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**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, 2022

**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 five thousand (5,000) 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, 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 common 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, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $3,775,500. The registrant has no non-voting common equity. Solely for purposes of this disclosure, shares held by executive officers, directors and certain shareholders of the registrant as of such date have been excluded because such persons or entities may be deemed to be affiliates of the registrant.

As of March 10, 2023, the registrant had 59,233,024,799 ordinary shares, no par value per share, outstanding, and 11,846,532 ADSs outstanding, with each ADS representing five thousand (5,000) 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."

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

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

- the potential oversight of programs or product candidates that may be more profitable or more successful;
- our manufacturing processes may not be validated and our methodology may not be accepted by the scientific community;
- the ability to conduct clinical trials, because of difficulties enrolling patients or other reasons;
- the requirements of being a publicly traded company may strain our resources;
- potential adverse effects resulting from failure to maintain effective internal controls;
- 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."

Readers 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. Any forward-looking statements in this Annual Report are made as of the date hereof, and 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.

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## PART I

### Item 1. Business

#### Company Overview

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

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." In addition, on October 28, 2021, Cellect sold the entire share capital of its subsidiary, Cellect Biotherapeutics Ltd., which retained all of Cellect's then existing assets, to EnCellX Inc. ("EnCellX"), a newly formed U.S. privately held company.

#### Netherton Syndrome

NS is a rare autosomal recessive genetic disease caused by a mutation in the SPINK5 gene and has an incidence of approximately 1/200,000 births. 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, pruritis, asthma, and severe 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 be 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.

**Our Product Candidates**

***QRX003***

QRX003 is a once-daily topical lotion being developed for the treatment of NS. The active ingredient in QRX003 is a competitive broad-spectrum serine protease inhibitor whose mechanism of action is to target the kallikreins responsible for the process of skin shedding. As a result of the genetic mutation of the SPINK5 gene, that causes NS, 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 daily to the skin, QRX003 is designed to perform the function of the missing LEKTI protein and down regulate, but not to 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 conducting clinical trials in NS patients under an open IND with the FDA. In addition, we intend to pursue the clinical development of QRX003 in other rare dermatological diseases including Peeling Skin Syndrome, SAM Syndrome, and Palmoplantar Keratoderma. QRX003 was developed using Invisicare® polymer delivery technology licensed from Skinvisible Pharmaceuticals, Inc. ("Skinvisible"). See "—Intellectual Property—License Agreement with Skinvisible." The Invisicare® polymer delivery technology moisturizes the skin whilst simultaneously providing a protective barrier against allergens, toxins and other environmental agents..

***QRX004***

QRX004 contains two active ingredients as a potential treatment for RDEB. One active ingredient induces a read-through of nonsense mutations and leads to creation of robust and sustained type VII collagen, which is designed to improve wound closure, reduce blistering and stronger skin. This product is being developed using Invisicare® delivery technology in-licensed from Skinvisible. See "—Intellectual Property—License Agreement with Skinvisible."

***QRX007 and QRX008***

In November 2021, we entered into the Research Agreement with QUT, pursuant to which we have an option to in-license the QRX007 product. QRX007 is a bi-functional protein designed to be highly selective and potent inhibitor of the KLK5 and KLK7 kallikreins as a potential treatment for NS. QRX007 is in pre-clinical testing for NS. In May 2022, we entered into another Research Agreement with QUT, pursuant to which we have an option 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.

**Regulatory Status of QRX003 for the Treatment of NS**

On November 29, 2019, we submitted a pre-IND meeting request to the FDA regarding the proposed development of QRX003 as a potential treatment for NS. On January 30, 2020, we received feedback from the FDA, which we believe has provided us with a clear path forward for the development of QRX003 as a potential treatment for NS.

With regard to the proposed clinical program, the agency confirmed that in the case of a rare disease, findings from a single Phase 3 trial along with supportive data could be used to establish efficacy. In response to our query, the agency stated that QRX003 may be a candidate for one or more expedited regulatory approval pathways.

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, which cleared us to initiate clinical testing of QRX003 in NS patients. This study is fully up and running, and five of the projected six clinical sites in the U.S. have been opened. Patients are actively being screened and recruited into the study and dosing has commenced. This study is a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in NS patients. The test materials are applied once daily, over a twelve-week period, to pre-selected areas of the patient's body. Based on discussions with the FDA, a number of different clinical endpoints are being assessed in the study, including but not limited to, an Investigators Global Assessment (IGA), Patient's Global Assessment (PaGA) and Pruritis. In its

communication allowing our study to proceed, the FDA provided further feedback on our development program. The FDA provided advice on our initial study so that the study could better inform future studies.

In November 2022, we submitted a protocol for our second clinical study in NS patients to the FDA under our currently open IND. This study was cleared by the FDA to initiate in December 2022. We are currently enrolling patients into this study. This study will be conducted in ten NS patients who are currently receiving off-label systemic therapy, primarily systemic biologic therapy. This will be an open-label study with no placebo control.

Both of our NS clinical studies will run concurrently and utilize the same clinical trial sites and investigators. With regard to nonclinical studies to support further clinical development and an eventual NDA submission, the agency stated that the typical battery of toxicology studies would apply to this product candidate.

In March 2022, we submitted a briefing document to the EMA seeking guidance regarding the clinical and regulatory development of QRX003 for the European Union ("EU"), to which we received comprehensive and constructive feedback. We also intend to apply for Orphan Drug status in the U.S. and Europe as well as Rare Pediatric Disease designation in the U.S. for QRX003.

**Commercial Strategy**

QRX003 has the potential to become the first approved treatment for NS to reach the market both in the U.S. and Europe and may therefore likely be used in a large proportion of patients. We currently anticipate that QRX003, if approved, would be applied once daily to the diseased skin 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. 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, this concentration of care will enable us to market QRX003 with a small, dedicated salesforce to target patients and caregivers in the U.S. Outside of the U.S., we have currently established eight separate marketing partnerships for QRX003 that cover approximately 60 different countries including Australia, New Zealand, the Middle East, Central and Eastern Europe, Turkey, Canada, China, Taiwan, Hong Kong and some 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 will not result in a significant increase in the size of that infrastructure. In particular, it is highly likely that physicians who treat patients with NS would also treat patients with Peeling Skin Syndrome, SAM Syndrome, Palmoplantar Keratoderma and Epidermolysis Bullosa, 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 conducted 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, pharmacoeconomic data developed to support pricing and the potential for greater sales under negotiated government contracts.

**Competition**

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., Krystal Biotech, Inc., Sixera Pharmaceuticals, ResVita Bio, and Azitra Inc. Currently, to the best of our knowledge, there are no active studies on NS patients being conducted under an open IND by any of these companies.

**Manufacturing**

Our manufacturing strategy is to contract with third parties to manufacture our clinical and commercial active pharmaceutical ingredient (API) and drug product supplies. We currently have established manufacturing relationships with one API supplier and one drug product supplier and we are evaluating several other potential suppliers who 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 preclinical or clinical studies or, if our product candidates are approved, for commercial supply may be limited.

The formulation and processes used to manufacture our products are proprietary, and we have agreements with 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 |
|---|---|
| U.S. Patent No. 7,674,471 (exp. March 10, 2024) and U.S. Patent No. 8,318,818 (exp. July 10, 2025) directed to Invisicare® technology licensed from Skinvisible. | U.S. Trademark Registration No. 6918421 for word mark "RARE DISEASES ARE ONLY RARE IF YOU DON'T LIVE WITH ONE" filed by Quoin Inc. |
| U.S. Patent Application No. 63/481,535 directed to adjunctive therapy for NS with QRX003 filed by Quoin Inc. | U.S. Trademark Application No. 97/105,005 for design and words "Quoin Pharmaceuticals" filed by Quoin 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. or the European Union, whichever occurs first, 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 preclinical 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:

- preclinical laboratory tests, *in vitro* and *in vivo* preclinical 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.

Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Preclinical 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 preclinical 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 most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) 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 or (2) the single trial is supported by other confirmatory evidence.

*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 preclinical, 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 accepts it for filing.

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 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, 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

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 preclinical 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 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. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

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 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. 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, 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, 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 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.

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 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, 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 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. 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 the Creating Hope Reauthorization Act in December 2020, allowing a product that is designated as a product for a rare pediatric disease prior to October 1, 2024 to be eligible to receive a rare pediatric disease priority review voucher upon approval of a qualifying NDA or BLA prior to October 1, 2026.

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.

Commercial Product Pricing

In the United States and some foreign jurisdictions, many of the markets in which we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class in certain cases. Cost reduction initiatives and other provisions of this and other more recent legislation could decrease the coverage and reimbursement that is provided for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act or other more recent legislation may result in a similar reduction in payments from private payors.

Healthcare Reform

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. Recently, healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act ("IRA") in August 2022, which will, among other things, allow U.S. Department of Health and Human Services ("HHS") to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services ("CMS") reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. 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. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. It is unclear to what extent additional statutory, regulatory, and administrative initiatives will be enacted and implemented.

European Regulatory Authorities

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.

**Employees**

As of December 31, 2022, we had four full-time employees and no 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 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 our officers and directors.

Moreover, among other reasons, including but not limited to fraud or 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, 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.

**Available Information**

We are subject to the informational requirements of the Exchange Act. Prior to January 1, 2023, we qualified as a "foreign private issuer" as such term is defined in Rule 405 under the Securities Act. Effective January 1, 2023, we are obligated to file or furnish reports, proxy statements, and other information on U.S. domestic issuer forms with 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. 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 when such reports are available on the SEC's website. From time to time, we also use 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.

**Item 1A. Risk Factors**

*Investing in our securities involves a high degree of risk. You should carefully consider the risk factors discussed below as well as other information we include in this Annual Report, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the market price of our securities could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. For a summary of the risk factors included in this Item 1A and for further details on our forward-looking statements, see "Cautionary Note Regarding Forward-Looking Statements and Summary of Risk Factors" 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 preclinical 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 with ever receive approval from the U.S. Food and Drug Administration, or 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 you 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 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 devoted most of our financial resources to research and development, including our preclinical and ongoing clinical development activities. To date, we have funded our operations primarily through our founders' funding expenditures and the sale of equity and convertible securities.

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

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:

- have initiated clinical development of our product candidates, including our first lead product—QRX003—a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome ("NS");
- 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;
- ultimately 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 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 preclinical 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 preclinical studies and clinical trials, is expensive. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidates towards or through clinical trials. 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 preclinical 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 preclinical 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.

***Changes in U.S. tax laws or regulations may increase tax uncertainty and adversely affect results of our operations and our effective tax rate.***

We may be subject to the Excise Tax (as defined below) included in the IRA in connection with redemptions of our ordinary shares or ADSs after December 31, 2022. In particular, an excise tax is imposed on "covered corporations" (generally, publicly-traded domestic corporations and publicly-traded foreign corporations treated as domestic corporations pursuant to Section 7874 of the Code) equal to 1% of the fair market value of certain stock repurchased after December 31, 2022 (the "Excise Tax"). As a result of the consummation of the Merger, we should be treated as a domestic corporation and therefore as a covered corporation. Consequently, it is likely that the Excise Tax will generally apply to any redemptions of our ordinary shares or ADSs after December 31, 2022. The Excise Tax base is reduced by the fair market value of any issuances of the covered corporation's stock during its taxable year. The fair market value of any of our ordinary shares or ADSs that are redeemed may exceed the fair market value of any of our stock issued during the same taxable year. Consequently, the Excise Tax may reduce the amount of cash we have available to shareholders.

**Risks Related to the Discovery and Development of Product Candidates**

***Preclinical and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from preclinical 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 preclinical development and clinical testing as is the case with our lead asset for NS, which is currently being tested in two 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 either the FDA or 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 preclinical 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 preclinical 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 preclinical 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, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical 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 dose and clinical outcome assessments and related efficacy endpoints
- 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 our 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;
- 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 the 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 preclinical 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. While we have not yet initiated clinical trials for any of our product candidates, it is possible that there will be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity 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 preclinical 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 preclinical 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 preclinical 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 obtain or maintain orphan drug designation or 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 intend to apply for orphan drug designation in the United States for QRX003 for the treatment of NS. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. Even if we obtain orphan drug designation for a product candidate in specific indications, 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.

***We may pursue Rare Pediatric Disease designation for QRX003 for the treatment of NS or other of our product candidates. There is no assurance that we will obtain such designation. Moreover, a Rare Pediatric Disease designation by 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 intend to pursue Rare Pediatric Disease designation for QRX003 for the treatment of NS, but there is no assurance that we will receive such designation. On December 27, 2020, the Creating Hope Reauthorization Act extended the Rare Pediatric Disease Priority Review Voucher Program, and after September 30, 2024, the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. However, there is no guarantee that any of our product candidates will be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program. 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., Krystal Biotech, Inc., Sixera Pharmaceuticals, ResVita Bio, and Azitra Inc. Currently, to the best of our knowledge, there are no active studies on NS patients being conducted under an open IND by any of these companies.

***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 and 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 programs are in either preclinical 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 and Europe 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, and Europe we will also consider the option to enter into strategic alliances for future product candidates in the United States and Europe 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 and Europe, 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 and Europe, 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 and Europe, 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 and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers, government payors and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that coverage and adequate reimbursement will be available for any future product candidates. In the United States, the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates. Inadequate reimbursement amounts may reduce the demand for, or the price of, our future products. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. 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 preclinical 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 preclinical studies of product candidates. We currently rely and expect to continue to rely on third parties to conduct some or all aspects of our preclinical 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 preclinical studies to enable us to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

***We rely on third-party manufacturers to produce the supply of our preclinical 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 our 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 currently have established manufacturing relationships with one API supplier and one drug product supplier and we are evaluating several other potential suppliers who 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 preclinical 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 supply from any vendor approved in the NDA is interrupted, there could be a significant disruption in commercial supply. An alternative vendor 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 supplier is relied upon for commercial production. Switching vendors 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 intend to 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 intend 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 will control only certain aspects of our CROs' activities. Nevertheless, we will be 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 will be 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 assure 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 will require a sufficiently large 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 will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These 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 intend to rely on other third parties to package, store and deliver drug products to the clinical trial sites for any clinical trials that we may conduct. 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 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 and other employees.

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.

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. 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 or employee 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 and other employees. 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 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 our management and other employees.

**Other Risks Related to Our Business Operations and Industry**

***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 preclinical 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. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure or give rise to operational mistakes, loss of business opportunities, loss of employees or reduced productivity among remaining employees. 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 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 preclinical 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.

***Recent and future healthcare legislation may further impact our business operations.***

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA") was enacted, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA included a number of provisions that may reduce the profitability of drug products, including revising the rebate methodology for covered outpatient drugs under the Medicaid Drug Rebate Program, extending Medicaid rebates to individuals enrolled in Medicaid managed care plans, and requiring drug manufacturers to pay an annual fee based on their market share of prior year total sales of branded programs to certain federal health care programs.

