired side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend, or limit their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- regulatory authorities may require the addition of labeling statements, such as black box warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-marketing surveillance;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our future products and impair our ability to generate revenues from the commercialization of these products.

Even if we complete the necessary pre - clinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a future product.

We cannot commercialize a product until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for many reasons including:

- regulatory authorities disagreeing with the design or implementation of our clinical trials;
- such authorities may disagree with our interpretation of data from pre - clinical studies or clinical trials;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- unfavorable or unclear results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a New Drug Application (“NDA”) or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional pre - clinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- such authorities may find deficiencies in the manufacturing processes, testing systems or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies; or

- regulations of such authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Additional delays may result if an FDA advisory committee recommends restrictions on approval or recommends non-approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process.

Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements, and our products may face future development and regulatory challenges.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The FDA may also require risk evaluation and mitigation strategies as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Additionally, the manufacturing processes, packaging, distribution, adverse event reporting, labeling, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing FDA regulatory requirements, in addition to other potentially applicable federal and state laws. These requirements include monitoring and reporting of adverse events ("AEs") and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice ("cGMP") regulations. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. If we or a regulatory agency discovers previously unknown problems with a product such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning or untitled letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product or require a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our future products, if approved, and generate revenues.

We may not be able to maintain orphan drug designation or obtain orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing the drug for the type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation entitles a party to financial incentives, such as tax advantages and user fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such

designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in certain circumstances, such as a showing of clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity.

We received orphan drug designation in the United States for QRX003 for the treatment of NS in October 2025. Even though we obtained orphan drug designation for QRX003 in Netherton Syndrome, we may not be the first to obtain regulatory approval of the product candidate for the orphan-designated indication. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for orphan designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other future product candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

Our Rare Pediatric Disease designation from the FDA does not guarantee that the NDA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that any of our product candidates will receive marketing approval.

Under the Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying NDA for the treatment of a rare pediatric disease, the sponsor of such an application may be awarded a transferable rare pediatric disease priority review voucher that can be used to obtain priority review for a subsequent NDA or BLA. We were granted Rare Pediatric Disease designation for QRX003 for the treatment of NS by the FDA in June 2025. Under the current statutory sunset provisions, the FDA may only award a priority review voucher for a rare pediatric disease application approved by September 30, 2029, unless the program is extended. Additionally, designation of a drug for a rare pediatric disease does not guarantee that an NDA will meet the other eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease designation does not lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

As a result of our limited financial and human resources, we will have to make strategic decisions as to which product candidates to pursue and may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval.

If successfully developed and approved, our product candidates may face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical and human resources than us, and may be better equipped to develop, manufacture, market and distribute products. Many of these companies operate large, well-funded research, development and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us.

Currently, there are no approved products to treat NS. However, to our knowledge, there are a number of therapeutic products at various stages of development for the treatment of NS, including candidates from LifeMax Laboratories, Inc., Sixera Pharmaceuticals,

ResVita Bio, BioCryst and Azitra Inc. As of now, to the best of our knowledge, out of these companies only Azitra and BioCryst are actively dosing subjects in clinical studies of NS patients under an open IND.

We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies, universities and other research institutions. Our competitors may have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, drug products that are more effective or less costly than any product candidate that we may develop.

All of our product candidates are in either pre - clinical or clinical development and targeted toward indications for which there may be other product candidates in clinical development. We may face competition from other drugs currently approved or that may be approved in the future for the same therapeutic indications as our product candidates. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug development to:

- develop therapeutics that are superior to other products in the market;
- attract qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapeutics.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. We will not achieve our business plan if the acceptance of any of these products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or choose to reserve our future products for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing product candidates before we do, which would have a material adverse impact on our business.

The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

The degree of market acceptance of any product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any AEs;

- limitations or warnings contained in the FDA-approved label for such products;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our, or any of our collaborators', sales and marketing strategies;
- our ability to obtain hospital or payor formulary approval;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If a product is approved but does not achieve an adequate level of acceptance by physicians, patients and healthcare payors, we may not generate sufficient revenues from such product and we may not become or remain profitable. Such increased competition may decrease any future potential revenue for future product candidates due to increasing pressure for lower pricing and higher discounts in the commercialization of our product.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.

We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. With respect to future programs, we may rely completely on an alliance partner for sales and marketing. In addition, we may enter into strategic alliances with third parties to commercialize other product candidates, if approved, including in markets outside of the United States, Europe and Japan or for other large markets that are beyond our resources. Although we intend to establish a sales organization if we are able to obtain approval to market any product candidates in the United States, Europe and Japan we will also consider the option to enter into strategic alliances for future product candidates in the United States, Europe and Japan if commercialization requirements exceed our available resources. This will reduce the revenue generated from the sales of these products.

Any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates, if approved, or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates, if approved, to healthcare professionals and in geographical regions, including the United States, Europe and Japan, that will not be covered by our own marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates that may be approved, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any approved products outside of the United States a variety of risks associated with international operations could materially adversely affect our business.

If we obtain approval to commercialize any approved products outside of the United States, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Coverage and adequate reimbursement may not be available for our product candidates, if approved, which could make it difficult for us to sell products profitably.

Market acceptance and sales of any product candidates that we develop will depend on coverage and reimbursement policies from third-party payors, such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Adoption of any drug by the medical community may be limited if third-party payers will not offer adequate coverage. In the United States, the principal decisions about reimbursement for new products are typically made by CMS. Private payors tend to follow CMS to a substantial degree. However, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Furthermore, coverage policies and third-party reimbursement rates may change at any time and may be affected by future healthcare reform measures. We cannot be sure that coverage and adequate reimbursement will be available for any future product candidates, if approved. Even if favorable coverage and reimbursement status is attained for one or more of our product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize product candidates that we develop and that may be approved. Thus, even if we succeed in bringing a product to market, it may not be considered medically necessary or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis.

There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for drug products, following approval. The availability of numerous generic treatments may also substantially reduce the likelihood of reimbursement for our future products. We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. For instance, government and private payors who reimburse patients or healthcare providers are increasingly seeking greater upfront discounts, additional rebates and other concessions to reduce prices for pharmaceutical products. If we fail to successfully secure and maintain reimbursement coverage for our future products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our future products and our business will be harmed.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control

the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be priced significantly lower.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct some aspects of our compound formulation, research and pre - clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such formulation, research or testing.

We do not expect to independently conduct all aspects of our drug development activities, compound formulation research or pre-clinical studies of product candidates. We currently rely and expect to continue to rely on third parties to conduct some or all aspects of our pre-clinical studies and formulation development.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the necessary pre-clinical studies to enable us to select viable product candidates for IND submissions and we will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

We rely, or will rely, on third-party manufacturers to produce the supply of our pre - clinical product, clinical product candidates and commercial supplies of any approved product candidates.

Reliance on third-party manufacturers entails risks, including risks that we would not be subject to if we manufactured the product candidates ourselves.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our third-party manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our third-party manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

Other risks of reliance on third-party manufacturers include:

- the inability to meet any product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms;

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for raw materials, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell future product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for any raw materials that are currently purchased from a single source supplier;
- operations of third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products, if approved. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

We rely on limited sources of supply for the drug substance of product candidates and any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

We have established manufacturing relationships with a limited number of suppliers to manufacture raw materials and the drug substance used to create our product candidates. The availability of such suppliers to manufacture raw materials and drug substance for our product candidates in sufficient quantities for evaluation in pre - clinical or clinical studies or, if our product candidates are approved, for commercial supply may be limited. Further, each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and its processes are required to be qualified by the FDA prior to commercialization. If product supply from any manufacturer approved in the NDA is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredients on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

Manufacturing of product candidates and conducting required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order to proceed with any clinical trials and obtain regulatory approval for commercial marketing. We may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical programs and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for product candidates or any approved products.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We currently rely on, and expect to continue to rely on, CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we have limited influence over their actual performance. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our clinical trials are

conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs will not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's or other regulatory agency's GCPs, for conducting, recording and reporting the results of IND-enabling studies and clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA and non-U.S. regulatory agencies enforce these GCPs through periodic inspections of trial sponsors, CROs, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or applicable non-U.S. regulatory agency may require us to perform additional clinical trials before approving any marketing applications for the relevant jurisdiction. Upon inspection, the FDA or applicable non-U.S. regulatory agency may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials require a sufficient number of test subjects to evaluate the safety and effectiveness of a potential drug product. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for such products and any product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We also currently rely on, and expect to continue to rely on, other third parties to package, store and deliver drug products to our clinical trial sites. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to develop and manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. Our patent applications may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all of the potentially relevant prior art relating to patents and patent applications that we use in our business has been found; such prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If the patent applications we hold or patents we have in-licensed with respect to our programs or product candidates fail to issue or if their breadth or strength of protection is threatened, as applicable, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. A patent may be challenged through one or more of several administrative proceedings including post-grant challenges, re-examination or opposition before the United States Patent and Trademark Office ("USPTO") or foreign patent offices. Any successful challenge of patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, in certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding, known as an interference, can be initiated to determine which applicant is entitled to the patent on that subject matter. Such an interference proceeding provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to require us to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license at all, or on commercially reasonable terms. Our defense of a patent or patent application in such a proceeding may not be successful and, even if successful, may result in substantial costs and distract our management.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, however the life of a patent, and the protection it affords is limited. Once the patent life has expired for a product, we may be open to competition from generic medications. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. One of our patents expired in March 2024 and another in July 2025.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, including processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all our employees to assign their inventions to us, and all our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidential information and invention agreements, we cannot provide any assurances that all such agreements have been or will be duly executed or will be enforceable. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

If we fail to obtain licenses or comply with our obligations in these agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various obligations on us.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Our defense in a lawsuit may fail and, even if successful, may result in substantial costs and distract our management. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have or may employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

Other Risks Related to Our Business Operations and Industry

The pausing or termination of government grants by the United States government could have a major effect on the pharmaceutical industry, and as a result, our operations and prospects.

In January 2025, a memo issued by the Office of Management and Budget, had disclosed a freeze on federal loans and grants. That memo has since been rescinded; however, future memos, executive orders or other actions by the government could result in the freeze of existing or new grants, or the termination of previously approved grants. Such actions could have a material adverse effect on the pharmaceutical industry as a whole, a portion of which relies on governmental grants, and as a result, on the Company's operations and prospects.

Inadequate funding, government shutdowns, workforce reductions or other policy changes affecting the FDA, the SEC or other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Our business depends on timely interactions with the FDA, including the review of regulatory submissions, scheduling of formal meetings, and oversight of clinical trials. Disruptions at the FDA and other federal agencies, including substantial leadership departures, personnel cuts, policy changes and those related to the federal government reductions in force or shutdown, may result in reduced staffing or suspension of non-essential FDA operations, which could delay or cancel meetings with the FDA, hinder regulatory guidance, cause delays in the implementation or enforcement of regulatory requirements in a timely fashion or at all, and postpone the review of IND applications, NDAs, and BLAs. These disruptions may also affect the initiation, conduct, and monitoring of clinical trials, particularly those requiring FDA authorization or ongoing regulatory engagement. Interruptions in FDA activities could materially delay our development timelines, increase operational costs, and adversely impact our ability to complete our ongoing and planned clinical trials and to advance product candidates toward approval and commercialization. Any such delays or uncertainties may have a significant negative effect on our business, financial condition, and results of operations.

In addition, government funding of the FDA, SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable, and spending allocation priorities may undergo significant changes through congressional budgeting and appropriations processes. Disruptions at the FDA and other agencies may also extend the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough employees, experience substantial funding cuts and pause or delay critical activities. If a prolonged government shutdown occurs, it could, for example, significantly impact the ability of (i) the FDA and/or the USPTO to review and process regulatory submissions in a timely matter, and (ii) the National Institutes of Health ("NIH") to conduct research or provide grants, all of which could have a material adverse effect on our business.

In addition, future government shutdowns could impact our ability to obtain necessary capital in order to properly capitalize and continue our operations. During such shutdowns, while the SEC's EDGAR system remains operational, the unavailability of the SEC staff to review filings, issue and resolve comments, or declare registration statements effective may delay our ability to complete public offerings and obtain timely regulatory approvals. These delays could impact our access to capital markets, hinder strategic transactions, and create uncertainty around our disclosure obligations. Additionally, the lack of interpretive guidance or exemptive relief during a shutdown may increase legal and compliance risks.

Our future success depends on our ability to attract and retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team, and any reduction or loss of their services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in pre - clinical studies and clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit any executive or key employee or the loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.

We may need to expand our organization and may experience difficulties in managing our growth, which could disrupt our operations.

In the future we may expand our employee base to increase our managerial, scientific, operational, commercial, financial and other resources and we may hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. Moreover, if our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional or nonintentional failures to comply with the regulations of the FDA and non-U.S. regulators, to provide accurate information to the FDA and non-U.S. regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics and business conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, additional reporting requirements and/or oversight, particularly if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance, disgorgement, imprisonment, and contractual damages. Even if we are ultimately successful in defending against any such action, we could be required to divert financial and managerial resources in doing so and adverse publicity could result, all of which could harm our business.

Future relationships with customers and third-party payors as well as certain of our business operations may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, further subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. Remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. A conviction for violation of the Anti-Kickback Statute requires

mandatory exclusion from participation in federal healthcare programs. This statute has been applied to arrangements between pharmaceutical manufacturers and those in a position to purchase products or refer others, including prescribers, patients, purchasers and formulary managers. In addition, the Affordable Care Act amended the Social Security Act to provide that the U.S. government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act penalties for which are described below.

- Federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act ("FCA"), which imposes criminal or civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the federal government, including Medicare or Medicaid, that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false claim or statement.

- The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes civil and criminal penalties for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, which imposes certain requirements on certain types of individuals and entities, such as healthcare providers, health plans and healthcare clearing houses, known as "covered entities," as well as their "business associates," independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, relating to the privacy, security and transmission of individually identifiable health information.

- The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians, physician assistants, certain types of advance practice nurses and teaching hospitals, and further requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties; and

- Many state and foreign law equivalents of each of the above federal laws, such as: anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition, the European Union ("EU") has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC (the "Data Protection Directive"). The European General Data Protection Regulation ("GDPR") contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional

operations in the EU, including potentially conducting pre - clinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including regulation due to the GDPR.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations or laws that apply to us, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, additional reporting requirements and/or oversight, particularly if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our operations and commercial success may be impacted from changes to current regulations and future legislation.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay approval of our products, restrict or regulate post-approval activities, such as sales and promotional activities and expand post-approval requirements. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example:

- changes to manufacturing arrangements;
- additions or modifications to product labeling;
- the recall or discontinuation of products; or
- additional record-keeping requirements.

While we cannot be sure to what extent the trajectory of these legislative and regulatory proposals will be implemented, whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be, any such changes could adversely affect the operation of our business.

In addition, in the United States, existing regulatory policies may change, and additional government regulations may be enacted that could affect pricing and third-party payment for our product candidates, if approved, which could negatively affect our business, financial condition and prospects. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, several healthcare reform initiatives culminated in the enactment of the IRA in 2022, which, among other things, requires HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties.

These provisions have been, and may continue to be, subject to legal challenges. Although full economic effect of the IRA on our business and the pharmaceutical industry in general is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also reduce our profitability. We expect pricing pressures will continue globally.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, which include the FDA and CMS, and related agencies. For example, on May 12, 2025, President Trump issued an Executive Order that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers MFN price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs compete with drugs whose prices were reduced as a result of MFN pricing initiatives.

At the state level, legislatures are increasingly enacting legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, unanticipated adverse effects could result from the use of our future products or product candidates which may result in a potential product liability claim. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We maintain product liability insurance relating to the use of our therapeutics in clinical trials. However, such insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to obtain or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in damage to our reputation and/or subject us to costs, fines or lawsuits.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, supply chain attacks, ransomware attacks, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or inside external organizations on which we rely for support, systems, or hardware. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of business. Maintaining safeguards to comply with evolving security laws and to protect our systems and data may increase our operating costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and a delay in development of our drug candidates.

We have been, and may in the future be, adversely affected by health epidemics and pandemics which may significantly harm our business, prospects, financial condition and operating results.

We face risks related to health epidemics and other outbreaks. For example, during 2020, the spread of the novel coronavirus led to disruption and volatility in the global capital markets. If such disruption and volatility recurs, there could be an increase to our cost of capital and an adverse effect on our ability to access the capital markets. The extent to which a pandemic, epidemic or outbreak of an infectious disease impacts our operations, including our clinical trials, will depend on future occurrences, which are highly uncertain and cannot be predicted with confidence, including the duration of any outbreak and the actions to contain or treat its impact, among others. Any negative impact infectious diseases have on patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Business interruptions could delay us in the process of developing our future products.

We are vulnerable to natural disasters such as earthquakes and wildfires, as well as other events that could disrupt our operations. We do not carry insurance for earthquakes or other natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Risks Related to Being an Israeli Company

Shareholders may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us or our executive officers and directors, or asserting U.S. securities laws claims in Israel.

Service of process upon us in Israel or upon a non-U.S. resident director or officers may be difficult to obtain within the United States and it may be difficult to enforce judgments obtained in the United States against a non-U.S. director or executive officer. In addition, we have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or any officers and directors in Israel.

Moreover, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel or due to, among other reasons, absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel.

The rights and responsibilities of our shareholders are governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.

Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company, such as us, has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards us and other shareholders and to refrain from abusing its power in us, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to our articles of association, an increase of our authorized share capital, a merger, and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from taking advantage of other shareholders. In addition, a controlling shareholder (as defined below), or any shareholder who knows that it possesses the power to determine the outcome of a shareholders' vote, or who has the power to appoint or prevent the appointment of one of our office holders (as defined below), or who holds any other power in our regard, has a duty to act in fairness towards us. However, Israeli law does not define the substance of this duty of fairness. There is limited case law available to assist in understanding the implications of these provisions that govern shareholder behavior.

Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders, and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies, and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the holder of a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to those of our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances, but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred. Additional tax considerations or exemptions from the foregoing may apply to certain non-Israeli tax resident shareholders.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

Risks Related to Ownership of Our ADSs and Ordinary Shares

We do not know whether a market for our securities will be sustained and as a result it may be difficult for shareholders to sell our securities.

Although our ADSs trade on Nasdaq, an active trading market for the ADSs may not be sustained. It may be difficult for shareholders to sell their ADSs without depressing the market price for the ADSs. As a result of these and other factors, shareholders may not be able to sell their ADSs. Further, an inactive market may also impair our ability to raise capital by issuing securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using our equity as consideration.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which may harm our business.

As a publicly traded company, we incur significant legal, accounting, and other expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations, and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations, and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Disclosing deficiencies or weaknesses in our internal controls, failing to remediate these deficiencies or weaknesses in a timely fashion or failing to achieve and maintain an effective internal control environment may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of the ADSs. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

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

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

On April 29, 2024, we received a letter from the Listing Qualifications staff of The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). Pursuant to Nasdaq Rule 5810(c)(3)(A), we had an initial period of one hundred eighty (180) calendar days, or until October 29, 2024, which was subsequently extended a further one hundred eighty (180) calendar days, or until April 28, 2025, to regain compliance with Nasdaq's Minimum Bid Price Requirement. To regain compliance with the Nasdaq Listing Rules, on April 9, 2025, we effected a change in the ratio of ADSs evidencing Ordinary Shares from one (1) ADS representing one (1) Ordinary Share to one (1) ADS representing thirty-five (35) Ordinary Shares. On April 29, 2025, we received a letter from Nasdaq stating that our closing bid price per ADS was at $1.00 or greater for the last 13 consecutive business days. Accordingly, we regained compliance with Listing Rule 5550(a)(2) and the matter was closed.

Nasdaq Listing Rule 5810(c)(3)(A)(iv) states that any listed company that fails to meet the Minimum Bid Price Requirement and has effected a reverse stock split over the prior one-year period, or has effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, will not be eligible for an automatic 180-day grace compliance period and the Nasdaq Listing Qualifications Department is obligated to immediately issue a delisting determination. Therefore, if we were to fall out of compliance with the Minimum Bid Price Requirement prior to April 9, 2026, we would not be able to effect a reverse stock split and would immediately be issued a delisting determination. Further, the Nasdaq rule provides that a company will not be considered to have regained compliance with the Minimum Bid Price Requirement if the company takes an action to achieve compliance (such as a reverse split) and that action results in the Company's security falling below the numeric threshold for another listing requirement.

There can be no assurance that we will be able to maintain compliance with Nasdaq's Minimum Bid Price Requirement for continued listing or other continued listing requirements.

If we fail to meet any of Nasdaq's listing standards, our ADSs will be subject to delisting. If that were to occur, our ADSs would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our ADSs. This would adversely affect the ability of investors to trade our ADSs and would adversely affect the value of our ADSs. Delisting from Nasdaq would cause us to pursue eligibility for trading of our ADSs on other markets or exchanges, or on an over-the-counter market. In such case, our shareholders' ability to trade or obtain quotations of the market value of our ADSs would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices of these securities. There can be no assurance that our ADSs, if delisted from Nasdaq, would be listed on a national securities exchange, a national quotation service or the over-the-counter markets. Delisting from Nasdaq could also result in negative publicity, adversely affect the market liquidity of our ADSs, decrease securities analysts' coverage of us and/or diminish investor, supplier and employee confidence. In addition, our stock could become a "penny stock," which would make trading of our ADSs more difficult.

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

The market price for our ADSs may be volatile.

The market price for our ADSs is likely to be highly volatile and subject to wide fluctuations in response to numerous factors including the following:

- our failure to obtain the approvals necessary to commence clinical trials;
- results of clinical and pre - clinical studies;
- announcements of regulatory approval or the failure to obtain it, or changes or delays in the regulatory review process;
- announcements of new products or product enhancements by us or others;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws, regulations or decisions applicable to our product candidates or patents;
- any adverse changes to our relationship with manufacturers or suppliers;
- announcements concerning our competitors or healthcare industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of or results of, or involvement in, litigation, including, but not limited to, any product liability actions or intellectual property infringement actions;
- any major changes in our board of directors, management or other key personnel;
- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;

- public concern as to the safety of our products that we, our licensors or others develop;
- success of research and development projects;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts;
- future issuances of ordinary shares, ADSs or other securities;
- general market conditions and other factors, including factors unrelated to our operating performance, such as natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency), boycotts, adoption or expansion of government trade restrictions, and other business restrictions; and
- the other factors described in this "Risk Factors" section.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of the ADSs, which would result in substantial losses by our investors. In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of any particular company. These market fluctuations may also have a material adverse effect on the market price of the ADSs.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of our product candidates. In the past, medical, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with such events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs, divert management's attention and resources, and have a material adverse effect on our business, operating results and prospects.

Substantial future sales or perceived potential sales of our ADSs in the public market could cause the price of our ADSs to decline.

Substantial sales of our ADSs on Nasdaq may cause the market price of our ADSs to decline. Sales by us or our security holders of substantial amounts of our ADSs or the perception that these sales may occur in the future, could cause a reduction in the market price of our ADSs. The issuance of any additional ordinary shares or any additional ADSs, or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our ADSs and will have a dilutive effect on our existing shareholders.

Our shareholders may experience substantial dilution as a result of future issuances of our equity securities.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. Pursuant to our equity incentive plan, the Board may grant options to employees, directors and consultants. We may sell ordinary shares represented by ADSs, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, any of which may result in material dilution to our existing shareholders. New investors could also be issued securities with rights superior to those of our existing shareholders.

We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.

We have not paid any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Moreover, the Israeli Companies Law, 5759-1999 (the "Companies Law") imposes certain restrictions on our ability to declare and pay dividends. As a result, investors in our ADSs or ordinary shares will not be able to benefit from owning

these securities unless their market price becomes greater than the price paid by such investors and they are able to sell such securities. We cannot assure you that shareholders will ever be able to resell our securities at a price in excess of the price paid.

If we pay dividends or other distributions, an ADS holder may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, an ADS holder may not receive dividends or other distributions on our ordinary shares and an ADS holder may not receive any value for them, if it is illegal or impractical to make them available to such ADS holder.

The depositary for the ADSs has agreed to pay to the ADSs holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. ADS holders will receive these distributions, if any, in proportion to the number of ordinary shares their ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that holders of ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, holders of ADSs may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to such holders. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the depositary to exercise their rights.

Holders of ADSs do not have the same rights as holders of our ordinary shares and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law and our articles of association, the minimum notice period required to convene a shareholders meeting is not less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of the ADSs may not receive sufficient notice of a shareholders meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested.

Holders of ADSs may be subject to limitations on the transfer of their ADSs.

ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We depend on a variety of information systems and technologies (including cloud technologies) to manage our business. We maintain a cyber risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats.

The underlying processes and controls of our cyber risk management program incorporate recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology ("NIST") Cybersecurity Framework ("CSF"). We have undertaken, to conduct an annual assessment of our cyber risk management program and controls to identify, quantify, and categorize material cyber risks. In addition, we have developed a risk mitigation plan to address such risks, and where necessary, remediate potential vulnerabilities identified through the annual assessment process.

In addition, we maintain policies over areas such as information security, access on/offboarding, and access and account management, to help govern the processes put in place by management designed to protect our IT assets, data, and services from threats and vulnerabilities. Our cybersecurity risk management strategy and infrastructure includes maintenance of an IT assets inventory, periodic vulnerability scanning, identity access management controls including restricted access of privileged accounts, network integrity safeguarded by employing web-based software, industry-standard encryption protocols, critical data backups, infrastructure maintenance, incident response, cybersecurity strategy, and cyber risk advisory, assessment and remediation.

Our management team is responsible for oversight and administration of our cyber risk management program, and for informing our Board and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. Our management team relies on threat intelligence as well as other information obtained from governmental, public, or private sources, including external consultants who may be engaged by us for strategic cyber risk management, advisory and decision making. To the extent we utilize third-party vendors to provide information technology services for various areas, including human resources functions (e.g., payroll), we generally require these vendors to monitor and protect their information technology systems against cyber-attacks and other breaches. The Audit Committee of the Board of Directors oversees our cybersecurity risk exposures and the steps taken by management to monitor and mitigate cybersecurity risks. Member(s) of management brief the Audit Committee on cyber vulnerabilities identified through the risk management process, the effectiveness of our cyber risk management program, and the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on our processes to prevent, detect, and mitigate cybersecurity incidents.

We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. We acknowledge that the risk of cyber incident is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of our business. To date, we have not had a cybersecurity incident. We proactively seek to detect and investigate unauthorized attempts and attacks against our IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to service delivery; however, potential vulnerabilities to known or unknown threats will remain. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject us to additional liability and reputational harm. See Item 1A. "Risk Factors" for more information on cybersecurity risks.

Item 2. Properties

We do not own any property, and we do not have any contracts or options to acquire or lease any property in the future. We are operating out of a virtual office, which is adequate for our present and planned future operations, as our corporate staff has been working remotely.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our ADSs are currently listed on The Nasdaq Capital Market under the symbol "QNRX," with each ADS representing thirty - five (35) ordinary shares.

Holders

As of March 23, 2026, our ADSs were held by 15 holders of record, and our ordinary shares were held by 5 holders of record. The Bank of New York Mellon ("BNY") is the depositary for our ADR program, and Computershare Trust Company, N.A. is our transfer agent. The number of record holders was determined from the records of our depositary and transfer agent and does not include beneficial owners of ADSs or ordinary shares whose shares are held in the names of various securities brokers, dealers and registered clearing agencies.