Since its passage, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts to repeal or replace certain aspects of the ACA. Former President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. On December 22, 2017, former President Trump signed into law H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," informally titled the Tax Cuts and Jobs Act, which significantly revises the U.S. Internal Revenue Code of 1986, as amended (the "Code"). The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on December 23, 2019, former President Trump signed a spending bill that repealed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which started in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. The Medicare reductions were phased back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, also reduced Medicare payments to several categories of healthcare providers.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Recently, healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act (the "IRA"), in August 2022, which will, among other things, allow U.S. Department of Health and Human Services ("HHS") to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. 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. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

The IRA also made changes to Medicare Part D, which provides prescription drug benefits for seniors and people with disabilities. Medicare Part D enrollees once had a gap in their coverage (between the initial coverage limit and the point at which catastrophic coverage begins) where Medicare did not cover their prescription drug costs, known as the coverage gap. However, beginning in 2019, Medicare Part D enrollees paid 25% of brand drug costs after they reached the initial coverage limit - the same percentage they were responsible for before they reached that limit - thereby closing the coverage gap from the enrollee's point of view. Most of the cost of closing the coverage gap is being borne by innovator companies and the government through subsidies. Each manufacturer of an approved drug or biologic is required to enter into a Medicare Part D coverage gap discount agreement and provide a 70% discount on those drugs dispensed to Medicare Part D enrollees in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D. Beginning in 2025, the IRA eliminates the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D

enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. Although these discounts represent a lower percentage of enrollees' costs than the current discounts required below the out-of-pocket maximum (that is, in the coverage gap phase of Part D coverage), the new manufacturer contribution required above the out-of-pocket maximum could be considerable for very high-cost patients and the total contributions by manufacturers to a Part D enrollee's drug expenses may exceed those currently provided.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

***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 plan to obtain 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, including COVID-19, which may significantly harm our business, prospects, financial condition and operating results.***

We face various risks related to public health issues, including epidemics, pandemics and other outbreaks, including the recent COVID-19 pandemic. If the spread of COVID-19 continues, the development of clinical supply materials could be delayed and enrollment of patients in our pending clinical trials may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials would have to shift resources to cope with the COVID-19 pandemic and may limit access or close clinical facilities due to the COVID-19 pandemic. Additionally, if trial participants are unable to travel to clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we may experience higher drop-out rates or delays in clinical studies once commenced.

The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, stay-at-home or shelter-in-place orders, and business shutdowns. These measures are reintroduced, they may adversely impact our operations and the operations of our suppliers, vendors and business partners.

The extent to which the COVID-19 pandemic impacts our business, prospects and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration and spread of the pandemic, its severity, the actions to contain the virus or treat its impact and how quickly and to what extent normal economic and operating activities can resume.

The COVID-19 pandemic could materially disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell or securities, continue to slow down the overall economy or curtail consumer spending.

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

We are vulnerable to natural disasters such as earthquakes and wild fires, 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 Us 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 our non-U.S. resident directors and officers may be difficult to obtain within the United States and it may be difficult to enforce judgments obtained in the United States against our non-U.S. directors and executive officers. 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 our 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.

***Your rights and responsibilities as our shareholder will be 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 little Israeli case law addressing the provisions described above, and these provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on 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.***

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 or what the trading price of our securities will be and as a result it may be difficult for you to sell our securities held by you.***

Although our ADSs trade on Nasdaq, an active trading market for the ADSs may not be sustained. It may be difficult for you to sell your ADSs without depressing the market price for the ADSs. As a result of these and other factors, you may not be able to sell your 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.

***The requirements of being a publicly traded company may strain our resources and divert management's attention.***

As a publicly traded company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), as well as rules subsequently implemented by the SEC and Nasdaq under such acts have imposed various requirements on public companies. Shareholder activism, the current political environment and the current high level of government regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such 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 will be 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.

***We may be unable to comply with the applicable continued listing requirements of Nasdaq.***

ADSs representing our ordinary shares are currently listed on Nasdaq. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a minimum closing bid price requirement for our ADSs of $1.00 per ADS. There can be no assurance that we will be able to comply with the applicable listing standards. For example, if we were to fail to meet the minimum bid price requirement for 30 consecutive business days, we could become subject to delisting. Although Nasdaq may provide us with a compliance period in which to regain compliance with the minimum bid price requirement, we cannot assure you that we would be able to regain compliance within the period provided by Nasdaq. In order to regain compliance with such requirement, the closing bid price of our ADSs would need to meet or exceed $1.00 per share for at least 10 consecutive business days during the compliance period. If we were not able to regain compliance within the allotted compliance period for this requirement or any other applicable listing standard, including any extensions that may be granted by Nasdaq, our ADSs would be subject to delisting. In the event that our ADSs are delisted from Nasdaq and are not eligible for quotation or listing on another market or exchange, trading of our ADSs could be conducted only in the over-the-counter market established for unlisted securities such as OTC Markets. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for our ADSs, which could cause the price of our ADSs to decline further.

***If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our traded securities, our securities price and trading volume could be negatively impacted.***

The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding the ADSs, or provide more favorable relative recommendations about our competitors, the price of the ADSs would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could negatively impact the price of the ADSs or their trading volume.

***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 preclinical 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, if our ordinary shares or the ADSs are covered by 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, including for example, the COVID-19 pandemic), 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 ordinary shares or ADSs in the public market could cause the price of our ADSs 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 shares 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 and holders of ADSs.

***Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote.***

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, our management may grant options to our 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 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 you 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, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.***

The depositary for the ADSs has agreed to pay to you 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. You will receive these distributions, if any, in proportion to the number of ordinary shares your 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 you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

***Provisions of our outstanding common warrants could discourage an acquisition of us by a third party.***

Certain provisions of our outstanding common warrants could make it more difficult or expensive for a third party to acquire us. The common warrants prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the common warrants. Further, the common warrants provide that, in the event of certain transactions constituting "fundamental transactions," with some exceptions, holders of such warrants will have the right, at their option, to require us to purchase such common warrants from the holders for consideration of the same type as that offered to the holders of ordinary shares in such transaction in an amount determined pursuant to a formula set forth in such warrants. These and other provisions of our outstanding common warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

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

Holders of the ADSs do not have the same rights as our shareholders 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 14 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. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders meeting.

***You may be subject to limitations on transfer of your ADSs.***

Your 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 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 listed on The Nasdaq Capital Market, with each ADS representing 5,000 ordinary shares. Our ADSs were listed under the symbol "APOP" prior to the consummation of the Merger. In connection with the Merger, the ticker symbol for our ADSs changed to "QNRX" on October 29, 2021.

**Holders**

As of March 10, 2023, our ADSs were held by 81 holders of record, and our ordinary shares were held by 85 holders of record. 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.

**Recent Sales of Unregistered Securities**

Please see the disclosure under the headings "—Agreements with Altium Growth Fund, LP and Warrant Exercises" and "—Noteholder Warrant Exercises" in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a description of transactions during the past three years involving sales of our securities that were not registered under the Securities Act. In addition, in August 2022, we issued 44,187 ADSs to one of the principals of Axella Research LLC ("Axella"), a provider of regulatory and pre- clinical/clinical services to us with respect to QRX003 and QRX004, to settle in full the outstanding liability to Axella for accrued fees under our consulting agreements with Axella. See Note 13 to Consolidated Financial Statements included in this Annual Report for a description of agreements with Axella.

We believe that each of such issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated under the Securities Act. No underwriter or underwriting discount or commission was involved in any such transaction.

**Issuer Purchases of Equity Securities**

For the three months ended December 31, 2022, we did not repurchase any of our ADSs or ordinary shares.

### 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. Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"), reflect the operations of Quoin Pharmaceuticals Inc. ("Quoin Inc.") since inception and include the accounts of Quoin Ltd. since the closing of the Merger (as defined below). 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 clinical stage specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently no approved treatments or cures. Our initial focus is on the development of products, using our proprietary owned and in-licensed drug delivery technologies, that could help address rare skin diseases. Our first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary in-licensed Invisicare® technology, is under development as a potential treatment fort Netherton Syndrome ("NS"), a rare hereditary genetic disease. QRX003 is currently being tested in two clinical studies in the United States ("U.S.") under an open Investigational New Drug ("IND") application with the Food and Drug Administration ("FDA"). Dosing of patients has commenced for the first study, and we are preparing to commence enrollment into the second clinical study. We are also developing QRX004 as a potential treatment for Recessive Dystrophic Epidermolysis Bullosa ("RDEB"). In addition, we entered into Research Agreements with the Queensland University of Technology ("QUT"), under which we have obtained an option for global licenses to QRX007 for the potential treatment of NS and QRX008 for the potential treatment of scleroderma.

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

- seek the necessary regulatory approvals to complete the clinical development of QRX003 and, if successful, file for marketing approval in the United States and other territories;

- prepare to commercialize QRX003 by establishing our own sales infrastructure in the U.S. and Europe and entering into distribution partnerships in other territories such as those currently established for Canada, Australia/New Zealand, the Middle East, China, Hong Kong, Taiwan, Latin America, Central and Eastern Europe, Turkey; and

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

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

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

**Key Events**

***Merger***

On October 28, 2021, Cellect completed the business combination with Quoin Inc. in accordance with the terms of the Merger Agreement, by and among Cellect, Quoin Inc. and Merger Sub, which was a wholly-owned subsidiary of Cellect, 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."

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

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

***ADS Ratio Change***

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

***Nasdaq Listing***

On June 10, 2022, we received a letter from the Staff notifying us that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2). On August 15, 2022, the Staff determined that the closing bid price of our ADSs was at $1.00 per ADS or greater for the preceding 10 business days, and we regained compliance with the minimum bid price requirement. There can be no assurance that we will be able to meet the minimum bid price requirement for 30 consecutive business days, and our ADSs could be subject to delisting again. If our ADSs are delisted from Nasdaq, it will have material negative impacts on the actual and potential liquidity of our securities, as well as material negative impacts on our ability to raise future capital.

***Clinical Development***

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

In November 2022, we submitted a protocol for our second clinical study in NS patients to the FDA under our currently open IND. This study was cleared by the FDA to initiate in December 2022. We are currently enrolling patients into this study. This study will be conducted in ten NS patients who are currently receiving off-label systemic therapy, primarily systemic biologic therapy. This will be an open-label study with no placebo control. Both of our NS clinical studies will run concurrently and utilize the same clinical trial sites and investigators.

***Agreements with Altium Growth Fund, LP and Warrant Exercises***

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

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

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

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

***Noteholder Warrant Exercises***

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

***Public Offerings***

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

On February 24, 2023 (the "February Closing Date"), we completed an offering (the "February Offering") of 24,750,000,000 ordinary shares represented by 4,950,000 ADSs at a purchase price of $1.00 per ADS and a pre-funded warrant (the "February Pre-Funded Warrant") to purchase 10,250,000,000 ordinary shares represented by 2,050,000 ADSs at a per pre-funded warrant price of $0.9999, with each ADS and February Pre-Funded Warrant accompanied by an ordinary warrant (the "February Common Warrant") for aggregate gross proceeds of $7.0 million, resulting in net proceeds of approximately $6.0 million, after deducting the placement agent's fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the subsequent exercise of the February Common Warrants. Each February Common Warrant has an exercise price of $1.00 per ADS and expires on the fifth anniversary of the February Closing Date. On the February Closing Date, the holder of the February Pre-Funded Warrant exercised its Pre-Funded Warrant in full.

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

In connection with the February Offering, we entered into an Amendment No. 1 to Warrant to Purchase Ordinary Shares Represented by American Depositary Shares, dated February 24, 2023 (collectively, the "Warrant Amendments"), with each of the purchasers (the "2022 Purchasers") who participated in both the August Offering and February Offering. The Warrant Amendments amended certain terms of the August Common Warrants issued to such 2022 Purchasers in the August Offering. Specifically, the Warrant Amendments reduced the exercise price of such warrants to $1.10 and extended the term during which those warrants could remain exercisable until February 24, 2028.

***Components of Our Results of Operations***

**Operating Expenses**

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

**Research and Development Expenses**

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

Future research and development expenses may include:

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

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

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

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

**General and Administrative Expenses**

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

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities. These increases will likely include increased costs related to the hiring of personnel, including compensation and employee-related expenses, and fees to outside consultants, lawyers and accountants. Additionally, we anticipate increased costs associated with being a public company, including compliance with The Nasdaq Capital Market and SEC requirements, insurance and investor relations costs.

**Other Expenses**

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

***Results of Operations - Year ended December 31, 2022 compared to Year ended December 31, 2021***

The following table sets forth our results of operations for the year ended December 31, 2022, compared to the year ended December 31, 2021:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2022 | 2021 | Change |
| **Operating Expenses** | | | |
| General and administrative | $ 6,584,868 | $ 4,499,923 | $ 2,084,945 |
| Research and development | 2,672,836 | 1,562,927 | 1,109,909 |
| Total operating expenses | 9,257,704 | 6,062,850 | 3,194,854 |
| **Other Expenses** | | | |
| Forgiveness of trade payable | (416,000) | — | (416,000) |
| Fair value adjustments to convertible notes payable | — | 1,250,000 | (1,250,000) |
| Warrant liability (income) expense | (77,237) | 12,784,329 | (12,861,566) |
| Financing expense | — | 275,000 | (275,000) |
| Unrealized income | (1,307) | — | (1,307) |
| Interest income | (95,745) | — | (95,745) |
| Interest and financing expense | 714,081 | 1,090,409 | (376,328) |
| Total other expense | 123,792 | 15,399,738 | (15,275,946) |
| **Net loss** | $ (9,381,496) | $ (21,462,588) | $ 12,081,092 |

**General and Administrative Expenses**

General and administrative expenses were approximately $6,585,000 and $4,500,000, in the year ended December 31, 2022 and 2021, respectively, representing an increase of $2,085,000, or 46%. The increase was primarily due to the build-up of the company infrastructure post the Merger which included, $810,000 in increased costs of becoming a public company related to professional services, filing and insurance costs, $318,000 in increased salary and benefits expenses, $283,000 in travel related expenses and stock-based compensation expense of $664,000 following the issuance of options under the Amended and Restated Equity Incentive Plan (the "Amended Plan") in April 2022.

**Research and Development Expenses**

Our research and development expenses during the year ended December 31, 2022 and 2021 were approximately $2,673,000 and $1,563,000, respectively, representing an increase of $1,110,000, or approximately 71%. The increase was primarily due to $1,010,000 in increased expenditures on our development programs following the completion of our financings in October 2021, including work related to the filing of our IND for QRX003 in March 2022, work related to commencing the clinical studies for the development of QRX003 following the FDA clearance of our IND in April 2022. Also, included in the 2022 expenses were approximately $100,000 of stock-based compensation expense following the issuance of options under the Amended and Restated Equity Incentive Plan (the "Amended Plan") in April 2022. We expect to significantly increase our research and development efforts by conducting the remaining studies necessary for the development and approval of QRX003, see "Components of Our Results of Operations - Research and Development Expenses" above.