Dividends

We have never declared or paid any dividends on our ordinary shares. We do not anticipate paying any dividends in the foreseeable future. We currently intend to retain future earnings, if any, to finance operations and expand our business. Our board of directors has sole discretion whether to pay dividends. If our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our directors may deem relevant. The Companies Law imposes restrictions on our ability to declare and pay dividends.

Equity Compensation Plan Table

The information included in our Equity Compensation Plan Table under Item 12 of Part III of this Annual Report is hereby incorporated by reference into this Item 5 of Part II of the Annual Report.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes to those statements included in this Annual Report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Important factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in Part I, Item 1A. "Risk Factors" and the section entitled "Cautionary Note Regarding Forward-Looking Statements and Summary of Risk Factors."

Overview

We are a late-stage clinical specialty pharmaceutical company focused on the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently either no approved or very limited treatments or cures. Our lead product, QRX003, is under clinical development as a potential treatment for Netherton Syndrome, a rare hereditary genetic disease. QRX003 is entering pivotal registrational clinical testing under an open IND application with the FDA. We have opened six clinical sites in the U.S. along with international sites that are being opened in the UK, Spain, France and the Netherlands. QRX003 is currently being tested in seven pediatric NS patients in investigator-initiated studies in Ireland, Austria, the Netherlands and New Zealand. QRX003 is also being developed as a potential treatment for Peeling Skin Syndrome with the first subject being treated in New Zealand. We are in the process of expanding this study to include up to an additional five pediatric subjects. We entered into a Research Agreement with QUT, under which we have obtained an option for a global license to QRX008 for the potential treatment of scleroderma, as well as a Research Agreement with UCC for the development of novel topical formulations of rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are either limited or no approved therapies or cures, including microcystic lymphatic malformations, venous malformations and angiofibromas among others. We have also entered into 9 commercial partnerships for QRX003 spanning 61 countries outside of our core commercial territories of the U.S., Western Europe and Japan. These partnership countries include Canada, Australia, New Zealand, the Middle East, China, Taiwan, Hong Kong Singapore, Israel, Central and Eastern Europe, Turkey as well as several countries in Latin America.

Our mission is to develop and commercialize proprietary therapeutic drug products that treat rare and orphan diseases, particularly for those diseases where no approved treatment currently exists. To achieve this, we plan to:

- complete the late-stage clinical testing of QRX003 in NS and, if successful, file for marketing approval in the United States, Europe, Japan and the other territories for which we have commercial agreements in place;
- prepare to commercialize QRX003 by (i) establishing our own sales infrastructure in the U.S., Europe, and Japan and e(ii) work with our distribution partners to commercialize the product in Canada, Australia/New Zealand, the Middle East, China, Hong Kong, Taiwan, Latin America, Central and Eastern Europe, Turkey and Singapore;
- continue the development of QRX003 for Peeling Skin Syndrome and related rare, genetic skin diseases;
- commence clinical testing of one or more selected formulations of topical rapamycin; 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.

To date, no products have been commercialized and no revenue has been generated. 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. We will need to obtain further funding through public or private offerings of our capital stock, debt financing, pursuant to the exercise of warrants issued to investors in our prior public and private offerings, collaboration, strategic and/or licensing arrangements or other sources in order to complete the research and development of our product candidates and to fund our other operating requirements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. In addition, any exercise of our outstanding warrants is at the discretion of the warrant holders and is dependent, in part, upon the market price of our ADSs. There can be no assurance that any of our outstanding warrants will ever be in-the-money prior to their expiration and, as such, our outstanding warrants may expire without being exercised. Our failure to obtain additional funding 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".

Recent Developments

ADS Ratio Change

Effective April 9, 2025, the ratio of ADSs evidencing our Ordinary Shares, changed from 1 ADS representing one (1) Ordinary Share to 1 ADS representing thirty-five (35) Ordinary Shares (the "Ratio Change"), which resulted in a 1-for-35 reverse split of the issued and outstanding ADSs (the "Reverse Split"). Our Ordinary Shares were not affected by this adjustment.

Except as specifically provided, ADSs and related option, warrant, purchase price and exercise price information presented in this Annual Report, including our consolidated financial statements and the related notes, has been retroactively adjusted to reflect the Ratio Change and the Reverse Split.

Increase in Authorized Capital

On August 21, 2025, at our 2025 Annual General Meeting of Shareholders (the "2025 Annual Meeting"), our shareholders approved an amendment to our articles of association to increase our authorized Ordinary Share capital from 100,000,000 Ordinary Shares to 5,000,000,000 Ordinary Shares.

Public and Private Offerings

March 2024 Offering. On March 7, 2024, we completed an offering (the "March 2024 Offering") of the following securities (i) 811,250 ordinary shares represented by 23,179 ADSs, (ii) Series D warrants (the "Series D Warrants") to purchase 4,062,500 ordinary shares represented by 116,071 ADSs, (iii) Series E warrants (the "Series E Warrants") to purchase 4,062,500 ordinary shares represented by 116,071 ADSs, and (iv) Pre-funded warrants (the "March 2024 Pre-Funded Warrants") to purchase 3,251,255 ordinary shares represented by 92,893 ADSs for aggregate gross proceeds of approximately $6.5 million, resulting in net proceeds of approximately $5.5 million, after deducting the placement agent's fees and offering expenses paid by us. Each ADS (or March 2024 Pre-Funded Warrant to purchase one ADS in lieu thereof) was sold together with a Series D Warrant to purchase one ADS and a Series E Warrant to purchase one ADS. The ADSs and accompanying Series D Warrants and the Series E Warrants were sold at a combined public offering price of $56 and the March 2024 Pre-Funded Warrants and accompanying Series D Warrants and the Series E Warrants were sold at a combined public offering price of $55.9965, which is equal to the combined purchase price per ADS and accompanying Series D Warrants and the Series E Warrants, minus the exercise price of each March 2024 Pre-Funded Warrant of $0.0035. As of December 31, 2024, all March 2024 Pre-Funded Warrants had been exercised and were included in issued and outstanding ADSs. The Series D Warrants and the Series E Warrants have an exercise price of $56 per share, were exercisable immediately following the closing of the March 2024 Offering and expire in two years and five years, respectively, from the closing of the March 2024 Offering.

On March 7, 2024, we also entered into privately negotiated agreements with the holders of certain existing outstanding warrants to purchase up to 18,252 ADSs to, among other things, reduce the exercise price of such warrants to $56 and to extend the expiration date of such warrants until March 7, 2029. The incremental fair value of the modified warrants was approximately $209,000, which was accounted for as an offering expense in connection with the March 2024 Offering.

December 2024 Offering. On December 23, 2024, we completed an offering (the "December 2024 Offering" and, together with the March 2024 Offering, the "2024 Offerings") of the following securities (i) 3,137,778 ordinary shares represented by 89,651 ADSs, (ii) Series F warrants (the "Series F Warrants") to purchase 15,111,110 ordinary shares represented by 431,746 ADSs, (iii) Series G warrants (the "Series G Warrants" and together with the Series F Warrants, the "December 2024 Warrants") to purchase 15,111,110 ordinary shares represented by 431,746 ADSs, and (iv) Pre-funded warrants (the "December 2024 Pre-Funded Warrants") to purchase 11,973,332 ordinary shares represented by 342,095 ADSs for aggregate gross proceeds of approximately $6.8 million, resulting in net proceeds of approximately $5.8 million, after deducting the placement agent's fees and offering expenses paid by us. Each ADS (or December 2024 Pre-Funded Warrant to purchase one ADS in lieu thereof) was sold together with a Series F Warrant to purchase one ADS and a Series G Warrant to purchase one ADS. The ADSs and accompanying Series F Warrants and Series G Warrants were sold at a combined public offering price of $15.75 and the December 2024 Pre-Funded Warrants and accompanying Series F Warrants and Series G Warrants were sold at a combined public offering price of $15.7465, which is equal to the combined purchase price per ADS and accompanying Series F Warrants and Series G Warrants, minus the exercise price of each December 2024 Pre-Funded Warrant of $0.0035. The Series F Warrants and the Series G Warrants have an exercise price of $15.75 per share, were exercisable immediately

upon issuance and expire in two years and five years, respectively, from the closing of the December 2024 Offering. Durin 2025, certain investors in our December 2024 Offering exercised (i) the remaining outstanding 320,362 December 2024 Pre-Funded Warrants, (ii) 199,619 Series F Warrants and 23,182 Series G Warrants, resulting in net proceeds of approximately $3.5 million. As of December 31, 2025, all of the December 2024 Pre-Funded Warrants have been exercised and are included in issued and outstanding ADSs.

Certain of our officers and directors purchased an aggregate of 38,095 ADSs and accompanying December 2024 Warrants to purchase 76,190 ADSs, for a total purchase price of approximately $600,000, at the public offering price and on the same terms as the other purchasers in the December 2024 Offering.

On December 20, 2024, we also entered into privately negotiated agreements with the holders of certain existing outstanding warrants to purchase up to 200,071 ADSs to, among other things, reduce the exercise price of such warrants to $15.75 and to extend the expiration date of such warrants until December 23, 2029. The incremental fair value of the modified warrants was approximately $1.5 million, which was accounted for as an offering expense in connection with the December 2024 Offering.

October 2025 Private Placement. On October 10, 2025, we entered into the October 2025 Purchase Agreement with several institutional and accredited investors relating to the issuance and sale in a private placement transaction (the "October 2025 Private Placement") of (i) 530,320 ordinary shares represented by 15,152 ADSs and (ii) Pre-funded warrants to purchase 69,787,865 ordinary shares represented by 1,993,939 ADSs (the " October 2025 Pre-Funded Warrants"), together with (A) Series H Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series H Warrants"), (B) Series I Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series I Warrants"), (C) Series J Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series J Warrants"), and (D) Series K Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series K Warrants" and, together with the Series H Warrants, Series I Warrants, and Series J Warrants, the "October 2025 Ordinary Warrants"). The combined purchase price was $8.25 per each ADS and accompanying October 2025 Ordinary Warrants and $8.2499 per each October 2025 Pre-Funded Warrant and accompanying October 2025 Ordinary Warrants, which pricing was designed to be in accordance with the "Minimum Price" requirement as defined in the Nasdaq rules. The October 2025 Private Placement closed on October 14, 2025 (the "October 2025 Closing Date"). We received upfront net proceeds of approximately $15 million from the October 2025 Private Placement, after deducting estimated offering expenses payable by us, including placement agent fees and expenses. We intend to use the upfront net proceeds from the October 2025 Private Placement for general corporate purposes, which may include operating expenses, research and development, including completion of clinical development of QRX003 for Netherton Syndrome, working capital, future acquisitions and general capital expenditures. We may also receive up to an aggregate of $88 million of additional gross proceeds if the October 2025 Ordinary Warrants are exercised in full for cash. As of December 31, 2025, 684,348 of the October 2025 Pre-funded Warrants have been exercised and are included in issued and outstanding ADSs and all of the October 2025 Ordinary Warrants were outstanding.

Dennis Langer, one of our directors, participated in the October 2025 Private Placement. Mr. Langer purchased 530,320 ordinary shares represented by 15,152 ADSs and accompanying October 2025 Ordinary Warrants for a total purchase price of approximately $128,641, at a combined purchase price of $8.49 per ADS and accompanying October 2025 Ordinary Warrants. In accordance with Nasdaq Rules, Mr. Langer's purchase price was based upon the consolidated closing bid price from the trading day immediately preceding the date we entered into the October 2025 Purchase Agreement, plus $0.50.

Description of October 2025 Pre-Funded Warrants and October 2025 Ordinary Warrants

Beneficial ownership limitation. A holder of the October 2025 Pre-Funded Warrants or October 2025 Ordinary Warrants may not exercise any portion of such holder's October 2025 Pre-Funded Warrants or October 2025 Ordinary Warrants for ADSs to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% of the number of ordinary shares outstanding immediately after giving effect to the issuance of the ordinary shares represented by the ADSs issuable upon exercise of the applicable warrant.

October 2025 Pre-Funded Warrants. The October 2025 Pre-Funded Warrants have an exercise price of $0.0001 per ADS. The October 2025 Pre-Funded Warrants are exercisable at any time after their original issuance, subject to the beneficial ownership limitation (as described above) and will not expire until exercised in full. In addition, the October 2025 Pre-Funded Warrants may be exercised, in whole or in part, any time after issuance by means of a cashless exercise.

October 2025 Ordinary Warrants. The October 2025 Ordinary Warrants are exercisable at any time after their original issuance, subject to the beneficial ownership limitation (as described above). The Series H Warrants have an exercise price of $9.075 per ADS and, pursuant to the terms of the Series H Warrants, such warrants may be exercised until the earlier of (i) five (5) years from the October

2025 Closing Date or (ii) 30 days after the public announcement that we have received Type C meeting minutes from the FDA indicating openness to baseline-controlled pivotal studies for QRX003 for the treatment of Netherton Syndrome. As a result of the March Type C Meeting Minutes, the Company has determined that the Series H Warrants will remain exercisable until five (5) years from the October 2025 Closing Date. The Series I Warrants have an exercise price of $10.3125 per ADS and, pursuant to the terms of the Series I Warrants, such warrants may be exercised as follows: (i) 50% of the Series I Warrants may be exercised until the earlier of (A) five (5) years from the October 2025 Closing Date or (B) 30 days after the public announcement that the primary endpoint has been met in the monotherapy pivotal trial of QRX003 for the treatment of Netherton Syndrome, and (ii) 50% of the Series I Warrants may be exercised until the earlier of (A) five (5) years from the October 2025 Closing Date or (B) 30 days after the public announcement that the primary endpoint has been met in the adjuvant pivotal trial of QRX003 for the treatment of Netherton Syndrome. The Series J Warrants have an exercise price of $12.375 per ADS and, pursuant to the terms of the Series J Warrants, such warrants may be exercised until the earlier of (i) five (5) years from the October 2025 Closing Date or (ii) 30 days after the public announcement of the receipt of either accelerated or traditional approval by the FDA of QRX003 for the treatment of Netherton Syndrome. The Series K Warrants have an exercise price of $12.375 per ADS and, pursuant to the terms of the Series K Warrants, such warrants may be exercised until the earlier of (i) five (5) years from the October 2025 Closing Date or (ii) 30 days after the public announcement of the sale of a Priority Review Voucher (PRV).

Series H Warrants Exercise

On January 8, 2026, the Company received $0.2 million from the exercise of 25,000 Series H warrants issued in the October 2025 Private Placement.

Components of Our Results of Operations

Operating Expenses

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

Research and Development Expenses

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

Future research and development expenses may include:

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

Research and development activities will continue to be central to our business plan. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to be significant over the next several

years as personnel and compensation costs increase and we conduct late-stage clinical studies and prepare to seek regulatory approval for QRX003 and any other future product candidate.

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and employee - related expenses including non-cash stock-based compensation, professional fees and other corporate expenses. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities. These increases will likely include compensation and employee-related expenses including stock-based compensation, increased costs related to the potential hiring of personnel, travel costs and fees to outside consultants, lawyers and accountants.

Other Expenses (income)

Other expenses (income) consist primarily of interest income and unrealized loss (gain) on investments.

Results of Operations - Year ended December 31, 2025 compared to Year ended December 31, 2024

The following table sets forth our results of operations for the year ended December 31, 2025 compared to the year ended December 31, 2024:

	Year ended December 31,		
	2025	2024	Change
Operating Expenses			
General and administrative	$ 6,487,909	$ 5,925,833	$ 562,076
Research and development	9,802,807	3,602,632	6,200,175
Total operating expenses	16,290,716	9,528,465	6,762,251
Other (income) and expenses			
Unrealized gain	(3,980)	(7,502)	3,522
Realized and accrued interest income	(482,081)	(558,491)	76,410
Total other income	(486,061)	(565,993)	79,932
Net loss	$ (15,804,655)	$ (8,962,472)	$ (6,842,183)

General and Administrative Expenses

General and administrative expenses were approximately $6,488,000 and $5,926,000, in the year ended December 31, 2025 and 2024, respectively, representing an increase of $562,000, or 9.5%. The increase was primarily due to an increase in public company expenses of $215,000; legal fees of $117,000; marketing expenses of $114,000; consulting expenses of $105,000 and other (primarily corporate taxes) of $163,000; and increase in payroll and benefits of $63,000 offset by decreases in board cash fees expense of $142,000 and lower insurance costs by $77,000.

Research and Development Expenses

Our research and development (R&D) expenses during the years ended December 31, 2025 and 2024 were approximately $9,803,000 and $3,603,000, respectively, representing an increase of $6,200,000, or approximately 172%. The increase was primarily due to an increase of $6,094,000 worth of expenditures on our development programs, including work related to the clinical studies for the development of QRX003, manufacturing costs for material used in our clinical studies an increased allocation of internal compensation and travel costs to our research and development programs. The increase also included approximately $106,000 in non-cash stock-based compensation expense. We expect to continue 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 Commitments” below. Amortization of intangible assets was approximately $100,000 and $100,000 in each of the years ended December 31, 2025 and 2024.

Other Expenses:

Interest and financing expense

We earned approximately $482,000 in interest income and approximately $4,000 in unrealized gain and earned approximately $558,000 in interest income and approximately $7,500 in unrealized gain, in the year ended December 31, 2025 and December 31, 2024, respectively, from our cash and cash equivalents and investments in marketable debt securities. The decrease in interest income in the year ending December 31, 2025 is the result of lower average aggregate cash and investment balances and a decrease in interest rates.

Liquidity and Capital Resources

We have incurred net losses every year since inception. We have a limited operating history and have historically funded our operations through our founders’ funding expenditures and debt and equity financings. At December 31, 2025, the Company had cash balances totaling $3.8 million and investments of $14.9 million. 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. Based upon our current business plans and cash, cash equivalents and investments on hand, we have concluded that there is substantial doubt

about our ability to continue as a going concern for a period of at least one year from the issuance of the audited consolidated financial statements included in this report. In order to address our capital needs, we intend to consider multiple alternatives, including, but not limited to, the sale of additional equity or debt securities or other debt instruments, collaborative, strategic and/or licensing relationships or grants to support our future operations. 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. We will need to obtain further funding through public or private offerings of our capital stock, debt financing, pursuant to the exercise of warrants issued to investors in our prior public and private offerings, collaboration, strategic and/or licensing arrangements or other sources in order to complete the research and development of our product candidates and to fund our other operating requirements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. In addition, any exercise of our outstanding warrants is at the discretion of the warrant holders and is dependent, in part, upon the market price of our ADSs. There can be no assurance that any of our outstanding warrants will ever be in-the-money prior to their expiration and, as such, our outstanding warrants may expire without being exercised. If we are unable to improve our liquidity position, we may not be able to continue as a going concern.

We continue to seek sources of financing to fund our continued operations and research and development programs. To raise additional capital, we may sell additional equity or debt securities, or enter into collaborative, strategic, and/or licensing transactions. There can be no assurance that we will be able to complete any financing transaction in a timely manner or on acceptable terms or otherwise enter into a collaborative or strategic transaction. 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 or cease operations altogether, all of which could have a material adverse effect on our business, results of operations and financial condition.

Future Funding Requirements

We will need to obtain further funding through public or private offerings of our capital stock, debt financing, pursuant to the exercise of warrants issued to investors in our prior public and private offerings, collaboration, strategic and/or 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, pre-clinical 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;
- the market price of our ADSs; and
- the costs associated with being a public company.

Adequate additional funding may not be available to us on acceptable terms, or at all. In addition, restrictions under the October 2025 Purchase Agreement may limit our ability to raise capital. See "Risk Factors ─The terms of our October 2025 private placement may make it difficult for us to procure additional financing" for more information. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of QRX003, any future product candidate, or potentially discontinue operations.

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

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or proposed products, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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 – Year ended December 31, 2025 compared to Year ended December 31, 2024

As of December 31, 2025, we had approximately $18,745,000 in cash and investments in marketable securities. The table below presents our cash flows for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
	2025	2024
Net cash used in operating activities	$ (13,540,994)	$ (7,857,309)
Net cash used in investing activities	(4,277,775)	(1,888,282)
Net cash provided by financing activities	18,014,135	10,967,736
Effect of foreign exchange rate on changes on cash	(613)	—
Net change in cash and cash equivalents	$ 194,753	$ 1,222,145

Operating Activities

Net cash used in operating activities was approximately $13,541,000 and $7,857,000 for the year ended December 31, 2025 and 2024, respectively. The increase for the year ended December 31, 2025 was primarily due to a higher net operating loss driven by higher R&D expenditures offset by an increase in accounts payable and accrued expenses.

Investing Activities

Net cash used in investing activities was approximately $4,278,000 and $1,888,000 in the year ended December 31, 2025 and 2024, respectively, with the change in each period consisting of net proceeds from maturity and purchases of short maturity US Treasury Bills and Notes.

Financing Activities

Net cash provided by financing activities was approximately $18,014,000 for the year ended December 31, 2025, consisting of approximately $18,614,000 in net proceeds from the October 2025 Private Placement and warrant exercises, partially offset by repayments of amounts due to officers of $600,000. Net cash provided by financing activities was approximately $10,968,000 for the year ended December 31, 2024, consisting of approximately $11,568,000 in net proceeds from the 2024 Offerings, partially offset by repayments of amounts due to officers of $600,000.

Research and Development Commitments

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

In November 2020, Quoin Inc. entered into a Master Service Agreement with Therapeutics Inc. for the management of the pre-clinical and clinical development of QRX003 for Netherton Syndrome. The initial term of the agreement was three years with automatic one-year extensions, and the agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. A work order was entered into in June 2022 for the first QRX003 clinical study at an expected estimated cost of approximately $4.4 million through 2024. An additional change order was entered into in December 2022 for a second QRX003 clinical study at an expected estimated cost of approximately $830,000. An amended and restated change order for the two studies was entered into in December 2024 at an estimated total remaining cost from August 2024 of approximately $3.6 million for the two studies combined. In the years ended December 31, 2025 and 2024, we incurred research and development costs under these agreements of approximately $2.1 million and $1.1 million, respectively. During the year ended December 31, 2024, we received a credit of approximately $83,000 applied to prior expenses incurred during the period of January 2024 to March 2024.

In November 2021, we entered into a research agreement with QUT for a pre-clinical research program for the development of a product to treat Netherton Syndrome of approximately $250,000. In May 2022, we entered into a second research agreement with QUT for the development of a product to treat Scleroderma of approximately $610,000. Each agreement remains in place until the completion of the research program, which in each case was initially anticipated to be 18 months from execution. For the years ended December 30, 2025 and 2024, we did not incur any costs related to these agreements. In July 2025 we announced that, in light of the expected near-term completion of the QRX003 clinical program for Netherton Syndrome, we have discontinued Netherton Syndrome research program with QUT. We are planning to schedule a meeting with QUT to discuss the future direction of the Scleroderma research program.

In June 2024, we entered into a research agreement with The School of Pharmacy at UCC. The scope of the agreement encompasses the development of novel topical formulations of Rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are currently very limited or no approved therapies or cures. Under the terms of the agreement, based on the achievement of certain milestones, we will fund up to approximately €567,000 ($664,000) plus VAT over an anticipated 2-1/2 year period to support the UCC research program to investigate the development of a number of topical rapamycin formulations for future development as potential treatments for several rare and orphan diseases. Following completion of the research program, we will have the option to advance the clinical development of rapamycin formulations developed by UCC. Work on this research project commenced in December 2024. For the years ended December 31, 2025 and December 31, 2024, we incurred a research and development expense under these agreements of approximately $0.3 million and de-minimis respectively. On November 11, 2025 we announced that the target loading concentrations for two topical rapamycin delivery technologies have been successfully achieved. Specifically, a rapamycin loading concentration of 4% w/w has been achieved for our proprietary topical formulation while an even higher rapamycin concentration of 5% w/w has been formulated in a proprietary dermal patch system.

Critical Accounting Estimates

Critical accounting estimates 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 estimates relate to:

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. We accrue 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, we may also record payments made to those providers as prepaid expenses that will be recognized as expenses in future periods as the related services are rendered.

Stock based compensation

We recognize compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model. We account for forfeitures as they occur. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

Since we have a limited history of trading as a public company, our expected stock volatility is based on a weighting of its historical volatility along with a group of a publicly traded set of peer companies. We utilize 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 we have not paid dividends since our inception and do not anticipate paying dividends in the foreseeable future.

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.

We assess 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.

We recognize 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 year ended December 31, 2025 there was no impairment indicator which required an impairment loss measurement. During the year ended December 31, 2024, there was no impairment indicator which required an impairment loss measurement.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 7A.

Item 8. Financial Statements and Supplementary Data

The information required by this Item is set forth in the consolidated financial statements and notes thereto in Item 15 of Part IV of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures, which are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation, as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15e under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, are responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are made only in accordance with authorizations of our management and board of directors (as appropriate); and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Due to its inherent limitations, any system of internal control over financial reporting, no matter how well defined, may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the framework set forth in Internal Control — Integrated Framework by The Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). Based on this assessment using this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting because Quoin Pharmaceuticals Ltd. is not an accelerated filer or a large accelerated filer, and it is not subject to the attestation requirement.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act), that occurred during the quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the fourth quarter of 2025, none of our directors or executive officers adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as each term is defined in Item 408(a) of Registration S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Set forth below is certain information regarding the members of our board of directors (the "Board" or the "Board of Directors") and our executive officers.

Name	Age	Position(s)
Dr. Michael Myers	64	Chairman of the Board and Chief Executive Officer
Denise Carter	57	Director and Chief Operating Officer
Joseph Cooper[1][3]	68	Director
James Culverwell[2]4]	69	Director
Dr. Dennis H. Langer[5]	74	Director
Natalie Leong[1][6]	41	Director
Michael Sember[2]	76	Director
Sally Lawlor	43	Chief Financial Officer

(1) Member of our Audit Committee.

(2) Member of our Compensation Committee.

(3) Member of our Nominating and Governance Committee.

(4) Chairperson of our Audit Committee

(5) Chairperson of our Compensation Committee

(6) Chairperson of our Nominating and Governance Committee

Set forth below is a summary of the business experience of each of our directors and executive officers.

Dr. Michael Myers, *Chief Executive Officer and Director*. Dr. Myers is the co-founder of Quoin Inc. and has served as Chairman and Chief Executive Officer of Quoin Inc. since its inception in 2018. Dr. Myers has served as Chairman and Chief Executive Officer of Quoin Ltd. since October 28, 2021. Dr. Myers has over 36 years of industry experience in the drug delivery and specialty pharmaceutical sectors. From 2003 to October 2015, he served as Chief Executive Officer of Innocoll AG (n/k/a Innocoll Biotherapeutics N.A. Inc.), a biotherapeutics pharmaceutical company, and was responsible for taking that company public in 2014. From 2001 to 2002, he served as President of the drug delivery division of West Pharmaceutical Services, Inc., a publicly traded company and a designer and manufacturer of injectable pharmaceutical packaging and delivery systems. From 1996 to 1999, Dr. Myers served as the President of Pharmaceutical Operations for Fuisz Technologies (Biovail), a developer of food and drug delivery systems and technologies. From 2000 to 2001, Dr. Myers served as Executive Vice President and Chief Commercial Officer of Flamel Technologies (n/k/a Avadel Pharmaceuticals PLC, a publicly traded company and a specialty pharmaceutical company. From 1987 to 1995, Dr. Myers served as the Head of Pharmaceutical Development for Elan Corporation, a biotechnology drug company. Since 2019, Dr. Myers has served as a director of Sonoran Bioscience and Wellesley Pharmaceuticals, each a specialty pharmaceutical company. Dr. Myers has served as a director of Cranial Devices, a clinical stage medical device company since 2023. Dr. Myers earned his Ph.D. in Chemistry from University College Cork, Ireland. We believe Dr. Myers is qualified to serve on our Board due to his extensive knowledge as one of Quoin Inc.'s co-founders and Chief Executive Officer, and his extensive clinical development, commercial and management experience with both public and private life sciences companies.

Denise Carter, *Chief Operating Officer and Director*. Ms. Carter is the co-founder of Quoin Inc. and has served as a director and Chief Operating Officer of Quoin Inc. since its inception in 2018. Ms. Carter has served as a director and Chief Operating Officer of Quoin Ltd. since October 28, 2021. Ms. Denise Carter has over 30 years of experience in the drug delivery and specialty pharmaceutical industries. From June 2003 to October 2015, Ms. Carter held various positions at Innocoll AG (n/k/**a**

Innocoll Biotherapeutics N.A. Inc.), including President of Innocoll Pharmaceuticals and Executive Vice President of Business Development and Corporate Affairs of Innocoll AG. From 2001 to 2003, Ms. Carter was the Vice President of Business Development of the drug delivery division of West Pharmaceuticals, Inc., a publicly traded company. From 2000 to 2001, she was the Senior Director of Business Development of Eurand, a specialty pharmaceutical company. From 1996 to 1999, Ms. Carter was the Director of Business Development and Alliance Management of Fuisz Technologies (Biovail). From 1999 to 2000, Ms. Carter was the Director of Business Development of Cardinal Health, Inc., a multi-national health care service company. Ms. Carter earned her MBA from Wharton School of Business, University of Pennsylvania and a B.S. in Chemistry from the College of William and Mary. We believe Ms. Carter is qualified to serve on our Board due to her extensive knowledge as one of Quoin Inc.'s co-founders and Chief Operating Officer, and her extensive business development, sales and marketing and fundraising experience in the life sciences industry.

Sally Lawlor, *Chief Financial Officer.* Ms. Lawlor has served as Chief Financial Officer of Quoin Ltd. since August 18, 2025 and has 20 years of experience in financial leadership roles in public and private companies as well as a "Big Four" accounting firm. Ms. Lawlor served as both Senior Director – Group Tax (from January 2023 through August 2025) and Director – Group Tax (December 2021 through January 2023) at Sebela Pharmaceuticals Inc., a pharmaceutical company delivering therapeutic options for gastrointestinal diseases and with a focus on innovation in women's health. In her most recent role at Sebela Pharmaceuticals, Ms. Lawlor managed financial reporting under U.S. GAAP and IFRS, oversaw global tax planning and compliance, as well as budgeting, forecasting, and external audits. Prior to Sebela, from December 2017 through September 2021, Ms. Lawlor served in senior tax leadership positions at Aptiv Plc, a global technology company that designs, develops and manufactures software and hardware solutions to enable a safer, greener and more connected future of mobility. Prior thereto, Ms. Lawlor spent eleven years at KPMG advising multinational clients, primarily in the pharmaceutical and technology sectors. Ms. Lawlor is a Fellow of Chartered Accountants Ireland and a member of the Irish Taxation Institute. She earned her Bachelor of Common Law from University College Cork. Ms. Lawlor is the niece of Dr. Michael Myers, the Company's Chairman and Chief Executive Officer.

Joseph Cooper, *Director*. Mr. Cooper has served as a director of Quoin Inc. since May 2021. Mr. Cooper has served as a director of Quoin Ltd. since October 28, 2021. Mr. Cooper has significant experience in finance, operation, corporate development and general management roles within the pharmaceutical and healthcare industry. Since July 2023, Mr. Cooper has served as Chief Financial Officer for Hydrinity Skin Sciences, a medical aesthetics company. From 2012 to 2023, Mr. Cooper served as the President of Boulder Cove LC, a pharmaceutical and healthcare consulting company. From September 2019 to December 2022, Mr. Cooper served as the Chief of Strategy and Corporate Development for Resonea, Inc., a digital health company. From August 2018 to December 2019, Mr. Cooper served as the Chief Business Officer of NuvOx Pharmaceuticals, a clinical stage pharmaceutical company. From January 2015 to August 2018, Mr. Cooper served as Chief Financial and Operating Officer for First Place, AZ, a non-profit healthcare services organization. From 1996 to 2010, Mr. Cooper served as the Executive Vice President of Corporate and Product Development of Medicis Pharmaceutical Corp., a publicly traded pharmaceutical and medical aesthetics company. Since January 2018, Mr. Cooper has served as a director of Sonoran Biosciences, a specialty pharmaceutical company. From 2006 to 2007, Mr. Cooper served as a director of Bioenvision, a publicly traded pharmaceutical company. Mr. Cooper holds an MBA from the WP Carey School of Business at Arizona State University and a BA from Northeastern Illinois University. We believe Mr. Cooper is qualified to serve on our Board due to his extensive executive and board experience with pharmaceutical and healthcare companies.

James Culverwell, *Director*. Mr. Culverwell has served as a director of Quoin Inc. since April 2021. Mr. Culverwell has served as a director of Quoin Ltd. since October 28, 2021. Since May 2013, Mr. Culverwell has served as the Chief Executive Officer and is currently Chairman of the Board of Directors of HOX Therapeutics, a prostate cancer research company. In 2005, Mr. Culverwell founded Sudbrook Associates, which provided strategic advice and fund raising services for life science companies. From 1992 to 2004, Mr. Culverwell was Senior Vice President and Global Coordinator Healthcare Research at Merrill Lynch. From 1982 to 1992, Mr. Culverwell was Director of Healthcare Equity Research at ABN Amro Bank N.V., a private banking company. Since February 2022, Mr. Culverwell has served as a director and Audit Committee Chairman of TC BioPharm (Holdings) plc, a publicly traded company and a cancer treatment development company. Since January 2005, Mr. Culverwell has served as a director, Audit Committee Chairman, and member of the Compensation Committee of SafeGuard Biosystems, a high throughput molecular diagnostics company. From April 2016 to September 2019, Mr. Culverwell served as a director and Audit Committee Chairman of Amryt Pharma PLC, a publicly traded company and a commercial-stage biopharmaceutical company. From February 2013 to July 2017, Mr. Culverwell served as a director and Audit Committee Chairman of Innocoll AG. He received an MSc with honors from the University of Aberdeen. We believe Mr. Culverwell is qualified to serve on our Board due to his extensive experience serving on the audit and compensation committees for multiple public and private life sciences and healthcare companies.

Dennis H. Langer, M.D., J.D., *Director*. Dr. Langer has served as a director of Quoin Inc. since 2019. Dr. Langer has served as a director of Quoin Ltd. since October 28, 2021. From 2005 to 2010, Dr. Langer served as a Managing Partner at Phoenix IP Ventures, LLC, a private equity and venture capital fund specializing in life sciences companies. From 2005 to 2010, Dr. Langer was also a Co-Founder and Director of Ception Therapeutics, Inc., until its acquisition by Cephalon, Inc. From 2004 to 2005, Dr. Langer was the President, North America for Dr. Reddy's Laboratories, Inc., a multi-national pharmaceutical company. Dr. Langer was with GlaxoSmithKline, a multi-national pharmaceutical and biotechnology company, from 1994 - 2004, where he served as Senior Vice President, Project, Portfolio and Alliance Management, Senior Vice President, Product Development Strategy, and Senior Vice

President, Healthcare Services R&D. From 1991 to 1994, he served as President and Chief Executive Officer at Neose Technologies, Inc., a clinical stage biopharmaceutical company. From 2004 to June 2022, Dr. Langer served as a director of Myriad Genetics, Inc., a publicly traded company and a genetic testing and precision medicine company. From 2021 to June 2022, Dr. Langer served as a director of Brooklyn ImmunoTherapeutics, Inc. (n/k/a Eterna Therapeutics Inc.), a publicly traded company and a biotechnology company. From 2007 to 2019, Dr. Langer served as a director of Dicerna Pharmaceuticals Inc., a publicly traded company and a biopharmaceutical company. From 2005 to 2006, Dr. Langer served as a Director of Sirna Therapeutics, Inc., a publicly traded company and biopharmaceutical company, until its acquisition by Merck and Co., Inc. Dr. Langer has served on the Dean's Advisory Board of Harvard Law School since 2010, and as a Director of the Whitehead Institute for Biomedical Research since 2020. He received an M.D. from Georgetown University School of Medicine, a J.D. from Harvard Law School, and a B.A. in Biology from Columbia University. We believe Dr. Langer is qualified to serve on our Board due to his extensive experience as an executive and board member of public and private life sciences and healthcare companies.

Natalie Leong, *Director*. Ms. Leong has served as a director of Quoin Inc. since April 2021. Ms. Leong has served as a director of Quoin Ltd. since October 28, 2021. Since January 2023, Ms. Leong has been the Senior Vice President of Product Management for B.S.D. Capital, Inc. (d/b/a Lendistry), a minority-led small business lender. Ms. Leong was the Head of Finance and Product Strategy (October 2019 – October 2020) and subsequently Head of Product Management (October 2020 – November 2022) for LoanStreet Inc., a financial SaaS company. From May 2016 to July 2019, Ms. Leong served as the Lead for the Asset Liability Committee for the US at RBC Capital Markets. In addition, from August 2018 to October 2019, she served as the Lead for Global Originations FP&A for RBC Capital Markets. From October 2011 to May 2016, Ms. Leong worked as the Vice President of Capital Insights at National Australia Bank. From February 2008 to October 2011, Ms. Leong served as a Senior Auditor at National Australia Bank. Ms. Leong earned her MBA at The Wharton School, University of Pennsylvania. She earned a B.Comm degree (Finance and Economics) and a B.A. degree (French and Literature) from the University of Melbourne in 2007. We believe Ms. Leong is qualified to serve on our Board due to her extensive financial and business management experience.

Michael Sember, *Director*. Mr. Sember has served as a director of Quoin Inc. since May 2021. Mr. Sember has served as a director of Quoin Ltd. since October 28, 2021. Since 2007, he has served as a Principal of Accela Advisors, a biopharmaceutical consulting firm specializing in strategic planning, business development and coaching for startups. From 2022 until 2023, Mr. Sember served as the Chief Executive Officer of RaeSedo, Inc, a startup therapeutics company spin out of the University of Arizona. From January 2018 to October 2020, Mr. Sember served as the Chief Executive Officer of Regulonix Holding, Inc., a drug development company. From October 2015 to March 2019, he served as the Mentor in Residence to companies formed from inventions discovered at the University of Arizona. From 2013 to 2015, Mr. Sember was the Corporate Turnaround Specialist and Chief Executive Officer of Palyon Medical Corporation, a drug delivery system company. From 1991 to 2002, Mr. Sember was Executive Vice President of Corporate Business Development for Élan Corporation, responsible for strategic collaborations and mergers and acquisitions. From 1973 to 1991, Mr. Sember served as the Senior director of Global Program Management at Marion Laboratories (later Marion Merrell Dow). From 2013 to 2015, Mr. Sember was the Chairman of the Board of Paylon Medical Corporation, a drug delivery system company. From 2012 to 2013, Mr. Sember was the Chairman of the Board of BioIndustry Organization of Southern Arizona, a non-profit trade group. Mr. Sember earned a Bachelor of Science degree from the University of Pittsburgh and an MBA from Rockhurst University. We believe Mr. Sember is qualified to serve on our Board due to his broad executive and capital raising experience in the life sciences industry.

Directors' Term of Office

Directors hold office until the next annual meeting of shareholders and until a successor is duly elected and qualified or until his or her earlier retirement, resignation or removal.

Code of Ethics

We have adopted a Code of Ethics and Business Conduct (the "Code of Ethics") that applies to all of our directors, officers and employees, including our principal executive officer and our principal financial and accounting officer. A copy of our Code of Ethics has been posted to the "Investors—Corporate Governance" section of our website www.quoinpharma.com, and it is attached as an exhibit to this Annual Report. If we make any amendment to the Code of Ethics or grant any waivers, including any implicit waiver, from a provision of the Code of Ethics, we will disclose the nature of such amendment or waiver on our website www.quoinpharma.com. to the extent required by the rules and regulations of the SEC. The information on the website is not and should not be considered part of this Annual Report and is not incorporated by reference in this annual Report.

Board of Directors

The Board of Directors has established three standing committees: the Audit Committee, the Compensation Committee and the Nominating and Governance Committee.

Audit Committee

The Audit Committee of the Board of Directors consists of Joseph Cooper, James Culverwell, and Natalie Leong, with Mr. Culverwell chairing the committee.

Under the Nasdaq listing standards, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise. Our Board has determined that each member of the Audit Committee satisfies the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act, has the requisite financial sophistication as required by the Nasdaq listing standards and is an audit committee financial expert, as defined by the SEC rules.

Our Board adopted the Amended and Restated Charter of the Audit Committee that sets forth the responsibilities of the Audit Committee under Nasdaq listing standards, as well as the requirements for such committee under the Companies Law, including the following:

- overseeing our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor;
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors;
- determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;
- determining the approval process for transactions that are 'non-negligible' (i.e., transactions with a controlling shareholder that are classified by the audit committee as non-negligible, even though they are not deemed extraordinary transactions), as well as determining which types of transactions would require the approval of the audit committee, which determination may be based on annually pre-determined criteria;
- determining whether to approve certain related party transactions (including transactions in which an office holder (as defined below) has a personal interest and whether such transaction is extraordinary or material under the Companies Law);
- review and discuss the Company's policies regarding information technology security and protection from cyber risks;
- examining the work plan of the internal auditor before its submission to our board of directors and proposing amendments thereto or, upon a decision of the board of directors, acting as the corporate body to approve such work plan;
- examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools at his disposal to fulfill his responsibilities;
- examining the scope of our independent auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors; and
- establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation Committee

The Compensation Committee of the Board consists of James Culverwell, Dennis Langer and Michael Sember, with Dr. Langer chairing the committee. The Board of Directors has determined that each member of the Compensation Committee is independent under Nasdaq listing standards.

Our Board adopted the Amended and Restated Charter of the Compensation Committee that sets forth the responsibilities of such committee under Nasdaq listing standards, as well as the requirements for such committee under the Companies Law, including the following:

- recommending to our board of directors a policy regarding the terms of engagement of the company's office holders, to which we refer as a "compensation policy";
- recommending whether the compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);
- recommending to the board of directors updates to the compensation policy from time to time;
- assessing implementation of the compensation policy;
- resolving whether to approve arrangements with respect to the terms of office and employment of office holders, which require the approval of the compensation committee pursuant to the Companies Law;
- exempting, under certain circumstances, a transaction with our Chief Executive Officer from the approval of our shareholders.;
- making other determinations that the Companies Law assigns to a compensation committee;
- reviewing and recommending for approval by the board of directors the overall compensation policies with respect to our Chief Executive Officer and other executive officers;
- reviewing and recommending for approval by the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers;
- evaluating the performance of our Chief Executive Officer and other executive officers in light of such goals and objectives;
- reviewing and approving the granting of options and other incentive awards, including the exercise of authorities delegated by the board of directors regarding the grant of equity incentives under our equity compensation plans;
- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors;
- overseeing our compliance with SEC and Nasdaq rules related to shareholder approval of certain executive compensation matters and equity compensation plans;
- considering and implementing policies with respect to oversight, assessment and management of risks associated with our compensation polices; and
- reviewing and establishing appropriate insurance coverage for our office holders.

Nominating and Governance Committee

Our Nominating and Governance Committee consists of Natalie Leong and Joseph Cooper, with Ms. Leong chairing the committee. The Board of Directors has determined that each member of the Nominating and Governance Committee is independent under Nasdaq listing standards.

Our Board adopted the Amended and Restated Charter of the Nominating and Governance Committee that sets forth the responsibilities of such committee under Nasdaq listing standards, as well as the requirements for such committee under the Companies Law, including the following:

- evaluating our corporate leadership structure, and reviewing important issues and developments in corporate governance, and developing appropriate recommendations for the Board; and

- overseeing and assisting our board in reviewing and recommending nominees for election as directors and members of committees of our board.

Internal Auditor

As required under the Companies Law by virtue of being a public company, the board of directors has appointed an internal auditor based on the recommendation of the audit committee. The role of the internal auditor is, among other things, to review the company's compliance with applicable law and orderly business procedure. Under the Companies Law, the internal auditor cannot be an interested party, an office holder, or a relative of an interested party or an office holder. Nor may the internal auditor be the company's independent auditor or its representative. An "interested party" is defined in the Companies Law as (i) a holder of 5% or more of the issued share capital or voting power in a company, (ii) any person or entity who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as chief executive officer of the company. The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities of the internal auditor and to assess his or her work plan and performance.

Insider Trading Policy

The Company maintains an Insider Trading Policy governing the purchase, sale and other disposition of its securities by its officers, directors and employees. The Company believes its Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, as well as the Nasdaq listing standards applicable to the Company. The Insider Trading Policy prohibits trading while in possession of material, non-public information and during blackout periods. While the Company's executive officers and directors are not required to enter into trading plans in advance of any transactions in Company securities, executive officers and directors are permitted to enter into trading plans that are intended to comply with the requirements of Rule 10b5-1 of the Exchange Act. The Insider Trading Policy requires all directors, officers and certain other specified employees who have regular access to material, non-public information about the Company in the normal course of their duties to comply with pre-clearance procedures prior to engaging in any transaction in Company securities. The Insider Trading Policy also requires the Company to comply with all insider trading laws, rules and regulations, and any applicable listing standards when engaging in transactions in its own securities. A copy of our Insider Trading Policy is attached as an exhibit to this Annual Report.

Fiduciary Duties of Directors, Executive Officers and Shareholders

The Companies Law codifies the fiduciary duties that office holders owe to a company. An office holder is defined in the Companies Law as a general manager, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of such person's title, a director, and any other manager directly subordinate to the general manager. Each person listed in the table under "Management" is an office holder under the Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would act under the same circumstances. The duty of loyalty requires that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for the office holder's approval or performed by virtue of his or her position; and

- all other important information pertaining to any such action.

The duty of loyalty includes a duty to:

- refrain from any conflict of interest between the performance of the office holder's duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

Shareholder duties

Pursuant to the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power with respect to the company, including, among other things, in voting at a general meeting and at shareholder class meetings with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- interested party transactions that require shareholder approval.

In addition, a shareholder has a general duty to refrain from discriminating against other shareholders.

Certain shareholders also have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who knows that it has the power to determine the outcome of a shareholder vote, and any shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or exercise any other rights available to it under the company's articles of association with respect to the company. The Companies Law does not define the substance of this duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty of fairness.

Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions

The Companies Law requires that an office holder promptly disclose to the board of directors any personal interest and all related material information known to such office holder concerning any existing or proposed transaction with the company. A personal interest includes an interest of any person in an act or transaction of a company, including a personal interest of one's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director, or general manager or in which such person has the right to appoint at least one director or the general manager, but excluding a personal interest stemming solely from one's ownership of shares in the company. A personal interest includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to the officer holder's vote on behalf of a person for whom he or she holds a proxy even if such shareholder has no personal interest in the matter.

If it is determined that an office holder has a personal interest in a non-extraordinary transaction (meaning any transaction that is in the ordinary course of business, on market terms or that is not likely to have a material impact on the company's profitability, assets or liabilities), approval by the board of directors is required for the transaction unless the company's articles of association provide for a different method of approval. Any such transaction that is adverse to the company's interests may not be approved by the board of directors.

Approval first by the company's audit committee and subsequently by the board of directors is required for an extraordinary transaction (meaning any transaction that is not in the ordinary course of business, not on market terms or that is likely to have a material impact on the company's profitability, assets or liabilities) in which an office holder has a personal interest.

A director and any other office holder who has a personal interest in a transaction which is considered at a meeting of the board of directors or the audit committee may generally (unless it is with respect to a transaction which is not an extraordinary transaction) not be present at such a meeting or vote on that matter unless a majority of the directors or members of the audit committee, as applicable, have a personal interest in the matter. If a majority of the members of the audit committee or the board of directors have a personal interest in the matter, then all of the directors may participate in deliberations of the audit committee or board of directors, as applicable, with respect to such transaction and vote on the approval thereof and, in such case, shareholder approval is also required.

Certain disclosure and approval requirements apply under Israeli law to certain transactions with controlling shareholders, certain transactions in which a controlling shareholder has a personal interest, and certain arrangements regarding the terms of service or employment of a controlling shareholder. For these purposes, a controlling shareholder is any shareholder that has the ability to direct the company's actions, including any shareholder holding 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights in the company. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder.

Exculpation, insurance and indemnification of office holders

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care, but only if a provision authorizing such exculpation is included in its articles of association. Our articles of association include such a provision. An Israeli company may not exculpate a director from liability arising out of a prohibited dividend or distribution to shareholders.

An Israeli company may indemnify an office holder from the following liabilities and expenses incurred for acts performed as an office holder, either in advance of an event or following an event, provided a provision authorizing such indemnification is contained in its articles of association:

- a financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the above mentioned events and amount or criteria;

- reasonable litigation expenses, including legal fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction;

- reasonable litigation expenses, including legal fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third-party or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for an offense that does not require proof of criminal intent;

- expenses, including reasonable litigation expenses and legal fees, incurred by an office holder in relation to an administrative proceeding instituted against such office holder, or certain compensation payments made to an injured party imposed on an office holder by an administrative proceeding, pursuant to certain provisions of the Israeli Securities Law; and

- expenses, including reasonable litigation expenses and legal fees, incurred by an office holder in relation to an administrative proceeding instituted against such office holder pursuant to certain provisions of the Israeli Economic Competition Law, 5758-1988.

An Israeli company may insure an office holder against the following liabilities incurred for acts performed as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of the duty of care to the company or to a third-party, including a breach arising out of the negligent conduct of the office holder;
- a financial liability imposed on the office holder in favor of a third-party;
- a financial liability imposed on the office holder in favor of a third-party harmed by a breach in an administrative proceeding, pursuant to certain provisions of the Israeli Securities Law; and
- expenses, including reasonable litigation expenses and legal fees, incurred by the office holder as a result of an administrative proceeding instituted against him or her, pursuant to certain provisions of the Israeli Securities Law.

An Israeli company may not exempt, indemnify or insure an office holder against any of the following:

- a breach of the duty of loyalty, except with respect to insurance coverage or indemnification, to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, monetary sanction, or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification, and insurance of office holders must be approved by the compensation committee and the board of directors (and, with respect to directors and the chief executive officer, by the shareholders). However, under regulations promulgated under the Companies Law, the insurance of office holders shall not require shareholder approval and may be approved by only the compensation committee if the engagement terms are determined in accordance with the company's compensation policy, which was approved by the shareholders by the same special majority required to approve a compensation policy, provided that the insurance policy is on market terms and the insurance policy is not likely to materially impact the company's profitability, assets, or obligations.

Our articles of association allow us to exculpate, indemnify, and insure our office holders to the maximum extent permitted by law. Our office holders are currently covered by a directors and officers' liability insurance policy.

We have entered into agreements with each of our directors and executive officers exculpating them in advance, to the fullest extent permitted by law, from liability to us for damages caused to us as a result of a breach of duty of care, and undertaking to indemnify them to the fullest extent permitted by law. This indemnification is limited to events determined as foreseeable by the board of directors based on our activities and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances.

In the opinion of the SEC, indemnification of directors and office holders for liabilities arising under the Securities Act, however, is against public policy and therefore unenforceable.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act and the regulations promulgated thereunder require our executive officers, directors and persons who beneficially own more than 10% of our ordinary shares to file forms with the SEC to report their ownership of the Company's shares and any changes in ownership. We have reviewed all forms filed electronically with the SEC during, and with respect to, fiscal 2025 or prior years. Based on that review and written information given to us by all of our directors and executive officers, we believe that all of our directors, executive officers and holders of more than 10% of our stock filed on a timely basis all reports that they were

required to file under Section 16(a) during fiscal 2025 other than as follows: (i) a late Form 4, covering one transaction, was filed late by James Culverwell; and (ii) a Form 3 was filed late by Sally Lawlor due to difficulty obtaining EDGAR filing codes.

Item 11. Executive Compensation

Summary Compensation Table

The following table sets forth information concerning the compensation awarded to, earned by, or paid to our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer (collectively referred to as "named executive officers") during the years ended December 31, 2025 and 2024.

Name and Principal Position	Year	Salary ($)	Bonus[2] ($)	Option Awards[3] ($)	Non Equity Incentive Plan Compensation[4] ($)	All Other Compensation[5] ($)	Total ($)
Dr. Michael Myers	2025	745,284	—	331,285	372,642	58,134	1,507,345
Chief Executive Officer	2024	662,475	—	353,013	331,238	60,075	1,406,801
Denise Carter	2025	595,440	—	331,285	297,720	57,840	1,282,285
Chief Operating Officer	2024	529,980	—	353,017	264,990	63,625	1,211,612
Sally Lawlor[1]	2025	165,206	83,134	174,784	—	11,168	434,292
Chief Financial Officer							

(1) Ms. Lawlor began serving as the Company's Chief Financial Officer on August 18, 2025. Ms. Lawlor's compensation is paid in Euros. For purposes of this table, we converted each element of her compensation into U.S. dollars based on the average foreign exchange rate for the period during which Ms. Lawlor was employed by the Company in 2025.

(2) Represents discretionary cash bonuses paid after the fiscal year with respect to that fiscal year's performance. Each discretionary cash bonus was granted in recognition of the applicable officer's promotion of our long-term goals, strategy and operating plan, the need to have appropriate incentives for our officers, and contribution to the achievement of our objectives in accordance with the applicable officer's respective corporate role during the year. Ms. Lawlor's fiscal 2025 discretionary cash bonus was approved by the Board and the Compensation Committee and was consistent with the Company's 2025 Compensation Policy (as described below).

(3) Represents the grant date fair value of option awards granted to each of our named executive officers calculated in accordance with FASB ASC Topic 718. The option values were calculated using a Black-Scholes Model for pricing options. See Note 6 to the Consolidated Financial Statements included in this Annual Report for all relevant valuation assumptions used to determine the grant date fair value of these options.

(4) Represents annual performance-based cash bonuses paid after the fiscal year with respect to that fiscal year's performance to Dr. Myers and Ms. Carter. See "─Annual Cash Incentive Bonuses." Dr. Myers' and Ms. Carter's fiscal 2025 annual performance-based bonuses were approved by the Board and the Compensation Committee, were consistent with the Company's 2025 Compensation Policy (as described below) and were within the limitations of the CEO Compensation Program (as described below) and the COO Compensation Program (as described below), as applicable.

(5) Represents amounts paid or accrued as office and automobile allowances, severance as well as the employer matching contribution to the executive's 401(k) plan contributions under our Section 401(k) retirement plan (the "Section 401(k) Plan") and PRSA Pension Scheme, broken down as follows:

		Office Allowance ($)	Car Allowance ($)	Medical Allowance ($)	401(k)/PRSA Contributions ($)	Total ($)
Michael Myers	2025	30,000	18,000	—	10,134	58,134
	2024	30,000	18,000	—	12,075	60,075
Denise Carter	2025	30,000	18,000	—	9,840	57,840
	2024	30,000	18,000	—	15,625	63,625
Sally Lawlor	2025	—	—	2,327	8,841	11,168

Employment Agreements

We entered into written employment agreements with our named executive officers that contain customary provisions, including non-compete and confidentiality provisions.