We amortize licensed or acquired intellectual property over its expected useful life, included in research and development expenses set out above. The license from Skinvisible was obtained in October 2019, see "Research and Development, Patents and Licenses." Amortization of intangible assets was approximately $104,000 in each of the years ended December 31, 2022 and 2021.

**Other Expenses:**

**Interest and financing expense**

Interest expense on the 2020 Notes and Bridge Notes was $714,000 and $1,090,000 in the year ended December 31, 2022 and 2021 respectively. Interest on the Bridge Notes was paid in October 2021 upon closing of the Primary Financing, and interest on the 2020 Notes did not accrue after October 2021 but remained unpaid and included as a liability on our consolidated balance sheet as of December 31, 2021 a portion of which was paid in the year ended December 31, 2022. Approximately $312,000 was paid to two of the five 2020 Noteholders during the year ended December 31, 2022. Based on the terms of the cash settlement with these two 2020 Noteholders, our estimate of the liability to the remaining three 2020 Noteholders was increased to $1,146,000 as of December 31, 2022. We expect to settle the remaining liability in 2023. We earned $96,000 in interest income in the year ended December 31, 2022 from our cash and investments in marketable securities. In the year ended December 31, 2021 we incurred $275,000 in finance expenses in connection with the Primary Financing.

**Fair value adjustment to convertible notes payable**

We elected to value the 2020 Notes and the Bridge Notes at fair value, which was remeasured at each reporting period. In the year ended December 31, 2021 we incurred a fair value adjustment of $1,250,000 related to the Bridge Notes. The Bridge Notes and 2020 Notes were converted into equity in October 2021 on the closing of the Primary Financing.

**Warrant liability expense**

We determined our warrants required liability treatment at fair value, which was remeasured at each reporting period. In the year ended December 31, 2022, and December 31, 2021 we incurred a fair value gain of ($77,000) related to the warrants associated with the 2020 Notes, and expense of $12,784,000 related to the warrants associated with the 2020 Notes and the Bridge Notes, respectively. The Bridge Note warrants which were exchanged for the Investor Exchange Warrants with a fixed exercise price of $49.74 per ADS and reclassified as an equity instrument in October 2021 upon closing of the Primary Financing. The 2020 Note warrants were exchanged for warrants on the same terms as the Investor Exchange Warrants and reclassified as an equity instrument in March 2022.

**Forgiveness of Trade Payable**

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

***Liquidity and Capital Resources***

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

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

**Future Funding Requirements**

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

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

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

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

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

***Summary Statement of Cash Flows***

As of December 31, 2022, we had approximately $12,854,000 in cash and investments in marketable securities. The table below presents our cash flows for the year ended December 31, 2022 and 2021:

| | Year ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Net cash used in operating activities | $ (8,480,732) | $ (5,720,090) |
| Net cash used in investing activities | (10,149,121) | (625,000) |
| Net cash provided by financing activities | 14,007,708 | 13,504,031 |
| Net increase (decrease) in cash | $ (4,622,145) | $ 7,158,941 |

**Operating Activities**

Net cash used in operating activities was approximately $8,481,000 and $5,750,000 for the year ended December 31, 2022 and 2021, respectively. The increase in 2022 was primarily due to the increase in research and development and general and administrative expenses, including significant expenses incurred in connection with becoming a public company and increased compensation costs.

**Investing Activities**

Net cash used in investing activities was $10,149,000 and $625,000 in the year ended December 31, 2022 and 2021, respectively. The increase in cash used in investing activities for the year ended December 31, 2022 was primarily due to the purchases of short maturity US Treasury Bills from the proceeds of the August Offering, offset by a decrease of $375,000 in license acquisition costs.

**Financing Activities**

Net cash provided by financing activities was $14,008,000 for the year ended December 31, 2022. The net cash provided increased due to the receipt of $14.9 million in net proceeds from the August Offering partially offset by repayments of amounts due to officers at the aggregate rate of $50,000 per month and approximately $312,000 partial pay-down of accrued interest on the 2020 Notes. Net cash from financing activities in the year ended December 31, 2021 was $13,504,000, primarily representing net proceeds received from the issuance of Bridge Notes and the Primary Financing.

**Research and development commitments**

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

In November 2020, Quoin Inc. entered into a Master Service Agreement for an initial term of three years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. A work order was entered into in June 2022 for the first QRX003 clinical study at an expected estimated cost of approximately $4.4 million through 2024. A further work order was entered into in December 2022 for the second QRX003 clinical study at an expected estimated cost of approximately $830,000 through 2024. For the years ended December 31, 2022 and 2021, we incurred a research and development expense under these agreements of approximately $1.2 million and $340,000 respectively.

In November 2021, we entered into a commitment with Queensland University of Technology for research related services associated with Netherton Syndrome of approximately $250,000 for an expected period of eighteen months. For the years ended

December 31, 2022 and 2021, we incurred research and development costs related to this agreement of approximately $77,000 and $25,000, respectively.

In May 2022, we entered into a commitment with Queensland University of Technology for research related services associated with Scleroderma of approximately $610,000 for an expected period of eighteen months. We incurred research and development expenses of approximately $276,000 for the year ended December 31, 2022.

***Critical Accounting Policies and Use of Estimates***

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

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

**Use of estimates:**

The preparation of financial statements in conformity with 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, fair value of debt instruments, stock-based compensation and warrants, research and development expense recognition, intangible asset estimated useful lives and impairment assessments, allowances of deferred tax assets, contingency recognition, and cash flow assumptions regarding going concern considerations.

**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 expense in future periods as the related services are rendered.

**Warrants:**

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

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

**Long-lived assets:**

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

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, 2022 and 2021, there were no impairment indicators 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 ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. As of December 31, 2022, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2022. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and implemented, can provide only reasonable assurance of achieving the desired control objectives.

**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) and 15d-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 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, 2022, 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, 2022.

**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 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**

During the year ended December 31, 2022, there were no changes in our internal control over financial reporting] that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

**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. Each director is entitled to serve until the 2023 annual meeting of shareholders and until a successor is duly elected and qualified or until his or her earlier retirement, resignation or removal.

| Name | Age | Position(s) |
|---|---|---|
| Dr. Michael Myers | 61 | Chairman of the Board and Chief Executive Officer |
| Denise Carter | 54 | Director and Chief Operating Officer |
| Joseph Cooper[1][3] | 65 | Director |
| James Culverwell[1][2] | 66 | Director |
| Dr. Dennis H. Langer[2] | 71 | Director |
| Natalie Leong[1][3] | 37 | Director |
| Michael Sember[2] | 73 | Director |
| Gordon Dunn | 58 | Chief Financial Officer |

(1) Member of our Audit Committee.
(2) Member of our Compensation Committee.
(3) Member 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 35 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. (NYSE: WST), 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 (Nasdaq: AVDL), 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 2022, Dr. Myers has served as a director of Ethicann Pharmaceuticals and SquareX Pharmaceuticals, each a clinical stage pharmaceutical company. Since 2019, Dr. Myers has served as a director of Sonoran Bioscience and Wellesley Pharmaceuticals, each a specialty pharmaceutical company. Dr. Myers earned his Ph.D. in Chemistry from the 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 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. (NYSE: WST). 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 fund raising experience in the life sciences industry.