Dr. Myers. Pursuant to his Executive Employment Agreement with Quoin Inc., dated March 9, 2018, which was amended as of November 9, 2021 (as amended, the "Myers Agreement"), Dr. Myers' annual base salary was set at $550,000. In addition, the Myers Agreement provided for target discretionary bonuses of not less than 45% of Dr. Myers' so annual base salary, payable at the discretion of the board of directors after approval of the Compensation Committee, subject to shareholder approval by a Special Majority for Compensation Matters. Pursuant to the Myers Agreement, Dr. Myers is also eligible to receive healthcare benefits as may be provided from time to time by us to our employees generally, and to receive paid time off annually in accordance with our policies in effect from time to time. Additionally, the Myers Agreement provides Dr. Myers with a monthly office allowance of $2,500 and a monthly automobile allowance of $1,500. At the 2024 annual meeting of shareholders (the "2024 Annual Meeting"), the Company's shareholders approved a compensation program for Dr. Myers. The program sets forth compensation limitations applicable to Dr. Myers which the Compensation Committee and the Board can utilize in setting Dr. Myers' compensation, beginning with the compensation to be paid in fiscal 2024, without the need to obtain further shareholder approval. See "─Compensation Program for Dr. Michael Myers".

After the 2024 Annual Meeting, the Compensation Committee and the Board took the following actions which were consistent with the Company's then applicable compensation policy and within the limitations of the CEO Compensation Program: (i) approved and ratified Dr. Myers' 2024 annual base salary at $662,475 (retroactive to January 1, 2024), (ii) approved and ratified a discretionary cash bonus for Dr. Myers for fiscal 2023 services of $301,125; and (iii) granted Dr. Myers an option to purchase 15,332 ADSs under Quoin's Amended and Restated Equity Incentive Plan, with an exercise price equal to $27.30 per ADS. In 2025, the Compensation Committee and the Board took the following actions which were consistent with the Company's then applicable compensation policy and within the limitations of the CEO Compensation Program: (i) approved and ratified Dr. Myers' 2025 annual base salary at $745,284 (retroactive to January 1, 2025), (ii) approved and ratified a discretionary cash bonus for Dr. Myers for fiscal 2024 services of $331,238; and (iii) granted Dr. Myers an option to purchase 42,857 ADSs under Quoin's Amended and Restated Equity Incentive Plan, with an exercise price equal to $9.07 per ADS. In February 2026, the Compensation Committee and the Board certified the achievement of 100% of the performance goals for Dr. Myers' annual performance-based cash bonus, resulting in a cash bonus for Dr. Myers for fiscal 2025 services of $372,642. See "─Annual Cash Incentive Bonuses." Dr. Myers' annual performance-based bonus was consistent with the Company's 2025 Compensation Policy (as described below) and was within the limitations of the CEO Compensation Program (as described below).

Ms. Carter. Pursuant to her Executive Employment Agreement with Quoin Inc., dated March 9, 2018, which was amended as of November 9, 2021 (as amended, the "Carter Agreement"), Ms. Carter's annual base salary was set at $440,000, which accrued monthly until paid by Quoin Inc. In addition, the Carter Agreement provided for target discretionary bonuses of not less than 45% of Ms. Carter's annual base salary, payable at the discretion of the board of directors after approval of the Compensation Committee, subject to shareholder approval by a Special Majority for Compensation Matters. Pursuant to the Carter Agreement, Ms. Carter is also eligible to receive healthcare benefits as may be provided from time to time by us to our employees generally, and to receive paid time off annually in accordance with Quoin's policies in effect from time to time. Additionally, the Carter Agreement provides Ms. Carter with a monthly office allowance of $2,500 and a monthly automobile allowance of $1,500. At the 2024 Annual Meeting, the Company's shareholders approved a compensation program for Ms. Carter. The program sets forth compensation limitations applicable to Ms. Carter which the Compensation Committee and the Board can utilize in setting Ms. Carter's compensation, beginning with the compensation to be paid in fiscal 2024, without the need to obtain further shareholder approval. See "─Compensation Program for Ms. Denise Carter".

After the 2024 Annual Meeting, the Compensation Committee and the Board took the following actions which were consistent with the Company's then applicable compensation policy and within the limitations of the COO Compensation Program: (i) approved and

ratified Ms. Carter's 2024 annual base salary at $529,980 (retroactive to January 1, 2024), (ii) approved and ratified a discretionary cash bonus for Ms. Carter for fiscal 2023 services of $240,900; and (iii) granted Ms. Carter an option to purchase 15,332 ADSs under Quoin's Amended and Restated Equity Incentive Plan, with an exercise price equal to $27.30 per ADS, the fair market value on the date of grant. In 2025, the Compensation Committee and the Board took the following actions which were consistent with the Company's then applicable compensation policy and within the limitations of the COO Compensation Program: (i) approved and ratified Ms. Carter's 2025 annual base salary at $595,440 (retroactive to January 1, 2025), (ii) approved and ratified a discretionary cash bonus for Ms. Carter for fiscal 2024 services of $264,990; and (iii) granted Ms. Carter an option to purchase 42,857 ADSs under Quoin's Amended and Restated Equity Incentive Plan. In February 2026, the Compensation Committee and the Board certified the achievement of 100% of the performance goals for Ms. Carter's annual performance-based cash bonus, resulting in a cash bonus for Ms. Carter for fiscal 2025 services of $297,720. See "─Annual Cash Incentive Bonuses." Ms. Carter's annual performance-based bonus was consistent with the Company's 2025 Compensation Policy (as described below) and was within the limitations of the COO Compensation Program (as described below).

Ms. Lawlor. In connection with Ms. Lawlor's appointment as Chief Financial Officer, the Company (through its wholly owned subsidiary, Quoin Therapeutics (Ireland) Ltd.) and Ms. Lawlor entered into a Service Agreement, dated as of August 18, 2025 (the "Lawlor Service Agreement"). The Lawlor Service Agreement provides that Ms. Lawlor will be paid an initial annual base salary of €380,000 ($443,381). In addition, the Service Agreement provides that the Company may, at its absolute discretion, pay an annual performance related bonus (which shall not qualify as pensionable remuneration) of up to 50% of salary in an amount to be determined by the Compensation Committee of Board. The Company has arranged for the provision of a PRSA scheme to which the Company will contribute 5% of gross basic salary matched by a 5% contribution by Ms. Lawlor to the PRSA. In addition, the Company will contribute a sum of €5,000 ($5,834) to Ms. Lawlor's health insurance scheme. In connection with her hiring, on December 1, 2025, the Company granted Ms. Lawlor an option to purchase 10,330 ADSs under Quoin's 2025 Equity Incentive Plan, with an exercise price equal to $19.36 per ADS. In February 2026, the Company's Compensation Committee and the Board approved a discretionary cash bonus for Ms. Lawlor for fiscal 2025 services of $83,134. Ms. Lawlor's discretionary cash bonus was consistent with the Company's 2025 Compensation Policy (as described below).

Compensation Program for Dr. Michael Myers

At the 2024 Annual Meeting, the Company's shareholders approved a compensation program for the Company's Chief Executive Officer and Chairman of the Board, Dr. Michael Myers. The program sets forth the following compensation limitations applicable to Dr. Myers which the Compensation Committee and the Board can utilize in setting Dr. Myers' compensation, beginning with the compensation to be paid in fiscal 2024, without the need to obtain further shareholder approval:

(i) an annual increase of base salary of up to 15% of Dr. Myers' then effective base salary;

(ii) an annual cash bonus of up to 50% of Dr. Myers' annual base salary during the fiscal year for which the annual cash bonus is paid (for example, Dr. Myers' bonus to be paid in fiscal 2025 for fiscal 2024 services would be based upon a percentage, up to 50%, of Dr. Myers' annual base salary in fiscal 2024); and

(iii) an annual equity grant in any form permitted under the Company's equity incentive plan in effect from time to time with an annual value (determined in accordance with the Black-Scholes formula or another widely accepted and suitable formula for calculating the value of equity awards) of up to 500% of the maximum total fixed component (base salary and benefits) to which Dr. Myers is entitled in the grant year (together the "CEO Compensation Program").

In setting future compensation for Dr. Myers consistent with the terms of the CEO Compensation Program, the Compensation Committee and the Board will continue to annually review market competitive compensation as a reference, individual performance, the need to have appropriate incentives for our officers, and Dr. Myers' experience and expected contributions.

Compensation Program for Denise Carter

Also at the 2024 Annual Meeting, the Company's shareholders approved a compensation program for the Company's Chief Operating Officer and a member of the Board, Denise Carter. The program sets forth the following compensation limitations applicable to Ms. Carter which the Compensation Committee and the Board can utilize in setting Ms. Carter's compensation, beginning with the compensation to be paid in fiscal 2024, without the need to obtain further shareholder approval:

(i) an annual increase of base salary of up to 15% of Ms. Carter's then effective base salary;

(ii) an annual cash bonus of up to 50% of Ms. Carter's annual base salary during the fiscal year for which the annual cash bonus is paid (for example, Ms. Carter's bonus to be paid in fiscal 2025 for fiscal 2024 services would be based upon a percentage, up to 50%, of Ms. Carter's annual base salary in fiscal 2024); and

(iii) an annual equity grant in any form permitted under the Company's equity incentive plan in effect from time to time with an annual value (determined in accordance with the Black-Scholes formula or another widely accepted and suitable formula for calculating the value of equity awards) of up to 500% of the maximum total fixed component (base salary and benefits) to which Ms. Carter is entitled in the grant year (together the "COO Compensation Program").

In setting future compensation for Ms. Carter consistent with the terms of the CEO Compensation Program, the Compensation Committee and the Board will continue to annually review market competitive compensation as a reference, individual performance, the need to have appropriate incentives for our officers, and Ms. Carter's experience and expected contributions.

Annual Cash Incentive Bonuses

The Company believes that performance-based cash bonuses assist the Company in motivating and retaining executive talent whose abilities and leadership skills are critical to the Company's long-term success by aligning such officers' efforts with the strategic and clinical goals of the Company through competitive annual incentive opportunities.

The annual performance-based cash bonuses for fiscal 2025 for Dr. Myers and Ms. Carter were subject to a formulaic framework based on certain clinical; regulatory; chemistry, manufacturing and controls; intellectual property and financial performance measures with weightings of 35%, 30%, 10%, 5% and 20%, respectively. There would be no annual performance-based cash bonus payout with respect to any category for which the Compensation Committee determined that the Company had not performed and/or did not successfully achieve the performance goal. We have not disclosed the specific performance goals/strategic measures because we believe this disclosure would reveal confidential strategic objectives and information that is not otherwise publicly disclosed by us and would result in competitive harm to us. The strategic measures were designed to be "stretch" goals that were achievable with what we believe represented an elevated level of effort and performance.

For fiscal 2025, the Compensation Committee and the Board set award levels for each of Dr. Myers and Ms. Carter as percentages of their base salaries as shown in the following table:

Participant	Base Salary	Target (% of Base Salary)
Michael Myers	$ 745,284	50 %
Denise Carter	$ 595,440	50 %

In February 2026, the Compensation Committee and the Board certified the achievement of 100% of the performance goals and determined that the annual performance-based cash bonuses should be paid out at 100% of target based on the Company's performance. Accordingly, based on the formula previously adopted, the Compensation Committee and the Board approved bonuses for each of Dr. Myers and Ms. Carter for fiscal 2025 of $372,642 and $297,720, respectively.

Health and Welfare Benefits

Our named executive officers are eligible to participate in the same employee benefit plans, and on the same terms and conditions, as all other full-time, salaried U.S. employees. These benefits include medical, dental, and vision insurance, an employee assistance program, health and dependent care flexible spending accounts, basic life insurance, accidental death and dismemberment insurance, short-term and long-term disability insurance, and commuter benefits.

We also maintain the "Section 401(k) Plan that provides eligible employees, including our named executive officers, with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees are able to participate in the Section 401(k) Plan as of the first day of the month following the date they meet the plan's eligibility requirements. Participants are able to defer up to 100% of their eligible compensation subject to applicable annual limits under the Internal Revenue Code (the "Code"). All participants' interests in their deferrals are 100% vested when contributed. Currently, we match up to 100% of a participant's first 1% of his or her eligible contributions to the Section 401(k) Plan, and we match up to 50% of the next 5% of his or her eligible contributions.

Outstanding Equity Awards at December 31, 2025

The following table sets forth information with respect to outstanding equity awards for each named executive officer as of December 31, 2025.

Name	Option Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable[1]	Option Exercise Price ($)[2]	Option Expiration
Dr. Michael Myers	04/12/2022	153	51	7,350	04/12/2032
	10/26/2023	926	1,388	201.25	10/26/2033
	12/9/2024	3,066	12,266	27.30	12/9/2034
	05/29/2025	—	42,857	9.07	5/29/2035
Denise Carter	04/12/2022	153	51	7,350	04/12/2032
	10/26/2023	926	1,388	201.25	10/26/2033
	12/9/2024	3,066	12,266	27.30	12/9/2034
	05/29/2025	—	42,857	9.07	05/29/2035
Sally Lawlor	12/01/2025	—	10,330	19.36	12/01/2035

(1) Represents the number of ADSs issuable upon the exercise of options. The 2022 options vest in four equal annual installments beginning on April 12, 2023. The 2023 options vest in three annual installments of 20% beginning on October 26, 2024 and a fourth installment of 40% on October 26, 2027. The 2024 options vest in three annual installments of 20% beginning on December 9, 2025 and a fourth installment of 40% on December 9, 2028. The 2025 options vest in three annual installments of 20% beginning on either May 29, 2026 or December 1, 2026, as applicable, and a fourth installment of 40% on either May 29, 2029 or December 1, 2029, as applicable.

(2) Represents the exercise price per ADS.

Equity Plans

Amended and Restated Equity Incentive Plan

At our Annual General Meeting held on April 12, 2022, our shareholders approved our Amended and Restated Equity Incentive Plan (the "2022 Plan"), which amended and restated our 2014 Global Incentive Option Scheme. The purpose of the 2022 Plan was to attract, retain and motivate our employees (including prospective employees), non-employee directors and consultants. As of August 21, 2025, no further awards may be issued under the 2022 Plan due to the adoption of the Company's 2025 Plan (as defined below). At December 31, 2025, 200,627 ADSs remain subject to outstanding options under the 2022 Plan.

2025 Equity Incentive Plan

Our 2025 Equity Incentive Plan (the "2025 Plan") was approved by our shareholders on August 21, 2025. The purpose of the 2025 Plan is to provide for the grant of equity-based incentive awards to the Company's employees, directors, officers, consultants, advisers and service providers in order to incentivize them to increase their efforts on behalf of the Company and to promote the success of the Company's business. The 2025 Plan provides for the grant of stock options (including incentive stock options and nonqualified stock options), restricted shares, restricted stock units, stock appreciation rights and other share-based awards. The 2025 Plan is administered by the Compensation Committee.

Subject to certain adjustments, the maximum number of ordinary shares (or ADSs representing such ordinary shares) available for issuance under the 2025 Plan is 3,000,000 ordinary shares (85,714 ADSs), subject to an automatic annual increase the first day of each year beginning in 2026 and on January 1st of each calendar year thereafter and ending on January 1, 2035, by a number of ordinary shares equal to the smaller of (A) fifteen percent (15%) of the number of ordinary shares issued and outstanding of the Company on a fully diluted basis on the last day of the immediately preceding calendar year; and (B) such amount as determined by our Board if so determined.

All awards granted pursuant to the 2025 Plan will be evidenced by a grant notification letter, in a form approved, from time to time, by the Compensation Committee. The grant notification letter will set forth the terms and conditions of the award, including the type of award, number of shares subject to such award, vesting schedule and conditions (including performance goals or measures) and the exercise price, if applicable. The exercise period of an award will be determined by the Compensation Committee and stated in the grant notification letter but will in no event be longer than ten years from the date of the grant thereof. All awards must be granted on or before July 8, 2035, the tenth anniversary of the date that the 2025 Plan was approved by our Board. All awards under the 2025 Plan will be subject to recoupment by the Company to the extent required to comply with applicable law or any policy of the Company (subject to applicable law) providing for the reimbursement of incentive compensation, whether or not such policy was in place at the time of grant of an award. At December 31, 2025, 15,330 ADSs remain subject to outstanding options under the 2025 Plan.

Company Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

The Company does not have a formal policy on the timing of awards of options in relation to the disclosure of material nonpublic information by the Company. The Board and the Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Option grants are effective on the date the award determination is made by the Board and/or the Compensation Committee, and the exercise price of options is the closing market price of our ADSs on the date of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

During the fiscal year ended December 31, 2025, we did not award any options to a named executive officer in the period beginning four business days before the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a current report on Form 8-K that discloses material nonpublic information, and ending one business day after the filing or furnishing of such report other than as set forth in the table below:

Name	Grant date	Number of securities underlying the award	Exercise price of the award per share	Grant date fair value of the award	Percentage change in the closing market price of the securities underlying the award between the trading day ending immediately prior to the disclosure of material nonpublic information and the trading day beginning immediately following the disclosure of material nonpublic information[2]
James Culverwell	08/21/25[1]	13,682	$ 9.07	$ 6.04	1.94 %
Dennis Langer	08/21/25[1]	13,682	$ 9.07	$ 6.04	1.94 %
Natalie Leong	08/21/25[1]	4,105	$ 9.07	$ 6.04	1.94 %

(1) The option grant was approved by the Compensation Committee and the Board on May 29, 2025, subject to shareholder approval. The Company's shareholders approved this option grant on August 21, 2025. The exercise price of the option was determined following the close of market on May 29, 2025.

(2) The Company filed a current report on Form 8-K on August 21, 2025, announcing the results of the 2026 annual meeting and the appointment of Sally Lawlor as the Company's new Chief Financial Officer effective as of August 18, 2025. The percentage change in the closing market price of the Company's ADSs between the trading day ending immediately prior to the filing of the 8/21/2025 Form 8-K and the closing market price of the Company's ADSs on the trading day beginning immediately following the filing of the 8/21/2025 Form 8-K was 1.94%.

Clawback Policy

The Board adopted a clawback policy which requires the clawback of erroneously awarded incentive-based compensation of past or current executive officers awarded during the three full fiscal years preceding the date on which the issuer is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the federal securities laws. There is no fault or misconduct required to trigger a clawback.

The Compensation Committee shall determine, in its sole discretion, the timing and method for promptly recouping such erroneously awarded compensation, which may include without limitation: (a) seeking reimbursement of all or part of any cash or equity-based award, (b) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid, (c) cancelling or offsetting against any planned future cash or equity-based awards, (d) forfeiture of deferred compensation, subject to compliance with Section 409A of the Internal Revenue Code and the regulations promulgated thereunder, and (e) any other method authorized by

applicable law or contract. Subject to compliance with any applicable law, the Compensation Committee may affect recovery under this policy from any amount otherwise payable to the executive officer, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by the executive officer.

Potential Payments Upon Termination or in Connection With a Change of Control

Employment Agreements

Pursuant to each of the Myers Agreement and the Carter Agreement, Dr. Myers and Ms. Carter, respectively, are entitled to the following benefits upon termination of their employment:

- **Termination for any reason:** Upon the termination of such executive's employment for any reason, such executive will receive (i) his or her Base Salary (as defined in the Myers Agreement or the Carter Agreement, as applicable) through the Exit Date (as defined in the Myers Agreement or the Carter Agreement, as applicable), (ii) any Bonuses (as defined in the Myers Agreement or the Carter Agreement, as applicable) to which he or she is entitled and has already earned for the prior fiscal year, and (iii) any other accrued or vested benefits or reimbursements through the Exit Date to which such executive is entitled to contractually or by operation of law.

- **Termination upon death or Disability:** In the event of the executive's termination due to his or her death or Disability (as defined in the Myers Agreement or the Carter Agreement, as applicable), then, in addition to the payments set forth above, the executive will receive his or her pro rata portion of the Bonus such executive would have been entitled to receive for the fiscal year in which the Exit Date occurs, based upon the percentage of the fiscal year that elapsed through the Exit Date. Additionally, in the event of termination due to Disability, the executive will receive, for a period of 24 months following the Exit Date, such executive monthly COBRA premium.

- **Termination without Cause or for Good Reason:** In addition to the payments set forth in the first bullet above, if Dr. Myers or Ms. Carter is terminated by the Company without Cause (as defined in the Myers Agreement or the Carter Agreement, as applicable), or Dr. Myers or Ms. Carter terminates his or her employment for Good Reason (as defined in the Myers Agreement or the Carter Agreement, as applicable), he or she will be entitled to receive (i) his or her Base Salary for 2 years from the Exit Date and 2 times the current years' Bonus, and (ii) continuation of such executive's medical benefits for 2 years from the Exit Date (unless the executive becomes employed elsewhere during such 2 year period and is eligible to receive comparable medical benefits).

As a condition precedent to receiving any of the foregoing benefits, Dr. Myers and/or Ms. Carter, as applicable, must first sign a Release (as defined in the Myers Agreement or the Carter Agreement, as applicable).

The foregoing descriptions of the Myers Agreement and the Carter Agreement do not purport to be complete and are qualified in their entirety by reference to the complete text of the Myers Agreement the Carter Agreement, copies of which are included as exhibits to this Annual Report.

Option Awards

Under the 2022 Plan and the 2025 Plan, upon termination of employment for any reason, other than in the event of death or disability or for "Cause" (as defined in the 2022 Plan and the 2025 Plan), all unvested options will expire and all vested options at time of termination will generally be exercisable for 90 days following termination, subject to the terms of the Plan and the governing option agreement. If we terminate a grantee for Cause, the grantee's right to exercise all vested and unvested the options granted to the grantee will expire immediately. Upon termination of employment due to death or disability, all the vested options at the time of termination will be exercisable for 12 months after date of termination, subject to the terms of the 2022 Plan and the 2025 Plan and the governing option agreement.

Compensation Policy under the Companies Law

In general, under the Companies Law, a public company must have a compensation policy approved by the board of directors after receiving and considering the recommendations of the compensation committee. In addition, our compensation policy must be approved

at least once every three years, first, by our board of directors, upon the recommendation of our compensation committee, and second, by a simple majority of the ordinary shares present, in person or by proxy, and voting (excluding abstentions) at a general meeting of shareholders, provided that either:

- such majority includes at least a majority of the shares held by shareholders who are not controlling shareholders and shareholders who do not have a personal interest in such compensation policy; or

- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation policy and who vote against the policy does not exceed two percent (2%) of the aggregate voting rights in the Company.

Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee and then the board of directors decide, on the basis of detailed grounds and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of shareholders, is for the benefit of the company. Our Board, following the recommendation of our Compensation Committee, approved adopting a new Compensation Policy for Executive Officer and Directors in 2025 (the "2025 Compensation Policy") and our shareholders approved and adopted the 2025 Compensation Policy at our 2025 Annual Meeting. The compensation policy must be based on certain considerations, include certain provisions and reference certain matters as set forth in the Companies Law. The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must be determined and later reevaluated according to certain factors, including: the advancement of the company's objectives, business plan and long-term strategy; the creation of appropriate incentives for office holders, while considering, among other things, the company's risk management policy; the size and the nature of the company's operations; and with respect to variable compensation, the contribution of the office holder towards the achievement of the company's long-term goals and the maximization of its profits, all with a long-term objective and according to the position of the office holder. The compensation policy must furthermore consider the following additional factors:

- the education, skills, experience, expertise and accomplishments of the relevant office holder;

- the office holder's position and responsibilities;

- prior compensation agreements with the office holder;

- the ratio between the cost of the terms of employment of an office holder and the cost of the employment of other employees of the company, including employees employed through contractors who provide services to the company, in particular the ratio between such cost to the average and median salary of such employees of the company, as well as the impact of disparities between them on the work relationships in the company;

- if the terms of employment include variable components — the possibility of reducing variable components at the discretion of the board of directors and the possibility of setting a limit on the value of non-cash variable equity-based components; and

- if the terms of employment include severance compensation — the term of employment or office of the office holder, the terms of the office holder's compensation during such period, the company's performance during such period, the office holder's individual contribution to the achievement of the company goals and the maximization of its profits and the circumstances under which he or she is leaving the company.

The compensation policy must also include, among other things:

- with regards to variable components:

- with the exception of office holders who report to the chief executive officer, a means of determining the variable components on the basis of long-term performance and measurable criteria; provided that the company may determine that an immaterial part of the variable components of the compensation package of an office holder shall be awarded based on non-measurable criteria, or if such amount is not higher than three months' salary per annum, taking into account such office holder's contribution to the company;

- the ratio between variable and fixed components, as well as the limit of the values of variable components at the time of their payment, or in the case of equity-based compensation, at the time of grant;

- a condition under which the office holder will return to the company, according to conditions to be set forth in the compensation policy, any amounts paid as part of the office holder's terms of employment, if such amounts were paid based on information later to be discovered to be wrong, and such information was restated in the company's financial statements;

- the minimum holding or vesting period of variable equity-based components to be set in the terms of office or employment, as applicable, while taking into consideration long-term incentives; and

- a limit to retirement grants.

Our compensation policy is designed to promote retention and motivation of directors and executive officers, incentivize superior individual excellence, align the interests of our directors and executive officers with our long-term performance and provide a risk management tool. To that end, a portion of our executive officer compensation package is targeted to reflect our short and long-term goals, as well as the executive officer's individual performance. On the other hand, our compensation policy includes measures designed to reduce the executive officer's incentives to take excessive risks that may harm us in the long-term, such as limits on the value of cash bonuses and equity-based compensation, limitations on the ratio between the variable and the total compensation of an executive officer and minimum vesting periods for equity-based compensation.

Our compensation policy also addresses our executive officers' individual characteristics (such as their respective position, education, scope of responsibilities and contribution to the attainment of our goals) as the basis for compensation variation among our executive officers and considers the internal ratios between compensation of our executive officers and directors and other employees. Pursuant to our compensation policy, the compensation that may be granted to an executive officer may include: base salary, annual bonuses and other cash bonuses (such as a signing bonus and special bonuses with respect to significant events, such as a significant partnership, collaboration agreement or the generation of positive clinical trial results or regulatory approval of one of the Company's products), equity-based compensation and termination of service grants.

An annual cash bonus may be awarded to executive officers upon the attainment of pre-set periodic objectives and individual targets. The annual cash bonus that may be granted to our executive officers is based primarily on measurable short- and long-term criteria. A non-material part of variable compensation for executive officers may be based on qualitative or non-measurable criteria which focus on the executive officer's contribution to the Company, subject to a maximum amount linked to the executive officer's base salary.

The equity-based compensation under our compensation policy for our executive officers is designed in a manner consistent with the underlying objectives in determining the base salary and the annual cash bonus, with its main objectives being to enhance the alignment between the executive officers' interests with our long-term interests and those of our shareholders and to strengthen the retention and the motivation of executive officers in the long term. Our compensation policy provides for equity compensation in any form permitted under our equity incentive plan then in place. The equity-based compensation shall be granted from time to time and be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the executive officer.

In addition, our compensation policy contains compensation recovery provisions which allow us under certain conditions to recover bonuses paid in excess, enables our chief executive officer to approve an immaterial change in the terms of employment of an executive officer (excluding the chief executive officer) in an amount up to two monthly base salaries, and allow us to exculpate, indemnify and insure our executive officers and directors to the maximum extent permitted by Israeli law subject to certain limitations set forth therein.

Our compensation policy also provides for compensation to the members of our board of directors in accordance with market compensation trends, provided however that in the case of an external director, such compensation will be paid in accordance with the amounts provided in the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director) of 2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel) of 2000, as such regulations may be amended from time to time.

Non-Employee Director Compensation

Under our non-employee directors' compensation program, as amended, non-employee directors are entitled to receive the following cash compensation for their services:

- each non-employee director receives an annual base retainer (the "Annual Retainer") of up to $125,000, which amount shall be determined annually at the discretion of the Compensation Committee and the Board;
- each committee chairperson receives an additional retainer of $15,000 for his or her service as a chairperson; and
- each member of a standing committee receives an additional retainer of $5,000 for such service on a standing committee.