**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. He has significant experience in operational, corporate development and general management roles within the pharmaceutical and healthcare industry. Since 2012, Mr. Cooper has 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. (NYSE: MRX), a 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 (Nasdaq: BIVN) a 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 (Nasdaq: TCBP), 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 (Nasdaq: AMYT), 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 the Managing Partner at Phoenix IP Ventures, LLC, a private equity and venture capital fund specializing in life sciences companies. 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. (Nasdaq: MYGN), 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., Nasdaq: ERNA), a biotechnology company. From 2007 to 2019, Dr. Langer served as a director of Dicerna Pharmaceuticals Inc. (Nasdaq: DRNA), a biopharmaceutical company. Dr. Langer serves on the Dean's Advisory Board of Harvard Law School. 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 of directors 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 2015, Mr. Sember has served as the Chief Executive Officer of RaeSedo, Inc., a therapeutics company. 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 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.

**Gordon Dunn,** *Chief Financial Officer*. Mr. Dunn has served as Chief Financial Officer of Quoin Ltd. since November 1, 2021. Mr. Dunn has over 30 years of finance experience. He served as Chief Financial Officer of Health Technologies Ltd. (d/b/a Qured), a UK-based healthcare provider, from March 2020 to October 2021, and as Chief Financial Officer of U-Research, an online company information platform, from July 2017 to March 2020. Mr. Dunn also served as Chief Financial Officer of Anton Corporation, a film and media finance company, from September 2016 to July 2017, and as Chief Financial Officer of Innocoll AG from 2012 to 2016. Prior to these roles, he had deep experience in investment banking and private equity, serving as Portfolio Manager of NewSmith Asset Management, a private equity fund from 2004 to 2014, and as Director of Investment Banking and Co-Head of Private Equity at Merrill Lynch, in addition to other roles, from 1994 to 2003. Mr. Dunn was an associate at Morrison & Foerster LLP from 1991 to 1993. Mr. Dunn earned his JD from New York University School of Law and a BA from Stanford University.

**Family Relationships**

There are no family relationships among any of our directors or executive officers.

**Legal Proceedings**

There are no material legal proceedings to which any of our directors or executive officers, or any associate of any of our directors or executive officers, is a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

**Delinquent Section 16(a) Reports**

Starting from January 1, 2023, our directors, officers (as defined under Rule 16a-1(f) under the Exchange Act) and stockholders who beneficially own more than 10% of any class of our equity securities registered pursuant to Section 12 of the Exchange Act (collectively, the "Reporting Persons") are required to file initial statements of beneficial ownership of securities and statements of changes in beneficial ownership of securities with respect to our equity securities with the SEC under Section 16(a) of the Exchange Act. Therefore, there were no late Form 3 or Form 4 filings in 2022.

**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 to the extent required by the rules and regulations of the SEC. We have not granted any waivers under our Code of Ethics.

**Board of Directors**

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. 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; and
- 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.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Companies Law, our audit committee is responsible for:

- 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 has a personal interest and whether such transaction is extraordinary or material under the Companies Law);
- 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 external 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 Mr. 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;
- the initial approval of transactions regarding the terms of compensation for all office holders, subject to further approvals that may be required by the board of directors and/or a general meeting of shareholders, depending on the circumstances;
- deciding, under the special circumstances set forth in the Companies Law, whether to exempt the approval of terms and conditions of a Chief Executive Officer's service from the requirement of shareholder approval;
- approving non-material amendments to the compensation arrangement of an office holder who is not a director;
- 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***

We are required to appoint an internal auditor in accordance with the recommendation of the audit committee in accordance with the Companies Law. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the chief executive officer of the company;
- an office holder (including a director) of the company (or a relative thereof); or
- a member of the company's independent accounting firm, or anyone on his or her behalf.

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. Our internal auditor is Mr. Edo Pollack, a Certified Public Accountant and partner-in-charge of the Israel office of Eisner Advisory Group LLC.

The Chairman of the board of directors is the direct supervisor of the internal auditor, unless the board of directors determines otherwise (and, in this regard, we have not determined otherwise). The internal auditor is required to submit his or her findings to the Chairman of the Board, the Chief Executive Officer, and the Chairman of the audit committee. The internal auditor may not be dismissed or suspended without his consent, other than by a decision of the board of directors requiring a quorum of the majority of the members of the board, after the board of directors has heard the audit committee's position on the matter, and the internal auditor has been afforded a reasonable opportunity to bring his position before the audit committee and the board of directors.

***Fiduciary Duties of Directors and Executive Officers***

The Companies Law codifies the fiduciary duties that office holders owe to a company. An "office holder" under the Companies Law means a director, a Chief Executive Officer, or other officer who occupies a general or chief management position, or serves in a position directly secondary to or directly reporting to the Chief Executive Officer. Each person named in the table of our directors and executive officers above 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.

***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 that he or she may be aware of concerning any existing or proposed transaction with the company, including all material information or documents related thereto. An interested office holder's disclosure must be made promptly, and in any event no later than the first meeting of the board of directors at which the transaction is considered. As used in the context of the Companies Law, a "personal interest" includes an interest of any person in an act or transaction of a company, including a personal interest of such person'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 chief executive officer, or in which he or she has the right to appoint at least one director or the chief executive officer, but excluding a personal interest stemming solely from an interest in shares in the company. A "personal interest" is furthermore deemed to include, in a proposal brought before a meeting of shareholders, the personal interest of a shareholder for whom a vote is being cast by power of attorney, as well as the personal interest of a person voting by virtue of a power of attorney, even if the person granting such power of attorney has no personal interest in the matter. A "relative" (in this context, and generally in the context of the Companies Law) means (a) a spouse, sibling, parent, grandparent, child or descendant, (b) a spouse's child or descendant, parent or sibling, or (c) the spouse of any of the foregoing. An office holder is not, however, obligated to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an "extraordinary transaction."

Under the Companies Law, an "extraordinary transaction" is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on a company's profitability, assets or liabilities.

Generally speaking, 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 not be present at such a meeting or vote on that matter (unless it is with respect to a transaction which is not an extraordinary transaction), 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 the deliberations of the audit committee or board of directors

(as the case may be) with respect to such transaction, and vote on the approval thereof; however in such case shareholder approval will be required.

Generally speaking, any transaction between the Company and an office holder, or between the Company and a person or entity in whom the office holder has a personal interest, requires approval by the board of directors; if such transaction is an extraordinary transaction, it requires approval first by the company's audit committee, and subsequently by the board of directors.

***Approvals Required for the Compensation of Directors and Executive Officers***

The Companies Law requires special approvals for a transaction regarding the terms of compensation of an office holder (whether or not by way of an employment agreement), which is deemed to include the payment or issuance of any benefit to the office holder which was not already promised under an existing agreement, including any form of cash, equity, termination benefits, exculpation, insurance or indemnification, or any additional benefit or amendment not covered by a previously approved agreement or arrangement.

Approval of the compensation of an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors, and, if such compensation transaction is not consistent with the company's compensation policy, or if the office holder is the Chief Executive Officer, the subsequent approval of a special majority for compensation matters at a general meeting of shareholders, namely, a simple majority of the company's shareholders, provided that (1) such majority includes a majority of the votes cast by the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded) or (2) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter and voted against the compensation policy, constitute two percent or less of the aggregate voting rights in the company (a "Special Majority for Compensation Matters").

Arrangements regarding the terms of compensation of an office holder who is a director require the approval of the compensation committee, followed by the board of directors, followed by a simple majority at a general meeting of shareholders; however, under certain circumstances a Special Majority for Compensation Matters is required. The respective approvals of the compensation committee and the board of directors must be in line with the company's duly approved compensation policy; however, in special circumstances, compensation terms may be approved notwithstanding an inconsistency with the compensation policy, provided that the compensation committee and the board have considered those provisions that must be included in the compensation policy under the Companies Law, and shareholder approval was obtained by a special majority.