In addition to cash compensation, our non-employee directors are also entitled to equity awards under our director compensation policy. Each non-employee director is entitled to receive an annual award of options with a value of no less than $20,000 and no more than $60,000, with such value being determined annually at the discretion of the Compensation Committee and the Board. In addition, each non-employee director who joins the Board is granted an inaugural award of options valued at $165,000. Furthermore, each non-employee director may elect to receive all or a portion of the Annual Retainer due to them in the form of options.

The following table sets forth information concerning the compensation awarded to, earned by or paid to non-employee directors for the year ended December 31, 2025.

Name	Fees Earned or Paid in Cash ($)[1]	Option Awards ($)[1][2]	Total ($)
Joseph Cooper	110,000	59,985	169,985
James Culverwell	20,000	142,624	162,624
Dr. Dennis H. Langer	15,000	142,624	157,624
Natalie Leong	90,000	84,779	174,779
Michael Sember	105,000	59,985	164,985

(1) For fiscal 2025, the Compensation Committee and the Board set the Annual Retainer at $100,000 and determined that the annual award of options should be valued at $60,000. Each of Mr. Culverwell and Mr. Langer elected to receive all of their fiscal 2025 Annual Retainer in the form of options to purchase ADSs in the amount of 13,682 ADSs each and Ms. Leong elected to receive a portion of her fiscal 2025 Annual Retainer in the form of options to purchase ADSs in the amount of 4,105 ADSs. Committee fees were paid in cash to all Board members.

(2) Represents the grant date fair value of option awards granted to each of our non-employee directors calculated in accordance with FASB ASC Topic 718. The option values were calculated using a Black-Scholes Model for pricing options. See Note 6 to Consolidated Financial Statements included in this Annual Report for all relevant valuation assumptions used to determine the grant date fair value of these options. As of December 31, 2025, the aggregate number of outstanding options held by each of our non-employee directors was Mr. Cooper—9,459; Mr. Culverwell—23,141; Dr. Langer—23,141; Ms. Leong 13,561; and Mr. Sember—9,459.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management[1]

The following table sets forth information relating to the beneficial ownership of our ordinary shares (including ordinary shares represented by ADSs) as of March 23, 2026 by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our directors and named executive officers; and
- all of our directors and officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally means sole or shared power to vote or direct the voting or to dispose or direct the disposition of any security. Unless otherwise indicated in the footnotes to this table, we believe that each of the persons named in this table has sole voting and investment power with respect to the securities indicated as being beneficially owned.

Except as indicated by footnote, the beneficial ownership information is based upon 1,803,626 ordinary shares outstanding as of March 23, 2026. A security that may be acquired by a person within 60 days of March 23, 2026, pursuant to the exercise of options or warrants are deemed to be outstanding for purpose of computing the percentage ownership of such person, but are not deemed to be outstanding for purposes of computing the percentage ownership of ordinary shares beneficially owned by any other person shown in the table. Each ADS represents thirty-five ordinary shares.

Unless indicated otherwise below, the address of our directors and executive officers is c/o Quoin Pharmaceuticals Ltd., 42127 Pleasant Forest Court, Ashburn, VA 20148-7349.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class
5% Beneficial Owners		
Ikarian Capital LLC and affiliate[(1)]	211,538	11.73 %
Directors and Named Executive Officers:		
Dr. Michael Myers[(2)]	53,165	2.95 %
Denise Carter[(3)]	53,160	2.95 %
Joseph Cooper[(4)]	408	0.02 %
James Culverwell[(5)]	8,989	0.50 %
Dr. Dennis Langer[(6)]	74,766	4.22 %
Natalie Leong[(7)]	408	0.02 %
Michael Sember[(8)]	408	0.02 %
Sally Lawlor[(9)]	440	0.02 %
All current directors and officers as a group (8 persons) [(10)]	191,745	10.71 %

(1) Consists of ADSs held by Ikarian Capital, LLC ("Ikarian") based on the Schedule 13G/A filed by Ikarian on February 6, 2026. These ADSs are also beneficially owned by Neil Shahrestani. The address of Ikarian and Mr. Shahrestani is c/o Ikarian Capital, LLC, 100 Crescent Court, Suite 1620, Dallas, Texas 75201

(2) Consists of (i) 17,223 ADSs held directly, (ii) 4,196 ADSs issuable upon the exercise of options which may be exercised within 60 days of March 23, 2026, (iii) 31,746 ADSs issuable upon the exercise of December 2024 Warrants acquired in the December 2024 Offering which may be exercised within 60 days of March 23, 2026

(3) Consists of (i) 17,219 ADSs held directly, (ii) 4,196 ADSs issuable upon the exercise of options which may be exercised within 60 days of March 23, 2026, and (iii) 31,746 ADSs issuable upon the exercise of December 2024 Warrants acquired in the December 2024 Offering which may be exercised within 60 days of March 23, 2026.

(4) Represents 408 ADSs issuable the upon exercise of options which may be exercised within 60 days of March 23, 2026.

(5) Consists of (i) 2,866 ADSs held directly, (ii) 408 ADSs issuable upon the exercise of options which may be exercised within 60 days of March 23, 2026, and (iii) 5,714 ADSs issuable upon the exercise of December 2024 Warrants acquired in the December 2024 Offering which may be exercised within 60 days of March 23, 2026.

(6) Consists of (i) 15,154 ADSs held directly, (ii) 408 ADSs issuable upon the exercise of options which may be exercised within 60 days of March 23 2026 and (iii) 60,608 ADSs issuable upon the exercise of October 2025 Ordinary Warrants acquired in the October 2025 Private Placement which may be exercised within 60 days of March 23, 2026.

(7) Represents 408 ADSs issuable upon the exercise of options which may be exercised within 60 days of March 23, 2026.

(8) Represents 408 ADSs issuable upon the exercise of options which may be exercised within 60 days of March 23, 2026.

(9) Consists of 440 ADSs held directly.

(10) Consists of (i) 57,218 ADSs held directly, (ii) 10,853 ADSs issuable upon the exercise of options which may be exercised within 60 days of March 23, 2026, (iii) 76,190 ADSs issuable upon the exercise of December 2024 acquired in the December 2024 Offering and (iv) 60,608 ADSs issuable upon the exercise of October 2025 Ordinary Warrants acquired in the October 2025 Private Placement which may be exercised within 60 days of March 23, 2026.

Equity Compensation Plan Table

The following table summarizes our equity compensation plan information as of December 31, 2025.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights[1]	Weighted-average exercise price of outstanding options, warrants and rights[2]	Number of securities authorized for future issuance under equity compensation plans (excluding securities reflected in column (a)[1][3][4]
	(a)	(b)	(c)
Equity compensation plans approved by security holders	215,957	$ 42.83	70,384
Equity compensation plans not approved by security holders	—	—	—
Total	215,957	$ 42.83	70,384

(1) Represents the number of ADSs issuable upon the exercise of options.

(2) Represents the exercise price per ADS.

(3) Represents the number of ADSs authorized for issuance under the 2025 Plan at December 31, 2025.

(4) The 2025 Plan contains an "*evergreen*" provision, pursuant to which on January 1st of each year, we automatically increase the maximum number of shares authorized for issuance pursuant to the 2025 Plan by a number of shares equal to the smaller of (a) 15% of the number of shares issued and outstanding of the Company on a fully diluted basis on the last day of the immediately preceding calendar year; and (b) such amount as determined by our Board if so determined.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Director Independence

Under the corporate governance standards of Nasdaq, a majority of our directors must meet the independence requirements specified in those rules. The Board determined that Joseph Cooper, James Culverwell, Dr. Dennis Langer, Natalie Leong, and Michael Sember, qualify as independent directors, as such term is defined under Nasdaq listing rules.

Certain Relationships and Related Transactions

Due to the limited funding of Quoin Inc. prior to the consummation of the Merger, the compensation, including salary, office and car allowances and other benefits, due to Dr. Myers and Ms. Carter under their respective employment agreements, as well as

reimbursement of expenses and other amounts paid by Dr. Myers and Ms. Carter to third parties on behalf of Quoin Inc., were not paid by Quoin Inc. to Dr. Myers and Ms. Carter, and were accrued as indebtedness to Dr. Myers and Ms. Carter. Following the closing of the Merger, Quoin Inc. began making payments of $25,000 per month to each of Dr. Myers and Ms. Carter to repay the above-described non-interest-bearing indebtedness. We repaid $300,000 and $300,000 of such indebtedness to Dr. Myers, and $300,000 and $300,000 to Ms. Carter, during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, approximately $1,359,000 and $965,000 of such indebtedness was outstanding to Dr. Myers and Ms. Carter, respectively.

On October 2, 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 mandatorily convertible into 12 ADSs, subject to adjustment and were converted in 2021. The ADSs issued to the 2020 Noteholders did not include accrued interest. Two of the five 2020 Noteholders received their amount due during the year ended December 31, 2022 and the Company's estimate of the liability to the remaining three 2020 Noteholders (including Messrs. Langer and Culverwell) was estimated to be $1,146,000 as of December 31, 2025 and December 31, 2024.

On December 23, 2024, we completed the December 2024 Offering of our ordinary shares represented by ADSs, Series F Warrants to purchase ordinary shares represented by ADSs, Series G Warrants to purchase ordinary shares represented by ADSs and pre-funded warrants to purchase ordinary shares represented by ADSs. The Company received aggregate gross proceeds from the December 2024 Offering of approximately $6.8 million, before deducting placement agent fees and other offering expenses. Dr. Myers, Ms. Carter, Mr. Dunn and Mr. Culverwell purchased an aggregate of 38,095 ADSs and accompanying Series F Warrants and Series G Warrants to purchase an aggregate of 76,190 ADSs, for a total purchase price of approximately $600,000, at the public offering price and on the same terms as the other purchasers in the December 2024 Offering.

On October 14, 2025, we completed the October 2025 Private Placement of ordinary shares represented by ADSs, 2025 Pre-Funded Warrants, and October 2025 Ordinary Warrants. Dennis Langer, one of our directors, participated in the October 2025 Private Placement, purchasing ordinary shares represented by 15,152 ADSs and accompanying October 2025 Ordinary Warrants for a total purchase price of approximately $128,641, at a combined purchase price of $8.49 per ADS and accompanying October 2025 Ordinary Warrants. In accordance with Nasdaq Rules, Mr. Langer's purchase price was based upon the consolidated closing bid price from the trading day immediately preceding the date we entered into the 2025 Purchase Agreements, plus $0.50.

Review, Approval and Ratification of Transactions with Related Persons

The general policy of Quoin Pharmaceuticals Ltd. and our audit committee is that all proposed related party transactions are reviewed and approved in advance by the audit committee to the extent required under the Companies Law and Nasdaq and other rules. The audit committee will determine whether such transactions or proposals are fair and reasonable to our company and our shareholders. In general, potential related-party transactions will be identified by our management and discussed with our audit committee at our audit committee's meetings. Detailed proposals, including, where applicable, financial and legal analyses, alternatives and management recommendations, will be provided to our audit committee with respect to each issue under consideration and decisions will be made by our audit committee with respect to the foregoing related-party transactions after opportunity for discussion and review of materials. When applicable, our audit committee will request further information and, from time to time, will request guidance or confirmation from internal or external counsel or auditors.

Item 14. Principal Accountant Fees and Services

CBIZ CPAs P.C. ("CBIZ CPAs") and Marcum LLP ("Marcum"), served as the independent registered public accounting firms, for the fiscal years ended December 31, 2025 and 2024, respectively. Effective November 1, 2024, CBIZ CPAs acquired the attest business of Marcum. Marcum continued to serve as the Company's independent registered public accounting firm through March 18, 2025. On March 18, 2025, Marcum resigned as the Company's independent registered public accounting firm, and CBIZ CPAs was engaged to serve as the independent registered public accounting firm of the Company for the year ending December 31, 2025.

The following table sets forth the aggregate accounting fees paid by us to CBIZ CPAs for all services for the years ended December 31, 2025 and 2024, as applicable.

	Year Ended December 31, 2025	Year Ended December 31, 2024
Type of Fees [(a)] (in thousands)		
Audit Fees	$ 250	$ —
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total	$ 250	$ —

(a) The aggregate fees included in Audit Fees are fees billed for the fiscal years.

Audit Fees. Audit fees refer to the aggregate fees, including expenses, for the audit of our annual financial statements and review of financial statements included in our quarterly reports and other services that are normally provided in connection with statutory and regulatory filings or engagements.

Audit-Related Fees. Audit-Related fees refer to the aggregate fees, including expenses, for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements not reported under "Audit Fees" above.

Tax Fees. Our independent registered public accounting firm did not provide any tax services during the periods.

All Other Fees. Our independent registered public accounting firm did not provide any "other services" during the periods.

Pre-Approval Policy

Our audit committee has a pre-approval policy for the engagement of our independent registered public accounting firm to perform audit and non-audit services. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the audit committee pre-approves annually a catalog of specific audit and non-audit services in the categories of audit services, audit-related services and tax services, if any, that may be performed by our independent registered public accounting firm. Unless the specific service has been previously pre-approved with respect to that year, the audit committee must approve the permitted service before the independent registered public accounting firm is engaged to perform it.

PART IV

Item 15. Exhibit and Financial Statement Schedules

(a)(1) Financial Statements

As part of this Annual Report, the consolidated financial statements are listed in the accompanying index to financial statements on page F-1.

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report.

		INCORPORATED BY REFERENCE			
EXHIBIT NUMBER	DESCRIPTION	FORM	EXHIBIT NUMBER	FILING DATE	FILED/ FURNISHED HEREWITH
2.1	Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021, by and among Cellect Biotechnology Ltd., CellMSC, Inc. and Quoin Pharmaceuticals, Inc.	6-K	10.1	March 24, 2021	
2.1.1	Amendment, dated September 24, 2021, to the Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021, by and among Cellect Biotechnology Ltd., CellMSC, Inc., and Quoin Pharmaceuticals, Inc.	6-K	99.2	September 27, 2021	
2.2	Amended and Restated Share Transfer Agreement, dated May 27, 2021 by and between Cellect Biotechnology Ltd. and EnCellX Inc.	F-4	2.2	June 16, 2021	
2.2.1	Amendment, dated September 26, 2021, to the Amended and Restated Share Transfer Agreement, dated as of May 27, 2021, by and between EnCellX, Inc. and Cellect Biotechnology Ltd.	6-K	99.3	September 27, 2021	
2.3	Securities Purchase Agreement, dated as of March 24, 2021, by and among Cellect Biotechnology Ltd., Quoin Pharmaceuticals, Inc. and the investors named on the Schedule of Buyers attached thereto	6-K	10.4	March 24, 2021	
2.3.1	Amendment Agreement, dated as of September 17, 2021, by and among Quoin Pharmaceuticals, Inc., Cellect Biotechnology, Ltd., and Altium Growth Fund, L.P.	6-K	99.1	September 17, 2021	
2.3.2	Second Amendment Agreement, dated as of March 13, 2022, by and among Quoin Pharmaceuticals, Inc., Quoin Pharmaceuticals Ltd., and Altium Growth Fund, L.P.	6-K	4.1	March 28, 2022	
2.3.3	Waiver Agreement, dated June 6, 2022, by and among Quoin Pharmaceuticals Ltd., Quoin Pharmaceuticals, Inc. and Altium Growth Fund, LP	6-K	10.2	June 6, 2022	

2.3.4	Agreement, dated July 14, 2022, by and among Quoin Pharmaceuticals, Inc., Quoin Pharmaceuticals Ltd. and Altium Growth Fund, LP	6-K	10.1	July 15, 2022
2.4	Securities Purchase Agreement, dated as of March 24, 2021, by and among Quoin Pharmaceuticals, Inc. and the investors listed on the Schedule of Buyers attached thereto	6-K	10.6	March 24, 2021
2.5	Letter Agreement, dated September 17, 2021, between Quoin Pharmaceuticals, Inc. and Cellect Biotechnology, Ltd.	6-K	99.2	September 17, 2021
3.1	Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., as amended	10-K	3.1	March 13, 2025
3.1.1	Amendments to Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on August 21, 2025	8-K	3.1	August 21, 2025
4.1	Form of Deposit Agreement between Cellect Biotechnology Ltd. (n/k/a Quoin Pharmaceuticals Ltd.), The Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder	F-1/A	4.1	July 26, 2016
4.1.1	Specimen American Depositary Receipt (included in Exhibit 4.1).			
4.2	Form of Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the August 2022 Offering	F-1	4.13	August 3, 2022
4.2.1	Form of Amendment No. 1 to Warrant to Purchase Ordinary Shares Represented by American Depositary Shares, dated as of February 24, 2023	8-K	4.3	February 28, 2023
4.3	Form of Warrant to Purchase Ordinary Shares Represented by American Depositary Shares, issued in the February 2023 Offering	8-K	4.2	February 28, 2023
4.4	Form of Pre-Funded Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the March 2024 Offering	8-K	4.1	March 8, 2024
4.5	Form of Series D Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the March 2024 Offering	8-K	4.2	March 8, 2024
4.6	Form of Series E Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the March 2024 Offering	8-K	4.3	March 8, 2024
4.7	Form of Amendment to Warrants to Purchase Ordinary Shares Represented by American Depositary Shares issued in the March 2024 Offering	8-K	4.4	March 8, 2024
4.8	Form of Pre-Funded Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the December 2024 Offering	8-K	4.1	December 26, 2024

4.9	Form of Series F Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the December 2024 Offering	8-K	4.2	December 26, 2024	
4.10	Form of Series G Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the December 2024 Offering	8-K	4.3	December 26, 2024	
4.11	Form of Amendment to Warrants to Purchase Ordinary Shares Represented by American Depositary Shares, dated as of December 20, 2024	8-K	4.4	December 26, 2024	
4.12	Form of Pre-Funded Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the October 2025 Private Placement	8-K	4.1	October 15, 2025	
4.13	Form of Series H Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the October 2025 Private Placement	8-K	4.2	October 15, 2025	
4.14	Form of Series I Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the October 2025 Private Placement	8-K	4.3	October 15, 2025	
4.15	Form of Series J Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the October 2025 Private Placement	8-K	4.4	October 15, 2025	
4.16	Form of Series K Warrant to Purchase Ordinary Shares Represented by American Depositary Shares issued in the October 2025 Private Placement	8-K	4.5	October 15, 2025	
4.17	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934				**X**
10.1†	Amended and Restated Equity Incentive Plan of Quoin Pharmaceuticals Ltd., effective as of April 12, 2022	6-K	Annex C included in Exhibit 99.1	March 8, 2022	
10.1.1†	Form of Non-Qualified Stock Option Award Agreement for directors	F-1	10.34	August 3, 2022	
10.1.2†	Form of Non-Qualified Stock Option Award Agreement for officers	F-1	10.35	August 3, 2022	
10.2†	2025 Equity Incentive Plan of Quoin Pharmaceuticals, Ltd.	S-8	4.4	August 27, 2025	
10.2.1†	Form of Incentive Stock Option Grant Notification Letter	8-K	10.1	November 17, 2025	
10.2.2†	Form of Non-Qualified Stock Option Grant Notification Letter	8-K	10.2	November 17, 2025	
10.3†	Compensation Policy for Executives and Directors of Quoin Pharmaceuticals Ltd, adopted on August 21, 2025				**X**
10.4†	CEO Compensation Program	10-K	10.45	March 13, 2025	
10.5†	COO Compensation Program	10-K	10.46	March 13, 2025	
10.6†	Non-Employee Directors' Compensation Program, as amended	10-K	10.44	March 13, 2025	

10.7†	Executive Employment Agreement, dated March 9, 2018, by and between Quoin Pharmaceuticals, Inc. and Dr. Michael Myers	6-K	10.1	October 29, 2021
10.8†	Executive Employment Agreement, dated March 9, 2018, by and between Quoin Pharmaceuticals, Inc. and Denise Carter	6-K	10.2	October 29, 2021
10.9†	Service Agreement, dated November 1, 2021, by and between Quoin Pharmaceuticals, Inc. and Gordon Dunn	6-K	10.1	November 23, 2021
10.9.1†	Settlement Agreement, effective August 15, 2025, by and between Quoin Pharmaceuticals, Inc., and Gordon Dunn	8-K	10.1	August 27, 2025
10.10†	Service Agreement, dated August 18. 2025, by and between Quoin Therapeutics (Ireland) Ltd. and Sally Lawlor	8-K	10.1	August 21, 2025
10.11†	Form of Indemnification and Release Agreement, entered into by and between Quoin Pharmaceuticals Ltd. and each of the officers and directors of Quoin Pharmaceuticals Ltd.	6-K	Annex D included in Exhibit 99.1	March 8, 2022
10.12	Purchase Agreement, dated January 25, 2024, by and between Quoin Pharmaceuticals Ltd. and Alumni Capital LP	8-K	10.1	January 30, 2024
10.13	Form of Placement Agency Agreement by and between Quoin Pharmaceuticals Ltd. and A.G.P/Alliance Global Partners related to the August 2022 Offering	F-1/A	1.1	August 4, 2022
10.14	Form of Securities Purchase Agreement related to the August 2022 Offering	F-1/A	4.11	August 4, 2022
10.15	Form of Placement Agency Agreement by and between Quoin Pharmaceuticals Ltd. and A.G.P/Alliance Global Partners related to the February 2023 Offering	8-K	10.2	February 28, 2023
10.16	Form of Securities Purchase Agreement related to the February 2023 Offering	8-K	10.1	February 28, 2023
10.17	Form of Placement Agency Agreement by and between Quoin Pharmaceuticals Ltd. and A.G.P/Alliance Global Partners related to the March 2024 Offering	8-K	1.1	March 8, 2024
10.18	Form of Securities Purchase Agreement related to the March 2024 Offering	8-K	10.1	March 8, 2024
10.19	Placement Agency Agreement dated December 20, 2024, by and between Quoin Pharmaceuticals Ltd. and Maxim Group LLC related to the December 2024 Offering	8-K	1.1	December 26, 2024
10.20	Form of Securities Purchase Agreement, dated December 20, 2024 related to the December 2024 Offering	8-K	10.1	December 26, 2024

10.21	Form of Securities Purchase Agreement, dated October 10, 2025 related to the October 2025 Private Placement	8-K	10.1	October 15, 2025
10.22	Form of Registration Rights Agreement, dated October 10, 2025 related to the October 2025 Private Placement	8-K	10.2	October 15, 2025
10.23	License and Distribution Agreement, dated November 5, 2021, by and between Quoin Pharmaceuticals, Inc. and AFT Pharmaceuticals Ltd.	6-K	10.3	November 23, 2021
10.24	Supply Agreement, dated September 15, 2021, by and between Quoin Pharmaceuticals, Inc. and AFT Pharmaceuticals Ltd.	6-K	10.4	November 23, 2021
10.25	License and Distribution Agreement, dated November 7, 2021, by and between Quoin Pharmaceuticals, Inc. and GenPharm Services FZ LLC	6-K	10.5	November 23, 2021
10.26	Supply Agreement, dated November 7, 2021, by and between Quoin Pharmaceuticals, Inc. and GenPharm Services FZ LLC	6-K	10.6	November 23, 2021
10.27*	Distribution Agreement, dated December 15, 2021, by and between Quoin Pharmaceuticals, Inc. and Orpharm LLC	6-K	10.1	December 20, 2021
10.28*	License and Distribution Agreement, dated as of January 24, 2022, between the Company and E-Log Logistica LTDA	6-K	10.1	January 31, 2022
10.29*	License and Distribution Agreement, dated as of February 1, 2022, by and between Quoin Pharmaceuticals Ltd. and Er-Kim İlaç Sanayi ve Ticaret A.Ş, and the First Amendment to the License and Distribution Agreement, dated as of February 17, 2022, by and between Quoin Pharmaceuticals, Inc. and Er-Kim İlaç Sanayi ve Ticaret A.Ş	6-K	10.4	March 8, 2022
10.30*	License and Distribution Agreement, dated as of February 11, 2022, by and between Quoin Pharmaceuticals Ltd. and Neopharm (Israel) 1996 Ltd.	6-K	10.5	March 8, 2022
10.31	Supply Agreement, dated as of February 11, 2022, by and between Quoin Pharmaceuticals Ltd. and Neopharm (Israel) 1996 Ltd.	6-K	10.6	March 8, 2022
10.32	Master Services Agreement, dated November 2, 2020, by and between Therapeutics, Inc. and Quoin Pharmaceuticals, Inc.	20-F	4.39	April 13, 2022
10.33	Development and Supply Agreement, dated January 13, 2021, by and between TopChem Pharmaceuticals Limited and Quoin Pharmaceuticals Limited	20-F	4.38	April 13, 2022
10.34	Quotation – Tech Transfer and Clinical Manufacture for QRX003 Topical Lotion, dated April 8, 2021, by Ferndale Contract Manufacturing to Quoin Pharmaceuticals, Inc.	20-F	4.37	April 13, 2022

10.35	Exclusive License Agreement, dated October 17, 2019, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc.	20-F	4.30	April 13, 2022	
10.36	Exclusive License Agreement Renewal, dated May 8, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc.	20-F	4.31	April 13, 2022	
10.37.1	First Amendment to the Exclusive License Agreement, dated July 31, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc.	20-F	4.32	April 13, 2022	
10.37.2	Second Amendment to the Exclusive License Agreement, dated September 30, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc.	20-F	4.33	April 13, 2022	
10.37.3	Third Amendment to the Exclusive License Agreement, dated January 27, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc.	20-F	4.34	April 13, 2022	
10.37.4	Fourth Amendment to the Exclusive License Agreement, dated April 19, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc.	20-F	4.35	April 13, 2022	
10.37.5	Fifth Amendment to the Exclusive License Agreement, dated June 14, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc.	20-F	4.36	April 13, 2022	
10.38*	License and Distribution Agreement, dated June 14, 2022, by and between Quoin Pharmaceuticals, Inc. and WinHealth Investment (HK) Limited	6-K	10.1	June 17, 2022	
10.39*	License and Distribution Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited	6-K	10.2	July 15, 2022	
10.40*	Supply Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited	6-K	10.3	July 15, 2022	
10.41	License and Distribution Agreement, dated September 1, 2023, by and between Quoin Pharmaceuticals Inc. and Farma Mondo	8-K	10.1	September 13, 2023	
10.42	Research Agreement, dated November 1, 2021, by and between Quoin Pharmaceuticals, Inc. and Queensland University of Technology	6-K	10.2	November 23, 2021	
10.43*	Research Agreement, dated May 20, 2022, by and between Quoin Pharmaceuticals, Inc. and Queensland University of Technology, Australia	6-K	10.1	June 6, 2022	
14.1	Code of Ethics	10-K	14.1	March 15, 2023	
19.1	Quoin Pharmaceuticals Ltd. Insider Trading Policy	10-K	19.1	March 13, 2025	
21.1	Subsidiaries of Registrant				**X**
23.1	Consent of CBIZ CPAs P.C., Certified Public Accountants				**X**
23.2	Consent of Marcum LLP				**X**

31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934.				X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934.				X
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. § 1350.				X
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. § 1350.				X
97.1	Clawback Policy	10-K	97.1	March 14, 2024	
101	Information formatted Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Other Comprehensive Loss, (iii) Consolidated Statements of Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements.				X
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101)				X

# Indicates management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: March 26, 2026

QUOIN PHARMACEUTICALS LTD.

By: /s/ Dr. Michael Myers
Name: Dr. Michael Myers
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Dr. Michael Myers Dr. Michael Myers	Chairman and Chief Executive Officer (Principal Executive Officer)	March 26, 2026
/s/ Sally Lawlor Sally Lawlor	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 26, 2026
/s/ Denise Carter Denise Carter	Director and Chief Operating Officer	March 26, 2026
/s/ Joseph Cooper Joseph Cooper	Director	March 26, 2026
/s/ James Culverwell James Culverwell	Director	March 26, 2026
/s/ Dennis Langer Dennis Langer	Director	March 26, 2026
/s/ Natalie Leong Natalie Leong	Director	March 26, 2026
/s/ Michael Sember Michael Sember	Director	March 26, 2026

QUOIN PHARMACEUTICALS LTD.

Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Quoin Pharmaceuticals Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Quoin Pharmaceuticals Ltd. (the "Company") as of December 31, 2025, the related consolidated statements of operations and other comprehensive loss, shareholders' equity and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ CBIZ CPAS P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2020 (such date takes into account the acquisition of certain assets of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Morristown, New Jersey
March 26, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Quoin Pharmaceuticals Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Quoin Pharmaceuticals Ltd. (the "Company") as of December 31, 2024, the related consolidated statements of operations, shareholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our provides a reasonable basis for our opinion.

/s/ MARCUM LLP

Marcum LLP

We have served as the Company's auditor from 2020 to 2025.
Morristown, New Jersey
March 13, 2025

QUOIN PHARMACEUTICALS LTD.

Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,818,096	$ 3,623,343
Investments	14,927,165	10,433,535
Prepaid expenses and other current assets	1,261,974	869,126
Total current assets	20,007,235	14,926,004
Prepaid expenses - long term	—	300,000
Intangible assets, net	383,334	483,334
Total assets	$ 20,390,569	$ 15,709,338
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,262,222	$ 905,704
Accrued expenses	2,538,457	1,528,977
Accrued interest and financing expense	1,146,251	1,146,251
Due to officers - short term	600,000	600,000
Total current liabilities	5,546,930	4,180,932
Due to officers - long term	1,723,733	2,323,733
Total liabilities	$ 7,270,663	$ 6,504,665
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, no par value per share, 5,000,000,000 and 100,000,000 ordinary shares authorized at December 31, 2025 and December 31, 2024, respectively - 52,441,360 (1,498,325 ADS's) ordinary shares issued and outstanding at December 31, 2025 and 8,948,164 (255,661 ADS's) ordinary shares issued and outstanding at December 31, 2024	$ —	$ —
Accumulated other comprehensive loss	(613)	—
Additional paid in capital	84,090,966	64,370,465
Accumulated deficit	(70,970,447)	(55,165,792)
Total shareholders' equity	13,119,906	9,204,673
Total liabilities and shareholders' equity	$ 20,390,569	$ 15,709,338

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

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Operations and Other Comprehensive Loss

	Years Ended December 31, 2025	2024
Operating expenses		
General and administrative	$ 6,487,909	$ 5,925,833
Research and development	9,802,807	3,602,632
Total operating expenses	16,290,716	9,528,465
Other (income) and expenses		
Unrealized gain	(3,980)	(7,502)
Realized and accrued interest income	(482,081)	(558,491)
Total other income	(486,061)	(565,993)
Net loss	$ (15,804,655)	$ (8,962,472)
Other comprehensive loss		
Foreign currency translation	(613)	—
Total other comprehensive loss	(613)	—
Comprehensive loss	$ (15,805,268)	$ (8,962,472)
Loss per ADS		
Loss per ADS		
Basic	$ (14.80)	$ (68.02)
Fully-diluted	$ (14.80)	$ (68.02)
Weighted average number of ADS's outstanding		
Basic	1,068,152	131,759
Fully-diluted	1,068,152	131,759

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

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Shareholders' Equity
Years Ended December 31, 2025 and 2024

	Ordinary Shares	ADS's	Additional Paid in Capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
Balance at December 31, 2023	987,220	28,206	$ 51,867,336	$ (46,203,320)	$ —	$ 5,664,016
Net loss	—	—	—	(8,962,472)	—	(8,962,472)
Stock based compensation	—	—	1,258,890	—	—	1,258,890
Issuance of ADS and Pre-Funded Warrants	7,960,944	227,455	11,244,239	—	—	11,244,239
Balance at December 31, 2024	8,948,164	255,661	$ 64,370,465	$ (55,165,792)	$ —	$ 9,204,673
Net loss	—	—	—	(15,804,655)		(15,804,655)
Stock based compensation	—	—	1,147,236			1,147,236
Issuance of ADS and Pre-Funded Warrants, net	530,320	15,152	15,082,443			15,082,443
Exercise of Warrants, net	7,798,024	222,801	3,490,822			3,490,822
Exercise of Pre-Funded Warrants	35,164,852	1,004,711				—
Foreign currency adjustment					(613)	(613)
Balance at December 31, 2025	52,441,360	1,498,325	$ 84,090,966	$ (70,970,447)	$ (613)	$ 13,119,906

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

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2025	2024
Cash flows used in operating activities:		
Net loss	$ (15,804,655)	$ (8,962,472)
Stock based compensation	1,147,236	1,258,890
Amortization of intangibles	100,000	100,000
Realized and unrealized gain and accrued interest on investments	(215,855)	(251,590)
Changes in assets and liabilities:		
Increase (decrease) in accounts payable and accrued expenses	1,325,128	275,955
Decrease in prepaid expenses and other assets	(92,848)	(278,092)
Net cash used in operating activities	$ (13,540,994)	$ (7,857,309)
Cash flows provided by investing activities:		
Purchase of investments	$ (12,264,069)	$ (17,254,282)
Proceeds from redemption of investments	7,986,294	15,366,000
Net cash used by investing activities	$ (4,277,775)	$ (1,888,282)
Cash flows (used in) provided by financing activities:		
Payment of amounts due to officers	$ (600,000)	$ (600,000)
Proceeds from sale of equity securities, net	18,614,135	11,567,736
Net cash provided by financing activities	$ 18,014,135	$ 10,967,736
Effect of foreign exchange rate on changes on cash	(613)	—
Net change in cash and cash equivalents:	194,753	1,222,145
Cash and cash equivalents - beginning of year	3,623,343	2,401,198
Cash and cash equivalents - end of year	$ 3,818,096	$ 3,623,343
Supplemental information - Non cash items:		
Offering expenses associated with warrant modification	$ —	$ 1,725,148
Accrued offering expenses included in additional paid in capital	$ 40,870	$ 323,497

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

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

NOTE 1 – ORGANIZATION AND BUSINESS

Quoin Pharmaceuticals Ltd. ("Quoin Ltd.," or the "Company"), formerly known as Cellect Biotechnology Ltd. ("Cellect"), is the holding company for Quoin Pharmaceuticals, Inc., a Delaware corporation ("Quoin Inc."). Quoin Inc. was incorporated in Delaware on March 5, 2018. Quoin Inc. is the holding company for Quoin Therapeutics Ireland Limited ("Quoin Ireland"), an Irish private company limited by shares. Quoin Ireland was incorporated in Ireland on November 26, 2024. On October 28, 2021, Cellect completed the business combination with Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Cellect (the "Merger"). Immediately after completion of the Merger, Cellect changed its name to "Quoin Pharmaceuticals Ltd."

Effective April 9, 2025, the ratio of American Depositary Shares ("ADSs") evidencing ordinary shares changed from 1 ADS representing one (1) ordinary share to 1 ADS representing thirty-five (35) ordinary shares (the "Ratio Change"), which resulted in a 1 for 35 reverse split of the issued and outstanding ADSs (the "Reverse Split"). Our Ordinary Shares were not affected by this adjustment. Except as specifically provided, ADSs and related option, warrant, purchase price and exercise price information presented in these consolidated financial statements and accompanying footnotes has been retroactively adjusted to reflect the Ratio Change and the Reverse Split.

The Company is a late-stage clinical specialty pharmaceutical company focused on the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently either no approved or very limited treatments or cures. The Company's lead product, QRX003, is under clinical development as a potential treatment for Netherton Syndrome ("NS"), a rare hereditary genetic disease. QRX003 is entering pivotal registrational clinical testing under an open Investigational New Drug ("IND") application with the Food and Drug Administration ("FDA"). The Company has opened six clinical sites in the United States ("US") along with international sites that are being opened in the UK, Spain, France and the Netherlands. QRX003 is currently being tested in seven pediatric NS patients in investigator-initiated studies in Ireland, Austria, the Netherlands and New Zealand. QRX003 is also being developed as a potential treatment for Peeling Skin Syndrome with the first subject being treated in New Zealand. The company is in the process of expanding this study to include up to an additional five pediatric subjects. The Company has entered into a Research Agreement with the Queensland University of Technology ("QUT") in Australia, under which the Company has obtained an option for a global license to QRX008 for the potential treatment of scleroderma, as well as a Research Agreement with The School of Pharmacy at University College Cork ("UCC") for the development of novel topical formulations of rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are either limited or no approved therapies or cures, including microcystic lymphatic malformations, venous malformations and angiofibromas among others. Quoin has also entered into 9 commercial partnerships for QRX003 spanning 61 countries outside of its core commercial territories of the US, Western Europe and Japan. These partnership countries include Canada, Australia/New Zealand, the Middle East, China, Taiwan, Hong Kong, Singapore, Israel, Central and Eastern Europe, Turkey as well as several countries in Latin America. To date, no products have been commercialized and no revenue has been generated by the Company.

NOTE 2 - LIQUIDITY RISKS AND OTHER UNCERTAINTIES

The consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") assuming the Company will continue as a going concern. The Company has incurred net losses every year since inception and has an accumulated deficit of approximately $71.0 million at December 31, 2025. The Company has a limited operating history and has historically funded its operations through its founders' funding expenditures and debt and equity financings. At December 31, 2025, the Company had cash balances totaling $3.8 million and investments of $14.9 million.

The Company's ability to continue as a going concern is dependent upon the Company's ability to obtain additional funding. There can be no assurance that such funding will be available in sufficient amounts or on terms acceptable to the Company. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability of the recorded assets or the classification of liabilities that may be necessary should the Company be unable to continue as a going concern.

Based upon the Company's current business plans and cash, cash equivalents and investments on hand, management has concluded that there is substantial doubt about our ability to continue as a going concern for a period of at least one year from the issuance of the audited consolidated financial statements. In order to address the Company's capital needs, the Company intends to consider multiple alternatives, including, but not limited to, the sale of additional equity or debt securities or other debt instruments, collaborative, strategic,

and/or licensing transactions or grants to support our future operations. 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 The Company will need to obtain further funding through public or private offerings of its capital stock, debt financing, pursuant to the exercise of warrants issued to investors in the Company's prior public and private offerings, collaboration, strategic and/or licensing arrangements or other sources in order to complete the research and development of the Company's product candidates and to fund the Company's other operating requirements until it achieves commercial profitability, if ever. However, the Company may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. In addition, any exercise of the Company's outstanding warrants is at the discretion of the warrant holders and is dependent, in part, upon the market price of the Company's ADSs. There can be no assurance that any of the Company's outstanding warrants will ever be in-the-money prior to their expiration and, as such, the Company's outstanding warrants may expire without being exercised. 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.

Other risks and uncertainties:

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

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

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

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

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation:

The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP, which have been consistently applied. All intercompany accounts and transactions have been eliminated in consolidation.

Principles of Consolidation:

The accompanying consolidated financial statements include the accounts of Quoin Pharmaceuticals Ltd. and its wholly owned subsidiary. All intercompany transactions and balances are eliminated in consolidation. The functional currency of Quoin Ireland, a wholly-owned subsidiary of the Company, is remeasured into U.S. dollars using the exchange rate in effect at the consolidated balance sheet date. The Company translates the assets and liabilities of its Ireland subsidiary into the United States dollar at the exchange rate in effect on the balance sheet date and those unrealized gains and losses are reported in other comprehensive income. Expenses are remeasured using the average exchange rate in effect during the period. Gains and losses arising from remeasurement of the wholly owned subsidiary's financial statements are included in the determination of net loss.

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

Use of Estimates:

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

Cash and cash equivalents:

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

Warrants:

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

The Company assesses classification of its warrants and other free-standing derivatives at each reporting date to determine whether a change in classification between assets, liabilities and equity is required. The Company evaluated 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 consolidated balance sheets as of December 31, 2025 and December 31, 2024, respectively.

Investments:

Investments as of December 31, 2025 and 2024 consist primarily of U.S. Treasury Bills and Notes, which are classified as trading securities, totaling $14.9 million and $10.4 million, respectively. The amount as of December 31, 2025 also includes $0.2 million held as cash equivalents. The Company determines the appropriate balance sheet classification of its investments at the time of purchase and evaluates the classification at each balance sheet date. All of the Company's U.S. Treasury Bills and Notes held on December 31, 2025 have maturities within twelve months from the balance sheet date. As of December 31, 2025, the carrying value of the Company's U.S. Treasury Bills and Notes approximates their fair value due to their short-term maturities.

Long-lived assets:

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

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

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 its overall business,
- Significant underperformance relative to expected historical or projected development milestones,
- Significant negative regulatory or economic trends, and
- Significant technological changes which could render the platform technology obsolete.

The Company recognizes impairment when the sum of the expected undiscounted future cash flows is less than the carrying amount of the asset. Impairment losses, if any, are measured as the excess of the carrying amount of the asset over its estimated fair value. During the years ended December 31, 2025 and 2024, there were no impairment indicators which required an impairment loss measurement.

Operating Segment:

The Company operates in one business segment, which includes the business of research and development activities related to the development of therapeutic products that treat rare and orphan diseases for which there are currently very limited or no approved treatments or cures. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its Chief Executive Officer, who reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

In addition to the significant expense categories included within consolidated net loss presented on the Company's Consolidated Statements of Operations, see below for disaggregated amounts that comprise research and development expenses:

	Year ended December 31,	
	2025	2024
External clinical development expenses	$ 7,396,788	$ 2,083,119
Personnel related and stock-based compensation	1,532,280	1,073,564
Other research and development expenses	873,739	445,949
Total research and development expenses	$ 9,802,807	$ 3,602,632

Research and development:

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

Income taxes:

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

The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company maintains a full valuation allowance on its existing deferred tax assets.

The Company also accounts for uncertain tax positions using the more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. As of December 31, 2025 and 2024, the Company had no uncertain tax positions which affected its financial position and its results of operations or its cash flows and will continue to evaluate for uncertain tax positions in the future. If at any time the Company should record interest and penalties in connection with income taxes, the interest and the penalties will be expensed within the interest and general and administrative expenses, respectively.

Stock based compensation:

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

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

Fair value of financial instruments:

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

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

Earnings (loss) per share:

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

For the year ended December 31, 2025, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 8,931,650 ADS and outstanding stock options to purchase 215,957 ADS. For the year ended December 31, 2024, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 1,120,301 ADS and outstanding stock options to purchase 55,541 ADS. The inclusion of these warrants and stock options for both 2025 and 2024 in the denominator would be anti-dilutive. For the years ended December 31, 2025 and December 31, 2024 basic and diluted net earnings (loss) per share included 1,309,591 ADS and 320,362 ADS respectively issuable with respect to unexercised prefunded warrants (See Note 13).

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

Recent Accounting Pronouncements:

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The standard is intended to enhance the transparency and decision usefulness of income tax disclosures primarily through changes to the rate reconciliation and income taxes paid information. The Company adopted ASU No. 2023-09 prospectively effective January 1, 2025 (See Note14).

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, requiring public entities to disclose additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*. The amendments in this update provide clarifications intended to improve the consistency and usability of interim disclosure requirements and the applicability to Topic 270. The amendments also provide additional guidance for reporting material events occurring after the most recent annual period. The new guidance will be applied prospectively and is effective for fiscal years beginning after December 15, 2027, and interim periods within those annual reporting periods, with the option to apply retrospectively. Early adoption is permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements.

NOTE 4 – ACCRUED INTEREST AND FINANCING EXPENSE

On October 2, 2020, Quoin Inc. issued promissory notes (the "2020 Notes") to certain investors ("2020 Noteholders"). The 2020 Notes were mandatorily convertible into 12 ADSs, subject to adjustment and were converted in 2021. The ADSs issued to the 2020 Noteholders did not include accrued interest. Two of the five 2020 Noteholders received their amount due during the year ended December 31, 2022 and the Company's estimate of the liability to the remaining three 2020 Noteholders was estimated to be $1,146,000 as of December 31, 2025 and December 31, 2024.

There was no interest expense recognized in both the years ended December 31, 2025 and 2024.

NOTE 5 - FAIR VALUE OF FINANCIAL INSTRUMENTS

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

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

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

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

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

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

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

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis by fair value hierarchy at December 31, 2025 and 2024:

December 31, 2025	Level 1	Level 2	Level 3	Total
US Treasury Bills and Notes	$ 14,927,165	$ —	$ —	$ 14,927,165
Mutual Funds	224,093			224,093
Total Assets	$ 15,151,258	$ —	$ —	$ 15,151,258

December 31, 2024	Level 1	Level 2	Level 3	Total
US Treasury Bills and Notes	$10,433,535	$ —	$ —	$ 10,433,535
Total US Treasury Bills and Notes Asset	$10,433,535	$ —	$ —	$ 10,433,535

NOTE 6 – STOCK BASED COMPENSATION

In March 2022, the Board of Directors of the Company approved the Amended and Restated Equity Incentive Plan which was approved by the shareholders at the Company's Annual General Meeting of Shareholders held on April 12, 2022 (the "Amended Plan"). The Amended Plan increased the number of ordinary shares reserved for issuance under such equity incentive plan to 15% of the Company's outstanding ordinary shares on a fully-diluted basis, or 9,197,277 ordinary shares represented by 262,779 ADSs as of December 31, 2024. Under the Amended Plan, the Company could grant options to its directors, officers, employees, consultants, advisers and service providers. As of the year ended December 31, 2025 200,627 options are outstanding under the Amended Plan and following approval of the 2025 Equity Incentive Plan, no shares are available for issuance under the Amended Plan.

On August 21, 2025, at our 2025 Annual General Meeting of Shareholders, our shareholders approved the Quoin Pharmaceuticals Ltd. 2025 Equity Incentive Plan (the "2025 Plan") and authorized the issuance pursuant to the 2025 Plan of up to 3,000,000 Ordinary Shares represented by 85,714 ADSs, subject to an automatic annual increase equal to the smaller of (a) fifteen percent (15%) of the number of Ordinary Shares issued and outstanding on a fully diluted basis on the immediately preceding December 31, or (b) an amount determined by our Board of Directors. The 2025 Plan supersedes the Amended Plan. As of the year ended December 31, 2025, 2,463,450 shares represented by 70,384 ADSs are available for issuance under the 2025 Plan.

The following table summarizes stock-based activities under the Amended & 2025 Plans:

	ADS Underlying Options	Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2023	**7,946**	**$ 886.90**	**9.68**
Granted	47,595	27.30	
Outstanding at December 31, 2024	**55,541**	**$ 150.27**	**9.76**
Granted	171,313	9.99	
Canceled	(10,897)	74.19	
Outstanding at December 31, 2025	**215,957**	**$ 42.83**	**9.30**
Exercisable options at December 31, 2025	10,774	$ 485.14	8.29

The intrinsic value of outstanding options at December 31, 2025 was $0.8 million.

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

Stock options granted during the years ended December 31, 2025 and 2024 were valued using the Black-Scholes option-pricing model with the following weighted average assumptions:

	December 31, 2025	December 31, 2024
Expected volatility	108.8 %	106.6 %
Risk-free interest rate	4.4 %	3.9 %
Expected dividend yield	0.0 %	0.0 %
Expected life of options in years	6.4	6.4
Exercise Price	$ 9.99	$ 27.30
Fair value of stock	$ 9.66	$ 27.30
Estimate fair value of option	$ 8.22	$ 23.10

Stock based compensation expense was approximately $1.15 million ($400,000 included in research and development expense and $750,000 included in general and administrative expenses) in the year ended December 31, 2025. Stock based compensation expense was approximately $1.26 million ($293,000 included in research and development expense and $967,000 included in general and administrative expenses) in the year ended December 31, 2024. At December 31, 2025, the total unrecognized compensation expense related to non-vested options was approximately $2.5 million and is expected to be recognized over the remaining weighted average service period of approximately 3.35 years.

NOTE 7 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are as follows:

	December 31, 2025	December 31, 2024
Prepaid R&D costs	$ 920,947	$ 772,083
Prepaid insurance	277,808	309,889
Prepaid expense	63,219	87,154
Total	$ 1,261,974	$ 1,169,126
Less: Short-term portion	(1,261,974)	(869,126)
Long-term portion	**$ —**	**$ 300,000**

NOTE 8 – ACCRUED EXPENSES

Accrued expenses are as follows:

	December 31, 2025	December 31, 2024
Research contract expenses (note 12)	$ 934,524	$ 183,094
Payroll (note 11)	1,023,295	940,539
Payroll taxes (note 11)	54,936	77,726
Accrued severance	391,926	—
Professional fees	96,848	323,497
Other expenses	36,928	4,121
Total	**$ 2,538,457**	**$ 1,528,977**

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

NOTE 9 –IN-LICENSED TECHNOLOGY

Skinvisible:

In October 2019, Quoin Inc. entered into the Exclusive Licensing Agreement (as amended from time to time, the "License Agreement") with Skinvisible Pharmaceuticals, Inc. ("Skinvisible"), under which Skinvisible granted the Company an exclusive royalty-bearing license relating to the production and manufacture of prescription drug products related to certain patents held by Skinvisible, including those related to QRX003 and QRX004. The Company made Skinvisible a one-time non-refundable, non-creditable license fee of $1 million (the "License Fee"). In addition, the Company agreed to pay Skinvisible a single digit royalty percentage of the Company's net sales revenues for any licensed product covered by the patent rights licensed under the License Agreement. The Company also agreed to pay Skinvisible 25% of any revenues the Company receives as royalties in the event that the Company sublicense any licensed products to a third party. The License Agreement also requires that the Company make a $5 million payment to Skinvisible upon receiving approval in the U.S. or European Union, whichever occurs first, for the first drug product developed using intellectual property licensed thereunder. There were no milestone or royalty obligations due at December 31, 2025 and December 31, 2024.

NOTE 10 - INTANGIBLE ASSETS

Intangible assets are as follows:

	December 31, 2025	December 31, 2024
Technology license – Skinvisible	$ 1,000,000	$ 1,000,000
Accumulated amortization	(616,666)	(516,666)
Net book value	**$ 383,334**	**$ 483,334**

The Company recorded amortization expense of approximately $100,000 and $100,000 in the years ended December 31, 2025 and 2024, respectively. The annual amortization expense expected to be recorded for existing intangible assets for the years 2026 through 2029, is approximately $100,000, $100,000, $100,000 and $83,000, respectively.

NOTE 11 – RELATED PARTY TRANSACTIONS

Due to Officers/Founders:

Due to the limited funding of Quoin Inc. prior to the consummation of the Merger, the compensation, including salary, office and car allowances and other benefits, due to Dr. Myers and Ms. Carter under their respective employment agreements, as well as reimbursement of expenses and other amounts paid by Dr. Myers and Ms. Carter to third parties on behalf of Quoin Inc., were not paid by Quoin Inc. to Dr. Myers and Ms. Carter, and were accrued as indebtedness to Dr. Myers and Ms. Carter. Following the closing of the Merger, Quoin Inc. began making payments of $25,000 per month to each of Dr. Myers and Ms. Carter to repay the above-described non-interest-bearing indebtedness. The Company repaid $300,000 and $300,000 of such indebtedness to Dr. Myers and $300,000 and $300,000 to Ms. Carter in the year ending December 31, 2025 and 2024, respectively. As of December 31, 2025, approximately $1,359,000 and $965,000 of such indebtedness was outstanding to Dr. Myers and Ms. Carter, respectively.

Amounts due to officers at December 31, 2025 and 2024 consisted of the following:

	December 31, 2025	December 31, 2024
Salaries and other compensation	$ 2,323,733	$ 2,923,733
Less: Short-term portion	(600,000)	(600,000)
Long-term portion	**$ 1,723,733**	**$ 2,323,733**

Insider Participation in October 2025 and December 2024 Offering:

See Note 13.

Interest Payable:

See Note 4 for interest payable on the 2020 Notes.

NOTE 12 – RESEARCH, CONSULTING AGREEMENTS AND COMMITMENTS

Research and consulting agreement

In November 2020, Quoin Inc. entered into a Master Service Agreement with Therapeutics Inc. for the management of the pre - clinical and clinical development of QRX003 for Netherton Syndrome. The initial term of the agreement was three years with automatic one year extensions, and the agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. A work order was entered into in June 2022 for the first QRX003 clinical study at an expected estimated cost of approximately $4.4 million. An additional change order was entered into in December 2022 for a second QRX003 clinical study at an expected estimated cost of approximately $830,000. An amended and restated change order for the two studies was entered into in December 2024 at an estimated total remaining cost from August 2024 of approximately $3.6 million for the two studies combined. In the years ended December 31, 2025 and 2024, the Company incurred a research and development expense under these agreements of approximately $2.1 million and $1.1 million respectively. During the year ended December 31, 2024, the Company received a credit of approximately $83,000 applied to prior expenses incurred during the period of January 2024 to March 2024.

In November 2021, the Company entered into a research agreement with Queensland University of Technology (“QUT”) for a pre-clinical research program for the development of a product to treat Netherton Syndrome of approximately $250,000. In May 2022, the Company entered into a second research agreement with QUT for the development of a product to treat Scleroderma of approximately $610,000. Each agreement remains in place until the completion of the research program, which in each case was initially anticipated to be 18 months from execution. For the years December 31, 2025 and 2024, the Company incurred de-minimis research and development costs related to these agreements. In July 2025 the Company announced that, in light of the expected near-term completion of the QRX003 clinical program for Netherton Syndrome, the Company has discontinued Netherton Syndrome research program with QUT. The Company is planning to schedule a meeting with QUT to discuss the future direction of the Scleroderma research program.

On June 10, 2024, the Company signed a research agreement with The School of Pharmacy at University College Cork, Ireland (“UCC”). The scope of the agreement encompasses the development of novel topical formulations of rapamycin (sirolimus) as potential treatments for a number of rare and orphan diseases for which there are currently no approved therapies or cures. Under the terms of the agreement, based on the achievement of certain milestones, the Company will fund up to approximately €567,000 ($664,000) plus VAT over an anticipated 2-1/2 year period to support the UCC research program to investigate the development of a number of topical rapamycin formulations for future development as potential treatments for several rare and orphan diseases. Following completion of the research program, the Company will have the option to advance the clinical development of rapamycin formulations developed by UCC. Work on this research project commenced in December 2024. For the year ended December 31, 2025 and December 31, 2024, the Company incurred a research and development expense under these agreements of approximately $0.3 million and de-minimis, respectively.

Performance milestones and Royalties

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

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

NOTE 13 – SHAREHOLDERS' EQUITY

As of December 31, 2025, the authorized share capital of the Company was 5,000,000,000 ordinary shares, no par value, with each ADS representing thirty-five ordinary shares.

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

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

Alumni Equity Line and Purchase Agreement

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

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

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

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

In connection with each of the March 2024 Offering and the December 2024 Offering, the Company agreed not to sell any ADSs to Alumni under the Alumni Purchase Agreement for a period of 180 days from the closing date of such Offering, see below. Per mutual agreement between the parties, the Company has not filed the required registration statement or sold any ADS to Alumni under the

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

Alumni Purchase Agreement. The Company is restricted from selling ADSs under the Alumni Purchase Agreement for 180 days from the closing of the December 2024 Offering (see below).

The Company expensed approximately $112,000 in deferred offering costs incurred during the year ended December 31, 2024 of which approximately $34,000 was recorded in year ended December 31, 2023.