**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" or "Covered Office Holders") during the years ended December 31, 2022 and 2021.

| Name and Principal Position | Year | Salary ($) | Bonus[1] ($) | Option Awards[2] ($) | All Other Compensation[3] ($) | Total[4] ($) |
|---|---|---|---|---|---|---|
| ***Dr. Michael Myers*** | 2022 | 550,000 | — | 1,112,187 | 57,112 | 1,719,299 |
| Chief Executive Officer | 2021 | 518,000 | 427,500 | — | 57,209 | 998,209 |
| | | | | | | |
| ***Denise Carter*** | 2022 | 440,000 | — | 1,112,187 | 55,215 | 1,607,402 |
| Chief Operating Officer | 2021 | 416,000 | 342,000 | — | 51,009 | 809,009 |
| | | | | | | |
| ***Gordon Dunn***[4] | 2022 | 360,000 | — | 926,822 | 1,385 | 1,288,207 |
| Chief Financial Officer | 2021 | 60,000 | 60,000 | — | | 120,000 |

(1) For bonuses earned during the year ended December 31, 2021, represents: (i) with respect to Mr. Myers, Ms. Carter and Mr. Dunn, a discretionary cash bonus under the officer's respective employment agreement granted in recognition of the applicable officer's promotion of our long-term goals, strategy and operating plan, the need to form appropriate incentives for our officers, and contribution to the achievement of our objectives in accordance with the officer's respective corporate role during the year ended December 31, 2021; (ii) with respect to Mr. Myers and Ms. Carter, a transaction bonus related to the completion of the Merger and

private placement transactions during the year ended December 31, 2021, and (iii) with respect to Mr. Dunn, a signing bonus of $30,000 upon joining the company in November 2021. The amount of bonuses earned during the year ended December 31, 2022 is not calculable through the date of this Annual Report, and such amount will be disclosed in our Current Report on Form 8-K under Item 5.02(f) after we obtain applicable approvals of our shareholders under the Companies Law at our 2023 Annual Meeting of Shareholders.

(2) Represents the grant date fair value of option awards granted to each of our named executive officers on April 12, 2022, calculated in accordance with FASB ASC Topic 718. These options have an exercise price of $17.50 per ADS and vest in four equal annual installments beginning on April 12, 2023. The option values were calculated using a Black-Scholes Model for pricing options. See Note 7 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.

(3) Represents amounts paid as office and automobile allowance to Mr. Myers and Ms. Carter under their respective employment agreements, 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"), broken down as follows:

| | | Office Allowance ($) | Car Allowance ($) | 401(k) Contributions ($) | Total ($) |
|---|---|---|---|---|---|
| Michael Myers | 2022 | 30,000 | 18,000 | 9,112 | 57,112 |
| | 2021 | 27,500 | 16,500 | 8,709 | 52,709 |
| Denise Carter | 2022 | 30,000 | 18,000 | 7,215 | 55,215 |
| | 2021 | 27,500 | 16,500 | 7,009 | 51,009 |
| Gordon Dunn | 2022 | — | — | 1,385 | 1,385 |

(4) Mr. Dunn was appointed as our Chief Financial Officer on November 1, 2021.

***Employment Agreements***

We entered into written employment agreements with our Covered Office Holders 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 is entitled to an annual base salary of $550,000, which accrued monthly until paid by Quoin Inc. Dr. Myers may also receive, subject to employment by us on the applicable date of bonus payout, an annual target discretionary bonus of not less than 45% of his annual base salary, payable at the discretion of the board of directors after approval of our 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.

***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 is entitled to an annual base salary of $440,000, which accrued monthly until paid by Quoin Inc. Ms. Carter may also receive, subject to employment by us on the applicable date of bonus payout, an annual target discretionary bonus of not less than 45% of her annual base salary, payable at the discretion of the board of directors after approval of our 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.

***Mr. Dunn.*** Pursuant to his Service Agreement with Quoin Inc., dated November 1, 2021 (as amended, the "Dunn Agreement"), Mr. Dunn is entitled to an annual base salary of $360,000. In addition, Mr. Dunn is entitled to receive (i) a signing bonus equal to one-twelfth of his annual base salary, and (ii) subject to employment by us on the applicable date of bonus payout, an annual target

discretionary bonus of not less than 45% of his annual base salary, payable at the discretion of the Board, which will be prorated for 2021. Under the Dunn Agreement, upon our adoption of an option plan, we are obligated to grant an option to Mr. Dunn to purchase our ordinary shares, with $1.25 million grant date value, subject to the terms of such plan. Mr. Dunn is also eligible to receive healthcare benefits as may be provided from time to time by us to our employees generally and paid time off annually in accordance with our policies in effect from time to time.

***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, 2022***

The following table sets forth information with respect to outstanding equity awards for each named executive officer as of December 31, 2022.

| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable[1] | Option Exercise Price[2] ($) | Option Expiration Date |
|---|---|---|---|---|
| Dr. Michael Myers | — | 85,714 | 17.50 | 04/12/2032 |
| Denise Carter | — | 85,714 | 17.50 | 04/12/2032 |
| Gordon Dunn | — | 71,429 | 17.50 | 04/12/2032 |

(1) Represents the number of ADSs issuable upon the exercise of options. Each option vests in four equal annual installments beginning on April 12, 2023.

(2) Represents the exercise price per ADS.

***Amended and Restated Equity Incentive Plan***

At our annual meeting of shareholders on April 12, 2022 ("April 2022 Annual Meeting"), our shareholders approved our Amended And Restated Equity Incentive Plan (the "Plan"), which amended and restated our 2014 Global Incentive Option Scheme. The number of shares reserved for issuance under the Plan is equal to 15% of our outstanding ordinary shares on a fully-diluted basis. The purpose of the Plan is to attract, retain and motivate our employees (including prospective employees), non-employee directors and consultants. The Board has the power to administer the Plan, either directly or upon the recommendation of the Compensation Committee of the Board, in accordance with applicable law and the Company's Articles. Options granted under the Plan are subject to applicable vesting schedules and generally expire ten years from the grant date.

***Option Grants***

At our April 2022 Annual Meeting, our shareholders approved the grant an option to purchase 85,714 ADSs under the Plan to each of Dr. Myers and Ms. Carter, at an exercise price of $17.50 per ADS, vesting in four equal annual installments beginning on April 12, 2023. In addition, our Board approved the grant of an option to purchase 71,429 ADSs under the Plan to Mr. Dunn, at an exercise price of $17.50 per ADS, in four equal annual installments beginning on April 12, 2023. Under the Companies Law, shareholder approval was not required for the option grant to Mr. Dunn.

***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).

Mr. Dunn, pursuant to the Dunn Agreement, is also entitled to the following benefits upon termination of his employment:

- **Garden Leave**: During any period of notice to terminate Mr. Dunn's employment, Mr. Dunn will continue to be entitled to his basic salary and contractual benefits in the usual course.

- **Payment in lieu of notice**: Upon the termination of Mr. Dunn's employment at any time, Mr. Dunn will receive payment equal to his basic salary as of the termination date which he would have been entitled to receive under the Dunn Agreement during the notice period referred to in the bullet below, less income tax and national insurance contributions. Payment in lieu of notice will not include (i) any bonus or commission payments that might otherwise have been paid to Mr. Dunn during the period for which such payment in lieu of notice is made, (ii) benefits Mr. Dunn would have been entitled to during such time, and (iii) holiday entitlement that would have accrued during such time.