2024 Public Offerings

On March 7, 2024, (the "March 2024 Closing Date") the Company completed an offering (the "March 2024 Offering") of the following securities (i) 811,250 ordinary shares represented by 23,178 ADSs, (ii) Series D warrants (the "Series D Warrants") to purchase 4,062,500 ordinary shares represented by 116,071 ADSs, (iii) Series E warrants (the "Series E Warrants") to purchase 4,062,500 ordinary shares represented by 116,071 ADSs, and (iv) Pre-funded warrants (the "March 2024 Pre-Funded Warrants") to purchase 3,251,250 ordinary shares represented by 92,893 ADSs for aggregate gross proceeds of approximately $6.5 million, resulting in net proceeds of approximately $5.5 million, after deducting the placement agent's fees and offering expenses paid by us. Each ADS (or March 2024 Pre-Funded Warrant to purchase one ADS in lieu thereof) was sold together with a Series D Warrant to purchase one ADS and a Series E Warrant to purchase one ADS. The ADSs and accompanying Series D Warrants and Series E Warrants were sold at a combined public offering price of $56 and the March 2024 Pre-Funded Warrants and accompanying Series D Warrants and Series E Warrants were sold at a combined public offering price of $55.9965, which is equal to the combined purchase price per ADS and accompanying Series D Warrants and Series E Warrants, minus the exercise price of each March 2024 Pre-Funded Warrant of $0.0035. The Series D Warrants and Series E Warrants have an exercise price of $56 per share, were exercisable immediately following the closing of the March 2024 Offering and expire in two years and five years, respectively, from the closing of the March 2024 Offering.

On March 7, 2024, the Company also entered into privately negotiated agreements with the holders of certain existing outstanding warrants to purchase up to 18,252 ADSs to, among other things, reduce the exercise price of such warrants to $56 and to extend the expiration date of such warrants until March 7, 2029. The incremental fair value of the modified warrants was approximately $209,000, which was accounted for as an offering expense in connection with the March 2024 Offering.

On December 23, 2024, the Company completed an offering (the "December 2024 Offering" and, together with the March 2024 Offering, the "2024 Offerings") of the following securities (i) 3,137,778 ordinary shares represented by 89,651 ADSs, (ii) Series F warrants (the "Series F Warrants") to purchase 15,111,110 ordinary shares represented by 431,746 ADSs, (iii) Series G warrants (the "Series G Warrants" and together with the Series F Warrants, the "December 2024 Warrants") to purchase 15,111,110 ordinary shares represented by 431,746 ADSs, and (iv) Pre-funded warrants (the "December 2024 Pre-Funded Warrants") to purchase 11,973,332 ordinary shares represented by 342,095 ADSs for aggregate gross proceeds of approximately $6.8 million, resulting in net proceeds of approximately $5.8 million, after deducting the placement agent's fees and offering expenses paid by the Company. Each ADS (or December 2024 Pre-Funded Warrant to purchase one ADS in lieu thereof) was sold together with a Series F Warrant to purchase one ADS and a Series G Warrant to purchase one ADS. The ADSs and accompanying December 2024 Warrants were sold at a combined public offering price of $15.75 and the December 2024 Pre-Funded Warrants and accompanying December 2024 Warrants were sold at a combined public offering price of $15.7465, which is equal to the combined purchase price per ADS and accompanying December 2024 Warrants, minus the exercise price of each December 2024 Pre-Funded Warrant of $0.0035. As of December 31, 2025, 342,095 December 2024 Pre-Funded Warrants, have been exercised and are included in issued and outstanding ADSs. The December 2024 Pre-Funded Warrants were immediately exercisable upon issuance and may be exercised at any time until exercised in full. The Series F Warrants and the Series G Warrants have an exercise price of $15.75 per share, were exercisable immediately upon issuance and expire in two years and five years, respectively, from the closing of the December 2024 Offering.

In connection with the 2024 Offerings, the Company entered into Securities Purchase Agreements (the "2024 Purchase Agreements") dated March 7, 2024 and December 23, 2024, respectively, with certain institutional investors signatory thereto, pursuant to which the Company agreed to issue and sell to such investors, certain of the ADSs, pre-funded warrants and ordinary warrants sold in the 2024 Offerings. Pursuant to the terms of each of the 2024 Purchase Agreements, the Company agreed, subject to certain exceptions, (i) to not enter into variable rate financings for a period of 180 days following the closing of such 2024 Offering, and (ii) to not enter into any equity financings for 90 days from closing of such 2024 Offering.

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

Certain of the Company's officers and directors purchased an aggregate of 38,095 ADSs and accompanying December 2024 Warrants to purchase 76,190 ADSs, for a total purchase price of approximately $600,000, at the public offering price and on the same terms as the other purchasers in the December 2024 Offering.

On December 20, 2024, the Company also entered into privately negotiated agreements with the holders of certain existing outstanding warrants to purchase up to 200,071 ADSs to, among other things, reduce the exercise price of such warrants to $15.75 and to extend the expiration date of such warrants until December 23, 2029. The incremental fair value of the modified warrants was approximately $1.5 million, which was accounted for as an offering expense in connection with the December 2024 Offering.

October 2025 Private Placement

On October 10, 2025, the Company entered into the a securities purchase agreement (the "October 2025 Purchase Agreement") with several institutional and accredited investors (the "October Purchasers") relating to the issuance and sale in a private placement transaction (the "October 2025 Private Placement") of (i) 530,320 ordinary shares represented by 15,152 ADSs and (ii) pre-funded warrants to purchase 69,787,865 ordinary shares represented by 1,993,939 ADSs (the "October 2025 Pre-Funded Warrants"), together with (A) Series H Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series H Warrants"), (B) Series I Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series I Warrants"), (C) Series J Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series J Warrants"), and (D) Series K Warrants to purchase 70,318,185 ordinary shares represented by up to 2,009,091 ADSs ("Series K Warrants" and, together with the Series H Warrants, Series I Warrants, and Series J Warrants, the "October 2025 Ordinary Warrants"). The October 2025 Private Placement closed on October 14, 2025 (the "October 2025 Closing Date").

Beneficial ownership limitation. A holder of the October 2025 Pre-Funded Warrants or October 2025 Ordinary Warrants may not exercise any portion of such October 2025 Pre-Funded Warrants or October 2025 Ordinary Warrants for ADSs to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% of the number of ordinary shares outstanding immediately after giving effect to the issuance of the ordinary shares represented by the ADSs issuable upon exercise of the applicable warrant.

October 2025 Pre-Funded Warrants. The October 2025 Pre-Funded Warrants have an exercise price of $0.0001 per ADS. The October 2025 Pre-Funded Warrants are exercisable at any time after their original issuance, subject to the beneficial ownership limitation (as described above) and will not expire until exercised in full. In addition, the October 2025 Pre-Funded Warrants may be exercised, in whole or in part, any time after issuance by means of a cashless exercise.

October 2025 Ordinary Warrants. The October 2025 Ordinary Warrants are exercisable at any time after their original issuance, subject to the beneficial ownership limitation (as described above). The Series H Warrants have an exercise price of $9.075 per ADS and, pursuant to the terms of the Series H Warrants, such warrants may be exercised until the earlier of (i) five (5) years from the October 2025 Closing Date or (ii) 30 days after the public announcement that we have received Type C meeting minutes from the FDA indicating openness to baseline-controlled pivotal studies for QRX003 for the treatment of Netherton Syndrome. Upon receipt of Type C meeting minutes from the FDA, the Company, in March 2026, determined that the Series H Warrants will remain exercisable until five (5) years from the October 2025 Closing Date.The Series I Warrants have an exercise price of $10.3125 per ADS and, pursuant to the terms of the Series I Warrants, may be exercised as follows: (i) 50% of the Series I Warrants may be exercised until the earlier of (A) five (5) years from the October 2025 Closing Date or (B) 30 days after the public announcement that the primary endpoint has been met in the monotherapy pivotal trial of QRX003 for the treatment of Netherton Syndrome, and (ii) 50% of the Series I Warrants may be exercised until the earlier of (A) five (5) years from the October 2025 Closing Date or (B) 30 days after the public announcement that the primary endpoint has been met in the adjuvant pivotal trial of QRX003 for the treatment of Netherton Syndrome. The Series J Warrants have an exercise price of $12.375 per ADS and, pursuant to the terms of the Series J Warrants, such warrants may be exercised until the earlier of (i) five (5) years from the October 2025 Closing Date or (ii) 30 days after the public announcement of the receipt of either accelerated or traditional approval by the FDA of QRX003 for the treatment of Netherton Syndrome. The Series K Warrants have an exercise price of $12.375 per ADS and, pursuant to the terms of the Series K Warrants, such warrants may be exercised until the earlier of (i) five (5) years from the October 2025 Closing Date or (ii) 30 days after the public announcement of the sale of a Priority Review Voucher (PRV).

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

Dennis Langer, one of the Company's directors, participated in the October 2025 Private Placement. Mr. Langer purchased 530,320 ordinary shares represented by 15,152 ADSs and accompanying October 2025 Ordinary Warrants for a total purchase price of approximately $128,641, at a combined purchase price of $8.49 per ADS and accompanying October 2025 Ordinary Warrants.

The Company received upfront net proceeds of approximately $14.9 million from the October 2025 Private Placement, after deducting estimated offering expenses payable by us, including placement agent fees and expenses.

Maxim Group LLC served as the exclusive placement agent in connection with the October 2025 Private Placement and was paid (i) a cash fee equal to 7.0% of the aggregate gross proceeds of the October 2025 Private Placement (excluding the securities purchased by Mr. Langer, for which no cash fee was received), and (ii) up to $75,000 for legal fees and other out-of-pocket expenses.

During 2025, the Company also received approximately $3.5 million from the exercise of warrants.

Warrants

The following table summarizes warrant activities during the year ended December 31, 2024 and the year ended December 31, 2025:

	ADSs Underlying Warrants	Weighted Average Exercise Price Per ADS
Outstanding and exercisable at December 31, 2023	24,688	$ 564.52 *
Granted Warrants	1,095,635	17.39 *
Granted Pre-Funded Warrants	434,988	—
Exercised Pre-Funded Warrants	(114,626)	—
Terminated	(21)	$ 57,750.00
Outstanding and exercisable at December 31, 2024	1,440,664	$ 16.80
Granted Warrants	8,036,364	11.03
Granted Pre-Funded Warrants	1,993,939	—
Exercised Warrants	(222,801)	15.75
Exercised Pre-Funded Warrants	(1,004,711)	—
Terminated	(2,215)	$ 433.54
Outstanding and exercisable at December 31, 2025	10,241,240	$ 10.59

* Note that the exercise price of certain ordinary warrants issued in the Company's 2022 Offering and 2023 Offering were reduced from $462.00 to $56.00 per ADS for investors who participated in the March 2024 Offering, and the exercise price of certain ordinary warrants issued in the 2022 Offering, 2023 Offering and March 2024 Offering were reduced from $56.00 to $15.75 per ADS for certain investors who participated in the December 2024 Offering, see above.

As of December 31, 2025, outstanding ordinary warrants expire in 2026, 2027, 2028 and 2029 and have an intrinsic value of approximately $27.3 million, and outstanding pre-funded warrants have an intrinsic value of approximately $18.9 million.

NOTE 14 – INCOME TAXES

The Company's U.S. and foreign loss before income taxes are set forth below:

	2025	2024
United States	$ (15,722,913)	$ (8,962,472)
Foreign	(81,742)	—
Income before income taxes	**$ (15,804,655)**	**$ (8,962,472)**

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

Income tax expense differed from the amounts computed by applying the U.S. Federal statutory income tax rate to income (loss) before income taxes, as presented in conformity with ASU 2023-09 as follows:

	Year Ended December 31, 2025	
Book earnings (loss) before taxes	$ (15,804,655)	
U.S. Federal Statutory Tax Rate	(3,318,978)	21.0 %
State & Local Income Taxes, Net of Federal Income Tax Effect	489,322	(3.1)%
Foreign Tax Effects	—	0.0 %
Change in Foreign Valuation Allowance	10,218	(0.1)%
Foreign Rate Differential	6,948	0.0 %
Effect of Cross-Border Tax Laws	—	0.0 %
Tax Credits	—	0.0 %
Research and development tax credits	(80,482)	0.5 %
Changes in Valuation Allowances	2,567,925	(16.3)%
Nontaxable or Nondeductible Items	—	0.0 %
IRC 162(m)	323,581	(2.0)%
Other	1,466	0.0 %
Changes in Unrecognized Tax Benefits	—	0.0 %
Other Adjustments	—	0.0 %
Effective Tax Rate	$ —	0.0 %

Significant components of the Company's deferred tax assets and liabilities at December 31, 2025 and December 31, 2024 are as follows:

	2025	2024
Intangible Assets	$ 67,540	$ 60,277
Accrued Expenses	119,524	230,426
Stock Based Compensation	540,155	474,039
Research & Development	2,264,454	1,667,722
Unrealized Exchange Gain/Loss	3,482	—
Net Operating Loss	8,575,552	5,683,264
Foreign Operating Loss	10,218	—
R&D Credits	433,736	353,255
Total gross deferred tax assets/(liabilities)	**$ 12,014,660**	**$ 8,468,983**
Less valuation allowance	(12,014,660)	(8,468,983)
Net deferred tax assets/(liabilities)	**$ —**	**$ —**

The income tax benefit for the years ended December 31, 2024 as presented in conformity with ASU 2023-09 as follows, differed from the amounts computed by applying the U.S. federal income tax rate of 21% to loss before tax benefit as a result of nondeductible expenses, tax credits generated, utilization of net operating loss carryforwards, and increases in the Company's valuation allowance.

	2024
Federal Statutory Rate	$ (1,893,000)
Permanent Differences	208,000
Research and Development	(180,000)
State Income Tax	(139,000)
State rate change	(397,000)
Change in Valuation Allowance	2,253,000
Deferred True Up	148,000
Effective Tax	—

In assessing the realizability of the net deferred tax assets, the Company considers all relevant positive and negative evidence to determine whether it is more likely than not that some portion of the deferred income tax will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to expiration of the net operation loss carryforwards. At December 31, 2025 and 2024 the Company has recorded a full valuation allowance against its net deferred tax assets of approximately $12,014,660 and $8,468,983 respectively. The change in the valuation allowance during the year ended 2025 was approximately $3,546,000.

At December 31, 2025, the Company had federal net operation loss (NOL) carryforwards of approximately $34,811,000. At December 31, 2025, the Company had federal research and development credit carryforwards of approximately $434,000. The federal net operating loss carryforwards begin to expire in 2028, losses generated in 2018 or later of $34,811,000 will carry forward indefinitely. The federal credit carryforwards begin to expire in 2045. Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and experimental tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company may be subject to the net operating loss utilization provision of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation of the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital during a specified period prior to the change, and the federal published interest rate. Although the Company has not completed an analysis under Section 382 of the Code, it is likely that the utilization of the NOLs will be limited.

The Internal Revenue Code (the "IRC") contains limitations on the use of net operating loss carryforwards after the occurrence of a substantial ownership change as defined by IRC Section 382. The Company has not performed a detailed analysis, however utilization of such net operating loss carryforwards will likely be significantly limited due to the shares issued in the Primary Financing and the Merger.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2025 there were no uncertain positions. The Company's U.S. federal and state net operating losses have occurred since its inception in 2009 and as such, tax years subject to potential tax examination could apply from that date. This is because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the 12 months ended December 31, 2025 and 2024.

The Tax Cuts and Jobs Act of 2017 (TCJA) has modified the IRC 174 expenses related to research and development for the tax years beginning after December 31, 2021. Under the TCJA, the Company had to capitalize the expenditures related to research and development activities and amortize over five years for U.S. activities and 15 years for non-U.S. activities using a mid-year convention. Therefore, the capitalization of research and development costs in accordance with IRC 174 resulted in a gross deferred tax asset of $6,717,000 as at December 31, 2024. The One Big Beautiful Bill Act of 2025 (OBBBA) further amended IRC 174 by introduction IRC 174A allowing immediate deduction of R&D expenses for U.S. activities from 2025 onwards, reversing the five-year amortization under the TCJA. The OBBBA further provided the option of amending prior years' returns (2022-2024) to deduct previously capitalized R&D expenses. As of December 31, 2025, the Company does not intend to amend its prior year returns.

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2025 and 2024

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.

NOTE 16 – LICENSE AGREEMENTS

As of both December 31, 2025 and December 31, 2024, the Company had nine commercial license and supply agreements outstanding, whereby the Company will receive a royalty or other proceeds from the specified product revenues from the licensor, if and when the underlying products are approved and commercialized or sold via compassionate use or early access programs. No revenues have been received through December 31, 2025 from any of these agreements.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

As of the date of this Annual Report on Form 10-K, Quoin Pharmaceuticals, Ltd., an Israeli company ("we," "our" and the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: American Depositary Shares, each representing thirty-five (35) ordinary shares, no par value per share. The following description of such securities is intended as a summary of the terms of such securities as currently in effect and is qualified in its entirety by the provisions of our amended and restated articles of association, a copy of which is filed as an exhibit to this Annual Report on Form 10-K and is incorporated by reference herein. This description contains all material information concerning such securities but does not purport to be complete. We encourage you to read our amended and restated articles of association and the applicable provisions of the Israeli Companies Law, 5759-1999 (the "Companies Law"), for additional information.

DESCRIPTION OF ORDINARY SHARES

Ordinary Shares

Our authorized share capital consists of 5,000,000,000 ordinary shares, no par value. Our ordinary shares are not redeemable and do not have any preemptive rights.

Articles of Association

The following are summaries of material provisions of our articles of association and the Companies Law insofar as they relate to the material terms of our ordinary shares.

Purposes and Objects of the Company

Our purpose is set forth in Section 2 of our articles of association and includes every lawful purpose.

Registration Number

Our number with the Israeli Registrar of Companies is 520036484.

Voting Rights

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholders meeting. Shareholders may vote at shareholders meetings either in person, by proxy or by written ballot. Israeli law does not allow public companies to adopt shareholder resolutions by means of written consent in lieu of 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. As a general rule, an amendment to our articles of association requires the prior approval of a simple majority of our shares represented and voting at a general meeting.

Transfer of Shares

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of a stock exchange on which the shares are traded. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or Israeli law, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Amendment of Share Capital

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at an annual or special general meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits, or an issuance of shares for less than their nominal value (which would be applicable to our company should our articles be changed so as to permit the issue of shares having a nominal value, however our shares currently have no nominal value), require a resolution of our board of directors and court approval.

Dividends and liquidation rights

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our amended and restated articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements (less the amount of previously distributed dividends, if not reduced from the earnings), provided that the end of the period to which the financial statements relate is not more than six months prior to the date of the distribution. If we do not meet such criteria, then we may distribute dividends only with court approval; as a company listed on an exchange outside of Israel, however, court approval is not required if the proposed distribution is in the form of an equity repurchase, provided that we notify our creditors of the proposed equity repurchase and allow such creditors an opportunity to initiate a court proceeding to review the repurchase. If within 30 days such creditors do not file an objection, then we may proceed with the repurchase without obtaining court approval. In each case, we are only permitted to distribute a dividend if our board of directors and, if applicable, the court determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Exchange Controls

There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our ordinary shares or the proceeds from the sale of the shares, except, under certain circumstances, for shareholders who are subjects of countries that are, or have been, in a state of war with Israel. Israeli residents have an obligation to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

Shareholders Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year and in any event no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special meetings. Our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law and our articles of association provide that our board of directors is required to convene a special meeting upon the written request of (1) any two or more of our directors, (2) one quarter of the directors then in office; or (3) as a company listed on an exchange in the U.S., one or more shareholders holding, in the aggregate either (a) 10% or more of our issued and outstanding share capital and 1% of our outstanding voting rights, or (b) 10% or more of our outstanding voting rights. Under Israeli law, one or more shareholders holding at

least 1% of the voting rights at the general meeting of the shareholders may request that the board of directors include a matter in the agenda of a general meeting of the shareholders to be convened in the future, provided that it is appropriate to discuss such a matter at the general meeting. Notwithstanding the foregoing, as a company listed on an exchange outside of Israel, a matter relating to the appointment or removal of a director may only be requested by one or more shareholders holding at least 5% of the voting rights at the general meeting of the shareholders.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings of a company are the shareholders of record on a date to be decided by the board of directors which for us, as a company listed on an exchange outside Israel, may be between four and sixty days prior to the date of the meeting.

The Companies Law and our articles of association require that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- appointment, terms of service or termination of service of our auditors;
- appointment and dismissal of external directors, if and to the extent any are required to be appointed under the Companies Law;
- approval of acts and transactions requiring general meeting approval pursuant to the Companies Law;
- increases or reductions of our authorized share capital;
- a merger; and
- the exercise of our board of directors' powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

The Companies Law requires that a notice of any annual general meeting or special general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes, among other things, the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting. Under the Companies Law and our amended and restated articles of association, shareholders are not permitted to take action by way of written consent in lieu of a meeting.

Quorum

The quorum required for our general meetings of shareholders consists of at least two shareholders present in person or by proxy who hold or represent between them at least 33⅓% of the total outstanding voting rights, provided, however, that with respect to any general meeting that was convened pursuant to a resolution adopted by the board of directors and which at the time of such general meeting we qualify to use the forms and rules of a "foreign private issuer," the requisite quorum shall consist of two or more shareholders present in person or by proxy who hold or represent between them at least 25% of the total outstanding voting rights. A meeting adjourned for lack of a quorum will be adjourned for one week, to the same day in the following week and at the same time and place, or to a later date if so specified in the notice of the meeting, or to another day or place determined by our board of directors in a notice to shareholders. At the reconvened meeting, if a quorum is not present within half an hour from the scheduled time, any number of our shareholders present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Companies Law or by our articles of association. Under the Companies Law, certain actions require the approval of a special majority, including: (i) an extraordinary transaction with a controlling shareholder or in which the controlling shareholder has a personal interest, (ii) the terms of employment or other engagement of a controlling shareholder of the company or a controlling shareholder's relative (even if such terms are not extraordinary) and (iii) certain compensation-related matters described above under "Management—Compensation Committee—Compensation Policy under the Companies Law." Under our articles of association, the alteration of the rights, privileges, preferences

or obligations of any class of our shares (to the extent there are classes other than ordinary shares) requires the approval of a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to a majority of all classes of shares voting together as a single class at a shareholder meeting.

Dissolution

Generally under Israeli law, a resolution for the voluntary winding up of a company requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting on the resolution.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares (including holders of entitlements to shares, after deducting the nominal value (if any) of such shares and the price which would have been paid in order to exercise the right to such shares), in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Access to Corporate Records

Under the Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its register of shareholders and material shareholders, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar. Any of our shareholders may request to review any document in our possession that relates to any action or transaction with a related party, interested party, or office holder that requires shareholder approval under the Companies Law. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a trade secret or patent, or that the document's disclosure may otherwise prejudice our interests.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of a public Israeli company, and who would as a result hold over 90% of the target company's issued and outstanding share capital, is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company, and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares, is required to make a tender offer to all of the shareholders who hold shares of that class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law, provided that a majority of the offerees that do not have a personal interest in such tender offer, have accepted the tender offer. Alternatively, if shareholders who do not accept the tender offer represent less than 2% of the company's issued and outstanding share capital (or less than 2% of the applicable class of shares), approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer. A shareholder whose shares are so transferred may petition the court regarding the fair value to be paid in consideration of such shares, within six months from the date of acceptance of the full tender offer; this right of petition applies to all offeree shareholders, unless the acquirer stipulated in the tender offer that a shareholder accepting the offer may not seek appraisal rights, and prior to the acceptance of the full tender offer, the acquirer and the company disclosed the information required by law in connection with a full tender offer. To the extent a court so petitioned determines that the offered value was less than the fair value per share, the court may order the difference to be paid.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a "special tender offer" complying with the relevant provisions of the Companies Law if, as a result of the acquisition, the purchaser would become a holder of 25% or more of the voting rights in

the company, if there did not previously exist a holder of 25% or more of the voting rights in the company, or if, as a result of the acquisition, the purchaser would become a holder of more than 45% of the voting rights in the company, if there did not previously exist a holder of more than 45% of the voting rights in the company. This requirement does not apply if the acquisition: (a) occurs in the context of a private placement by the company that received shareholder approval as a private placement giving the offeree 25% or 45% of the company's voting rights (as the case may be); (b) is from a holder of 25% or more of the voting rights in the company and results in the acquirer becoming a holder of 25% or more of the voting rights in the company; or (c) is from a holder of more than 45% of the voting rights in the company and results in the acquirer becoming a holder of more than 45% of the voting rights in the company.

In the event that a special tender offer is made, the target company's board of directors is required to express its opinion on the advisability of the offer, or may abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

A special tender offer must be directed to all offerees, and the offerees may give notice of their agreement or opposition to the special tender offer. The special tender offer will be consummated only if: (a) at least 5% of the voting rights attached to the company's outstanding shares will be acquired by the offeror, and (b) among those shareholders who gave notice of their position (excluding any controlling shareholders of the offeror, holders of 25% or more of the voting rights in the target company, and any person having a personal interest in the acceptance of the tender offer, including relatives or corporations under the control of any of the above), the number of shares whose holders agreed to the offer exceeds the number of shares whose holders objected to the offer.

If a special tender offer is accepted by the procedure described above, then shareholders who did not respond to or who objected the offer may accept the offer within four days of the last day set for the acceptance of the offer.

An office holder in a company which is the target of a special tender offer who, in his or her capacity as an office holder, performs an act or omits to act for in order to cause the failure of an existing or foreseeable special tender offer, or to impair the likelihood of its acceptance, is liable to the offeror and offerees for damages, unless such office holder acted in good faith and had reasonable grounds to believe that such act or omission was beneficial to the company. As a safe harbor, office holders of the target company may negotiate with a potential purchaser in order to improve the terms of a special tender offer, or negotiate with third parties in order to obtain a competing offer.

In the event that a special tender offer is accepted, the purchaser, any person or entity controlling or controlled by the purchaser, or under common control with the purchaser, may not make a subsequent tender offer for the purchase of shares of the target company, and may not enter into a merger with the target company, for a period of one year from the date of the offer, unless the purchaser or such person or entity undertakes to effect such an offer or merger as a special tender offer in compliance with the Companies Law requirements.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain conditions described under the Companies Law are met, by each party's shareholders by a majority vote as described below.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voted at the shareholders meeting held by shareholders who are not the other party to the merger, or held by any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party to the merger (including relatives or entities in control of the above), vote against the merger. If the transaction would have been approved but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the relative value of the merger parties and the consideration offered to the shareholders. If the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders. If a merger is with a company's controlling shareholder, or if a controlling shareholder has a personal interest in the merger, then the merger will be subject to the special majority approval required

for an extraordinary transaction with a controlling shareholder (see: *Approval of Related Party Transactions under Israeli Law - Declaration of Personal Interest of Controlling Shareholders and Approval of Certain Transactions*). In the context of mergers (as well as other related party transactions), a "controlling shareholder" under Israeli law is deemed to include any shareholder holding 25% or more of the voting rights in the company if no other shareholder owns more than 50% of the voting rights in the company, and two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder for such purpose.

The Companies Law requires the board of directors of a merging company to discuss and determine whether, in its view, there exists a reasonable concern that as a result of the proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, and if not, the board of directors may not approve the merger. The Companies Law requires each merging company to inform its secured creditors of the proposed merger plan. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of any of the parties to the merger, and may further give instructions to secure the rights of creditors.

A merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger is filed with the Israeli Registrar of Companies, and 30 days have passed from the date the merger was approved by the shareholders of each merging company.

Antitakeover Measures

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters, and shares having preemptive rights. As of the date of this *Annual Report on Form 10-K*, we do not have any authorized or issued classes of shares other than our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of the holders of a majority of our shares at a general meeting. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon (the "Depositary"), as depositary, has registered and delivered American Depositary Shares, also referred to as ADSs. Each ADS represents thirty-five (35) ordinary shares (or a right to receive thirty-five (35) ordinary shares) deposited with The Bank of New York Mellon in Manchester, United Kingdom, as custodian for the Depositary. The Depositary's corporate trust office at which the ADSs will be administered is located at 240 Greenwich Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at 240 Greenwich Street, New York, New York 10286.

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. If ADSs are held directly by the holder, then that holder is registered as such, and is referred to in our description here an ADS holder. An indirect holder of ADSs indirectly must rely on the procedures of the holder's broker or other financial institution to assert the rights of ADS holder described in this Exhibit.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

We will not treat registered ADS holders as one of our shareholders, and they will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying ADSs. A registered holder of ADSs will have ADS holder rights. A deposit agreement among

us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay in non-U.S. currency on the ordinary shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency, and it will not be liable for any interest.

Before making a distribution, the depositary will deduct any withholding taxes, or other required governmental charges. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.

Shares. The depositary may distribute additional ADSs representing any ordinary shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell ordinary shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed ordinary shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional ordinary shares or any other rights, the depositary may (1) exercise those rights on behalf of ADS holders, (2) distribute those rights to ADS holders or (3) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, you will receive no value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of ordinary shares, new ADSs representing the new ordinary shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with non-U.S. currency. Alternatively, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs upon deposits of ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

ADS holders may surrender ADSs for the purpose of withdrawal at the Depositary's account at DTCC (BNYM's DTC participant #2504). Upon payment of its cancellation fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates in accordance with the Cancellation Instruction provided to The Bank of New York Mellon.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

ADS holders may surrender ADS to the depositary for the purpose of exchanging ADS for uncertificated ADSs. The depositary will cancel that ADS and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADS evidencing those ADSs.

Voting Rights

ADS holders may instruct the depositary how to vote the number of deposited ordinary shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary.

The depositary will try, as far as practical, subject to the laws of Israel and the provisions of our articles of association or similar documents, to vote or to have its agents vote the ordinary shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, ADS holders will not be able to exercise voting rights, unless they surrender your ADSs and withdraw the ordinary shares. However, ADS holders may not know about the meeting sufficiently in advance to withdraw the ordinary shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that ADS holders may not be able to exercise voting rights and there may be nothing they can do if your ordinary shares are not voted as requested.

In order to give ADS holders a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least thirty days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	***For*:**
$5.00 (or less) per 5,000 ADSs (or portion of 5,000 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$0.05 (or less) per ADSs per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw ordinary shares
Expenses of the Depositary	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement); converting foreign currency to U.S. dollars
Taxes and other governmental charges the Depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the Depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

ADS holders are responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADSs or allow a withdrawal of the deposited securities represented by your ADSs, until such taxes or other charges are paid. It may apply payments owed to the ADS holder or sell deposited securities represented by the ADSs to pay any taxes owed and the ADS holder will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADSs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without consent of the ADS holders for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the

time an amendment becomes effective, ADS holders are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our ordinary shares from an exchange on which they were listed and do not list the ordinary shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

- In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Right to Receive the Ordinary Shares Underlying ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (1) the depositary has closed its transfer books or we have closed our transfer books; (2) the transfer of ordinary shares is blocked to permit voting at a shareholders meeting; or (3) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-Release of ADSs

The deposit agreement permits the depositary to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The depositary may also deliver ordinary shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying ordinary shares are delivered to the depositary. The depositary may receive ADSs instead of ordinary shares to close out a pre-release. The depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depositary in writing that it or its customer owns the ordinary shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time if it thinks it is appropriate to do so.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, or DRS, and Profile Modification System, or Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holdings of uncertificated ADSs and holdings of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to

the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for your inspection at its office all communications from us that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you upon our request. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Annex A

QUOIN PHARMACEUTICALS LTD.

Compensation Policy for Executive Officers and Directors

(As Adopted by the Shareholders on , 2025)

Table of Contents

A. Overview and Objectives

1. **Introduction**

This document sets forth the Compensation Policy for Executive Officers and Directors (this **"Compensation Policy"** or **"Policy")** of Quoin Pharmaceuticals Ltd. **("Quoin"** or the **"Company"),** in accordance with the requirements of the Companies Law and the regulations promulgated thereunder, 5759-1999 (the **"Companies Law").**

Compensation is a key component of Quoin's overall human capital strategy to attract, retain, reward, and motivate highly skilled individuals that will enhance Quoin's value and otherwise assist Quoin to reach its business and financial long-term goals. Accordingly, the structure of this Policy is established to tie the compensation of each officer to Quoin's goals and performance.

For purposes of this Policy, "Executive Officers" shall mean "Office Holders" as such term is defined in Section 1 of the Companies Law, excluding, unless otherwise expressly indicated herein, Quoin's directors.

This policy is subject to applicable law and is not intended, and should not be interpreted as limiting or derogating from, provisions of applicable law to the extent not permitted.

This Policy shall apply to compensation agreements and arrangements which will be approved after the date on which this Policy is adopted and shall serve as Quoin's Compensation Policy for three (3) years, commencing as of its adoption.

The Compensation Committee and the Board of Directors of Quoin (the "**Compensation Committee**" and the "**Board**", respectively) shall review and reassess the adequacy of this Policy from time to time, as required by the Companies Law.

2. **Objectives**

Quoin's objectives and goals in setting this Policy are to attract, motivate and retain highly experienced leaders who will contribute to Quoin's success and enhance shareholder value, while demonstrating professionalism in a highly achievement-oriented culture that is based on merit and rewards excellent performance in the long term, and embedding Quoin's core values as part of a motivated behavior. To that end, this Policy is designed, among others:

2.1. To closely align the interests of the Executive Officers with those of Quoin's shareholders in order to enhance shareholder value;

2.2. To align a significant portion of the Executive Officers' compensation with Quoin's short and long-term goals and performance;

2.3. To provide the Executive Officers with a structured compensation package, including competitive salaries, performance-motivating cash and equity incentive programs and benefits, and to be able to present to each Executive Officer an opportunity to advance in a growing organization;

2.4. To strengthen the retention and the motivation of Executive Officers in the long term;

2.5. To provide appropriate awards in order to incentivize superior individual excellency and corporate performance; and

2.6. To maintain consistency in the way Executive Officers are compensated.

3. **Compensation Instruments**

Compensation instruments under this Policy may include the following:

3.1. Base salary;

3.2. Benefits;

3.3. Cash bonuses;

3.4. Equity based compensation;

3.5. Change of control provision; and

3.6. Retirement and termination terms.

4. **Overall Compensation — Ratio Between Fixed and Variable Compensation**

4.1. This Policy aims to balance the mix of "Fixed Compensation" (comprised of base salary and benefits) and "Variable Compensation" (comprised of cash bonuses and equity-based compensation) in order to, among other things, appropriately incentivize Executive Officers to meet Quoin's short- and long-term goals while taking into consideration the Company's need to manage a variety of business risks.

4.2. The total annual bonus and equity-based compensation of each Executive Officer shall not exceed 95% of the total compensation package of such Executive Officer on an annual basis.

5. **Inter-Company Compensation Ratio**

5.1. In the process of drafting and updating this Policy, Quoin's Board and Compensation Committee have examined the ratio between employer cost associated with the engagement of the Executive Officers, including directors, and the average and median employer cost associated with the engagement of Quoin's other employees (including contractor employees as defined in the Companies Law) (the "**Ratio**"**).**

5.2. The possible ramifications of the Ratio on the daily working environment in Quoin were examined and will continue to be examined by Quoin from time to time in order to ensure that levels of executive compensation, as compared to the overall workforce will not have a negative impact on work relations in Quoin.

B. Base Salary and Benefits

6. **Base Salary**

6.1. A base salary provides stable compensation to Executive Officers and allows Quoin to attract and retain competent executive talent and maintain a stable management team. The base salary varies among Executive Officers, and is individually determined according to the educational background, prior vocational experience, qualifications, company's role, business responsibilities and the past performance of each Executive Officer.

6.2. Since a competitive base salary is essential to Quoin's ability to attract and retain highly skilled professionals, Quoin will seek to establish a base salary that is competitive with base salaries paid to Executive Officers in a peer group of other companies operating in pharmaceutical sectors which are similar in their characteristics to Quoin's, as much as possible, while considering, among others, such companies' size and characteristics including their revenues, profitability rate, number

of employees and operating arena (in Israel or globally), the list of which shall be reviewed and approved by the Compensation Committee at least every two years. To that end, Quoin shall utilize as a reference, comparative market data and practices, which will include a compensation survey that compares and analyses the level of the overall compensation package offered to an Executive Officer of the Company with compensation packages in similar positions to that of the relevant officer) in such companies. Such compensation survey may be conducted internally or through an external independent consultant.

6.3. The Compensation Committee and the Board may periodically consider and approve base salary adjustments for Executive Officers. The main considerations for salary adjustment are similar to those used in initially determining the base salary, but may also include change of role or responsibilities, recognition for professional achievements, regulatory or contractual requirements, budgetary constraints or market trends. The Compensation Committee and the Board will also consider the previous and existing compensation arrangements of the Executive Officer whose base salary is being considered for adjustment. Any limitation herein based on the base salary shall be calculated based on the monthly base salary applicable at the time of consideration of the respective grant or benefit.

7. **Benefits**

7.1. The following benefits may be granted to the Executive Officers in order, among other things, to comply with legal requirements:

7.1.1. Vacation days in accordance with market practice;

7.1.2. Sick days in accordance with market practice;

7.1.3. Convalescence pay according to applicable law;

7.1.4. Monthly remuneration for a study fund, as allowed by applicable law and with reference to Quoin's practice and the practice in peer group companies;

7.1.5. Quoin shall contribute on behalf of the Executive Officer to an insurance policy or a pension fund, as allowed by applicable law and with reference to Quoin's policies and procedures and the practice in peer group companies; and

7.1.6. Quoin shall contribute on behalf of the Executive Officer towards work disability insurance, as allowed by applicable law and with reference to Quoin's policies and procedures and to the practice in peer group companies.

7.2. Non-Israeli Executive Officers may receive other similar, comparable or customary benefits as applicable in the relevant jurisdiction in which they are employed. Such customary benefits shall be determined based on the methods described in Section 6.2 of this Policy (with the necessary changes and adjustments).

7.3. In the event of relocation of an Executive Officer to another geography, such Executive Officer may receive other similar, comparable or customary benefits as applicable in the relevant jurisdiction in which he or she is employed or additional payments to reflect adjustments in cost of living. Such benefits shall include reimbursement for out of pocket one-time payments and other ongoing expenses, such as housing allowance, car allowance, and home leave visit, etc.

7.4. Quoin may offer additional benefits to its Executive Officers, which will be comparable to customary market practices, such as, but not limited to: cellular and land line phone benefits, company car and travel benefits, reimbursement of business travel including a daily stipend when traveling and other business related expenses, insurances, other benefits **(such as newspaper subscriptions, academic and professional studies),** etc., provided, however, that such additional benefits shall be determined in accordance with Quoin's policies and procedures.

C. Cash Bonuses

8. **Annual Cash Bonuses — The Objective**

8.1. Compensation in the form of an annual cash bonus is an important element in aligning the Executive Officers' compensation with Quoin's objectives and business goals. Therefore, a pay-for- performance element, as payout eligibility and levels are determined based on actual financial and operational results, in addition to other factors the Compensation Committee may determine, as well as individual performance.

8.2. An annual cash bonus may be awarded to Executive Officers upon the attainment of pre-set periodical objectives and individual targets determined by the Compensation Committee (and, if required by law, by the Board) at the beginning of each calendar year, or upon engagement, in case of newly hired Executive Officers, taking into account Quoin's short and long-term goals, as well as its compliance and risk management policies. The Compensation Committee and the Board shall also determine applicable minimum thresholds that must be met for entitlement to the annual cash bonus (all or any portion thereof) and the formula for calculating any annual cash bonus payout, with respect to each calendar year, for each Executive Officer. In special circumstances, as determined by the Compensation Committee and the Board (e.g., regulatory changes, significant changes in Quoin's business environment, a significant organizational change and a significant merger and acquisition events), the Compensation Committee and the Board may modify the objectives and/or their relative weights during the calendar year.

8.3. In the event the employment of an Executive Officer is terminated prior to the end of a fiscal year, the Company may pay such Executive Officer a full annual cash bonus or a prorated one. Such bonus will become due on the same scheduled date for annual cash bonus payments by the Company.

8.4. The actual annual cash bonus to be awarded to Executive Officers shall be approved by the Compensation Committee and the Board.

9. **Annual Cash Bonuses — The Formula**

Executive Officers other than the CEO

9.1. The performance objectives for the annual cash bonus of Quoin's Executive Officers, other than the chief executive officer (the "**CEO**"), may be approved by Quoin's CEO (in lieu of the Compensation Committee) and may be based on company and individual objectives. Measurable performance objectives will include the objectives and the weight to be assigned to each achievement in the overall evaluation, and will be based on actual results. The Company may also grant annual cash bonuses to Quoin's Executive Officers, other than the CEO, on a discretionary basis.

9.2. The target annual cash bonus that an Executive Officer, other than the CEO, will be entitled to receive for any given calendar year, will not exceed 100% of such Executive Officer's annual base salary.

9.3. The maximum annual cash bonus including for overachievement performance that an Executive Officer, other than the CEO, will be entitled to receive for any given calendar year, will not exceed 200% of such Executive Officer's annual base salary.

CEO

9.4. The annual cash bonus of Quoin's CEO will be mainly based on measurable performance objectives and subject to minimum thresholds as provided in Section 8.2 above. Such measurable performance objectives will be determined annually by Quoin's Compensation Committee (and, if required by law, by Quoin's Board) and will be based on company and personal objectives. These measurable performance objectives, which include the objectives and the weight to be assigned to each achievement in the overall evaluation, will be based on overall company performance measures, which are based on actual financial and operational results.

9.5. The less significant part of the annual cash bonus granted to Quoin's CEO, and in any event not more than 40% of the annual cash bonus, may be based on a discretionary evaluation of the CEO's overall performance by the Compensation Committee and the Board based on quantitative and qualitative criteria.

9.6. The target annual cash bonus that the CEO will be entitled to receive for any given calendar year, will not exceed 100% of his or her annual base salary.

9.7. The maximum annual cash bonus including for overachievement performance that the CEO will be entitled to receive for any given calendar year, will not exceed 200% of his or her annual base salary.

10. **Other Bonuses**

10.1. Special Bonus. Quoin may grant its Executive Officers a special bonus as an award for special achievements (such as in connection with mergers and acquisitions, offerings, achieving target budget or business plan under exceptional circumstances or special recognition in case of retirement) at the CEO's discretion (and in the CEO's case, at the Board's discretion), subject to any additional approval as may be required by the Companies Law (the "**Special Bonus**"). The Special Bonus will not exceed 200% of the Executive Officer's total compensation package on an annual basis. A Special Bonus can be paid, in whole or in part, in equity in lieu of cash and the value of any such equity component of a Special Bonus shall be determined in accordance with Section 13.3 below.

10.2. Signing Bonus. Quoin may grant a newly recruited Executive Officer a signing bonus at the CEO's discretion (and in the CEO's case, at the Board's discretion), subject to any additional approval as may be required by the Companies Law (the "**Signing Bonus**"). The Signing Bonus will not exceed twelve (12) monthly entry base salaries of the Executive Officer.

10.3. Relocation Bonus. Quoin may grant its Executive Officers a special bonus in the event of relocation of an Executive Officer to another geography (the "**Relocation Bonus**"). The Relocation bonus will include customary benefits associated with such relocation and its monetary value will not exceed 100% of the Executive Officer's annual base salary.

11. **Compensation Recovery ("Clawback")**

11.1. In the event of an accounting restatement, Quoin shall be entitled to recover from its Executive Officers the bonus compensation or performance-based equity compensation in accordance with the clawback policy adopted by the Company from time to time under the applicable stock exchange rules.

11.2. Nothing in this Section 11 derogates from any other "Clawback" or similar provisions regarding disgorging of profits imposed on Executive Officers by virtue of applicable securities laws or a separate contractual obligation.

D. Equity Based Compensation

12. **The Objective**

12.1. The equity-based compensation for Quoin's Executive Officers is designed in a manner consistent with the underlying objectives in determining the base salary and the annual cash bonus, with its main objectives being to enhance the alignment between the Executive Officers' interests with the long-term interests of Quoin and its shareholders, and to strengthen the retention and the motivation of Executive Officers in the long term. In addition, since equity-based awards are structured to vest over several years, their incentive value to recipients is aligned with longer-term strategic plans.

12.2. The equity-based compensation offered by Quoin is intended to be in a form of share options and/or other equity based awards, such as RSUs, in accordance with the Company's equity incentive plan in place as may be updated from time to time.

12.3. All equity-based incentives granted to Executive Officers shall be subject to vesting periods in order to promote long-term retention of the awarded Executive Officers. Unless determined otherwise in a specific award agreement or in a specific compensation plan approved by the Compensation Committee and the Board, grants to Executive Officers other than directors shall vest gradually over a period of between two (2) to four (4) years or based on performance.

12.4. All other terms of the equity awards shall be in accordance with Quoin's incentive plans and other related practices and policies. Accordingly, the Board may, following approval by the Compensation Committee, extend the period of time for which an award is to remain exercisable and make provisions with respect to the acceleration of the vesting period of any Executive Officer's awards, including, without limitation, in connection with a corporate transaction involving a change of control, subject to any additional approval as may be required by the Companies Law.

13. **General Guidelines for the Grant of Awards**

13.1. The equity-based compensation shall be granted from time to time and be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the Executive Officer.

13.2. In determining the equity-based compensation granted to each Executive Officer, the Compensation Committee and Board shall consider the factors specified in Section 13.1 above, and in any event the total fair market value of an annual equity-based compensation at the time of grant (not including bonus paid in equity in lieu of cash) shall not exceed 500% of such Executive Officer's total fixed component (base salary and benefits) to which such Executive Officer is entitled in the grant year.

13.3. The fair market value of the equity-based compensation for the Executive Officers will be determined according to acceptable valuation practices at the time of grant.

13.4. The Company may satisfy tax withholding obligations related to equity-based compensation by net issuance, sale-to-cover or any other mechanism as determined by the Board from time to time.

E. Retirement and Termination of Service Arrangements

14. **Advanced Notice Period**

Quoin may provide an Executive Officer, other than the CEO, according to his/her seniority in the Company, his/her contribution to the Company's goals and achievements and the circumstances of retirement a prior notice of termination of up to six (6) months, during which the Executive Officer may be entitled to all of the compensation elements, and to the continuation of vesting of his/her options and/or other equity based awards.

Quoin may provide the CEO a prior notice of termination of up to twelve (12) months, during which the Executive Officer may be entitled to all of the compensation elements, and to the continuation of vesting of his/her options and/or other equity based awards.

15. **Adjustment Period**

Quoin may provide an additional adjustment period of up to nine (9) months to an Executive Officer, other than the CEO, according to his/her seniority in the Company, his/her contribution to the Company's goals and achievements and the circumstances of retirement and to the CEO, during which the Executive Officer may be entitled to all of the compensation elements, and to the continuation of vesting of his/her options and/or other equity based awards.

16. **Additional Retirement and Termination Benefits**

Quoin may provide additional retirement and terminations benefits and payments as may be required by applicable law (e.g., mandatory severance pay under Israeli labor laws), or which will be comparable to customary market practices.

17. **Non-Compete Grant**

Upon termination of employment and subject to applicable law, Quoin may grant to its Executive Officers a non-compete grant as an incentive to refrain from competing with Quoin for a defined period of time. The terms and conditions of the non-compete grant shall be decided by the Board and shall not exceed such Executive Officer's monthly base salary multiplied by twelve (12).

18. **Limitation Retirement and Termination of Service Arrangements**

The total non-statutory payments under Sections 14-17 above shall not exceed the Executive Officer's monthly base salary multiplied by twenty-four (24).

F. Exculpation, Indemnification and Insurance

19. **Exculpation**

Quoin may exempt its directors and Executive Officers in advance for all or any of his/her liability for damage in consequence of a breach of the duty of care vis-a-vis Quoin, to the fullest extent permitted by applicable law.

20. **Insurance and Indemnification**

20.1. Quoin may indemnify its directors and Executive Officers to the fullest extent permitted by applicable law, for any liability and expense that may be imposed on the director or the Executive Officer, as provided in the indemnity agreement between such individuals and Quoin, all subject to applicable law and the Company's articles of association.

20.2. Quoin will provide directors' and officers' liability insurance (the **"Insurance Policy")** for its directors and Executive Officers as follows:

20.2.1. The limit of liability of the insurer shall not exceed the greater of $50 million or 50% of the Company's shareholders equity based on the most recent financial statements of the Company at the time of approval by the Compensation Committee; and

20.2.2. The Insurance Policy, as well as the limit of liability and the premium for each extension or renewal shall be approved by the Compensation Committee (and, if required by law, by the Board) which shall determine that the sums are reasonable considering Quoin's exposures, the scope of coverage and the market conditions and that the Insurance Policy reflects the current market conditions, and it shall not materially affect the Company's profitability, assets or liabilities.

20.3. Upon circumstances to be approved by the Compensation Committee (and, if required by law, by the Board), Quoin shall be entitled to enter into a "run off" Insurance Policy of up to seven (7) years, with the same insurer or any other insurance, as follows:

20.3.1. The limit of liability of the insurer shall not exceed the greater of $50 million or 50% of the Company's shareholders equity based on the most recent financial statements of the Company at the time of approval by the Compensation Committee; and

20.3.2. The Insurance Policy, as well as the limit of liability and the premium for each extension or renewal shall be approved by the Compensation Committee (and, if required by law, by the Board) which shall determine that the sums are reasonable considering the Company's exposures covered under such policy, the scope of cover and the market conditions, and that the Insurance Policy reflects the current market conditions and that it shall not materially affect the Company's profitability, assets or liabilities.

20.4. Quoin may extend the Insurance Policy in place to include cover for liability pursuant to a future public offering of securities. The Insurance Policy, as well as the additional premium shall be approved by the Compensation Committee (and if required by law, by the Board) which shall determine that the sums are reasonable considering the exposures pursuant to such public offering

of securities, the scope of cover and the market conditions and that the Insurance Policy reflects the current market conditions, and it does not materially affect the Company's profitability, assets or liabilities.

G. Arrangements upon Change of Control

21. The following benefits may be granted to the Executive Officers in addition to, or in lieu of, the benefits applicable in the case of any retirement or termination of service upon a "Change of Control" or, where applicable, in the event of a Change of Control following which the employment of the Executive Officer is terminated or adversely adjusted in a material way:

    21.1. Vesting acceleration of outstanding options or other equity-based awards;

    21.2. Extension of the exercising period of options or vesting of other equity-based awards for Quoin's Executive Officer for a period of up to one (1) year in case of an Executive Officer other than the CEO and two (2) years in case of the CEO, following the date of employment termination; and

    21.3. Up to an additional six (6) months of continued base salary and benefits following the date of employment termination (the "**Additional Adjustment Period**"). For avoidance of doubt, such additional Adjustment Period shall be in addition to the advance notice and adjustment periods pursuant to Sections 14 and 15 of this Policy, but subject to the limitation set forth in Section 18 of this Policy.

    21.4. A cash bonus not to exceed 200% of the Executive Officer's annual base salary in case of an Executive Officer other than the CEO and COO and 250% in case of the CEO and COO.

H. Board of Directors Compensation

22. Members of the Board and its chairperson may be entitled to receive an annual cash retainer for their service on the Board. Additional payments may be made to Board members for their service on the audit, compensation, nominating, or other committees of the Board, as well as for their service as chairpersons of such committees.

23. Members of the Board and its chairperson may also be granted (i) annual equity-based awards and (ii) welcome equity-based awards. Any payment or award under this Section 23 shall be approved as required by applicable law.

24. The compensation of the Company's external directors, if elected, shall be in accordance with the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director), 5760-2000, as amended by the Companies Regulations (Relief for Public Companies Traded on Stock Exchange Outside of Israel), 5760-2000, as such regulations may be amended from time to time.

25. Notwithstanding the provisions of Section 22 above, in special circumstances, such as in the case of a professional director, an expert director or a director who makes a unique contribution to the Company, such director's compensation may be different than the compensation of all other directors.

26. In addition, members of the Board may be entitled to reimbursement of expenses when traveling abroad on behalf of Quoin.

27. It is hereby clarified that the compensation stated under Section H will not apply to directors who serve as Executive Officers.

I. Miscellaneous

28. Nothing in this Policy shall be deemed to grant any of Quoin's Executive Officers or employees or any third party any right or privilege in connection with their employment by the Company. Such rights and privileges shall be governed by the respective personal employment agreements or other separate compensation agreements entered into between Quoin and the recipient of such rights and privileges. The Board may determine that none or only part of the payments, benefits and perquisites detailed in this Policy shall be granted, and is authorized to cancel or suspend a compensation package or part of it.

29. An Immaterial Change in the Terms of Employment of an Executive Officer other than the CEO may be approved by the CEO, provided that the amended terms of employment are in accordance with this Policy. An "Immaterial Change in the Terms of Employment" means a change in the terms of employment of an Executive Officer with an annual total cost to the Company not exceeding an amount equal to two (2) monthly base salaries of such employee.

30. In the event that new regulations or law amendment in connection with Executive Officers and directors compensation will be enacted following the adoption of this Policy, Quoin may follow such new regulations or law amendments, even if such new regulations are in contradiction to the compensation terms set forth herein.

****

This Policy is designed solely for the benefit of Quoin and none of the provisions thereof are intended to provide any rights or remedies to any person other than Quoin.

Exhibit 21.1

LIST OF SUBSIDIARIES

Quoin Pharmaceuticals Inc.
Quoin Therapeutics (Ireland) Limited

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Quoin Pharmaceuticals Ltd. on Form S-8 (File No.'s 333-270555, 333-289856, and 333-289891) Form S-3 (File No. 333-291385) and Form S-1 (File No.'s 333-283734, 333-277016, 333-266476 and 333-269543) of our report dated March 26, 2026 with respect to the consolidated financial statements of Quoin Pharmaceuticals Ltd. as of and for the year ended December 31, 2025, included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.
Morristown, New Jersey
March 26, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File No.'s 333-270555, 333-289856, and 333-289891) and Form S-1 (File No.'s 333-283734, 333- 277016, 333- 266476 and 333- 269543), and Form S-3 (File No. 333-291385), of our report dated March 13, 2025 with respect to the consolidated financial statements of Quoin Pharmaceuticals Ltd. as of and for the year ended December 31, 2024, included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Morristown, New Jersey
March 26, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

PURSUANT TO

RULES 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Michael Myers, certify that:

1. I have reviewed this Annual Report on Form 10-K of Quoin Pharmaceuticals Ltd. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Dr. Michael Myers
Name: Dr. Michael Myers
Title: Chief Executive Officer
Date: March 26, 2026

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

PURSUANT TO

RULES 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sally Lawlor, certify that:

1. I have reviewed this Annual Report on Form 10-K of Quoin Pharmaceuticals Ltd. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us, by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Sally Lawlor
Name: Sally Lawlor
Title: Chief Financial Officer
Date: March 26, 2026

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Quoin Pharmaceuticals Ltd. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I , Dr. Michael Myers, the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Dr. Michael Myers
Name: Dr. Michael Myers
Title: Chief Executive Officer
Date: March 26, 2026

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Quoin Pharmaceuticals Ltd. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sally Lawlor, the Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Sally Lawlor
Name: Sally Lawlor
Title: Chief Financial Officer
Date: March 26, 2026

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