- **Termination**: Subject to successful completion of the probationary employment period as set forth in the Dunn Agreement, and except in connection with certain "for cause" events, as set forth in Section 20.2 of the Dunn Agreement, the Company may terminate Mr. Dunn's employment by giving at least 12 months' prior written notice, and is obligated to continue paying Mr. Dunn his basic salary and other benefits during such notice period.

The foregoing descriptions of the Myers Agreement, the Carter Agreement and the Dunn 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 and the Dunn Agreement, copies of which are included as exhibits to this Annual Report.

*Option Awards*

Under the Plan, upon termination of employment for any reason, other than in the event of death or disability or for "Cause" (as defined in the 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 Plan and the governing option agreement.

Non-Employee Director Compensation

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

- each non-employee director receives an annual base retainer of $60,000;
- 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 under the Plan valued at $60,000. In addition, each non-employee director who joins the Board is granted an inaugural award of options valued at $165,000.

At our April 2022 Annual Meeting, our shareholders approved, pursuant to and in line with our non-employee directors' compensation program, the following option grants to each of our non-employee directors under the Plan:

- as an inaugural grant, an option to purchase 9,428.56 ADS, at an exercise price of $17.50 per ADS, vesting over a three-year period beginning on April 12, 2023; and
- as an annual grant for 2022, an option to purchase 3,428.56 ADS, at an exercise price of $17.50 per ADS, vesting over a three-year period beginning on April 12, 2023.

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, 2022.

| Name | Fees Earned or Paid in Cash ($) | Option Awards[2] ($) | Total ($) |
|---|---|---|---|
| Joseph Cooper | 70,000 | 163,570 | 233,570 |
| James Culverwell | 75,000 | 163,570 | 238,570 |
| Dr. Dennis H. Langer[1] | 90,000 | 163,570 | 253,570 |
| Natalie Leong | 80,000 | 163,570 | 243,570 |
| Michael Sember | 65,000 | 163,570 | 228,570 |

(1) Includes $15,000 Compensation Committee Chairman fee for the year ended December 30, 2021, which was paid in 2022.

(2) Represents the grant date fair value of option awards granted to each of our non-employee directors on April 12, 2022, calculated in accordance with FASB ASC Topic 718. These options have an exercise price of $17.50 per ADS and vest in three equal annual installments beginning on April 12, 2023. The option values were calculated using a Black-Scholes Model for pricing options. See Note 7 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.

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

**Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of March 10, 2023, 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 ordinary shares. 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 shares indicated as being beneficially owned.

Except as indicated by footnote, the beneficial ownership information is based upon 59,233,024,799 ordinary shares outstanding as of March 10, 2023. Ordinary shares that may be acquired by a person within 60 days of March 10, 2023, pursuant to the exercise of options 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 of any other person shown in the table. Each ADS represents 5,000 ordinary shares of Quoin Ltd.

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*: | | |
| Lind Global Fund II LP[1] | 4,950,000,000 | 8.2 % |
| | | |
| *Directors and Named Executive Officers*: | | |
| Dr. Michael Myers[2] | 668,622,900 | 1.1 % |
| Denise Carter[3] | 668,617,900 | 1.1 % |
| Joseph Cooper[4] | 21,428,533 | * |
| James Culverwell[5] | 40,498,533 | * |
| Dr. Dennis Langer[6] | 42,433,533 | * |
| Natalie Leong[7] | 21,428,533 | * |
| Michael Sember[8] | 21,428,533 | * |
| Gordon Dunn[9] | 89,285,700 | * |
| All directors and officers as a group (8 persons) [10] | 1,573,744,165 | 2.7 % |

* Less than 1%

(1) Based on Schedule 13G filed with the SEC on March 3, 2023 by Lind Global Fund II LP, a Delaware limited partnership ("Lind Global Fund"), Lind Global Partners II LLC, a Delaware limited liability company ("Lind Global Partners"), and Jeff Easton ("Mr. Eastern" and together with Lind Global Fund and Lind Global Partners," the "Lind Reporting Persons"), consists of 3,750,000,000 ordinary shares and 1,200,000,000 ordinary shares issuable upon the exercise warrants held by Lind Global Fund, giving effect to the provision in such warrants limiting the holder's ability to exercise the warrants if such exercise would cause the holder to beneficially own greater than 9.99% of our outstanding shares. Lind Global Partners, the general partner of the Lind Global Fund, may be deemed to have sole voting and dispositive power with respect to the shares held by Lind Global Fund. Mr. Easton, the managing member of Lind Global Partners, may be deemed to have sole voting and dispositive power with respect to the shares held by Lind Global Fund. The address of the principal office of each of the Lind Reporting Persons is 444 Madison Ave, Floor 41 New York, NY 10022.

(2) Consists of (i) 561,480,000 ordinary shares held directly and (ii) 107,142,900 ordinary shares issuable upon the exercise of options which will vest within 60 days.

(3) Consists of (i) 561,475,000 ordinary shares held directly and (ii) 107,142,900 ordinary shares issuable upon exercise of options which will vest within 60 days.

(4) Represents 21,428,533 ordinary shares issuable upon exercise of options which will vest within 60 days.

(5) Consists of (i) 19,070,000 ordinary shares held directly and (ii) 21,428,533 ordinary shares issuable upon exercise of options which will vest within 60 days.

(6) Consists of (i) 21,005,000 ordinary shares held directly and (ii) 21,428,533 ordinary shares issuable upon exercise of options which will vest within 60 days.

(7) Represents 21,428,533 ordinary shares issuable upon exercise of options which will vest within 60 days.

(8) Represents 21,428,533 ordinary shares issuable upon exercise of options which will vest within 60 days.

(9) Represents 89,285,700 ordinary shares issuable upon exercise of options which will vest within 60 days.

(10) Consists of (i) 1,163,030,000 ordinary shares held directly and (ii) 410,714,165 ordinary shares issuable upon the exercise of options.

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of us.

**Equity Compensation Plan Table**

The following table summarizes our equity compensation plan information as of December 31, 2022.

| 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 remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)[1] |
|---|---|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders | 307,142 | $ 17.50 | 971,243 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 307,142 | $ 17.50 | 971,243 |

(1) Represents the number of ADSs issuable upon the exercise of options.
(2) Represents the exercise price per ADS.

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

**Director Independence**

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**

In 2021, Quoin Inc. paid $100,000 of consulting expenses to a company controlled by Dennis Langer, our director, and approximately $8,000 and $48,000 were paid in 2021 and 2022, respectively, to Dr. Myers' son, who has been consulting Quoin Inc. on research and development matters from time to time.

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 $125,000 and $300,000 of such indebtedness to Dr. Myers and $160,000 and $300,000 to Ms. Carter in 2021 and 2022, respectively. As of December 31, 2022, there was approximately $2,259,000 and $1,865,000 of such indebtedness was outstanding to Dr. Myers and Ms. Carter, respectively.

Commencing in October 2020, Quoin Inc. issued promissory notes (the "2020 Notes") to five noteholders, including our directors, Messrs. Langer and Culverwell (collectively, "2020 Noteholders"). The 2020 Notes were issued at a 25% original issue discount with an aggregate face value of $1,213,313 with an interest at a rate of 20% per annum. The 2020 Noteholders also received warrants exercisable at any time after the issuance date. At the closing of the Merger in October 2021, 5,183 ADSs were issued to the 2020 Noteholders upon the conversion of the principal of the 2020 Notes, of which 626 ADSs were issued to Mr. Langer and 569 ADSs were issued to Mr. Culverwell. In December 2021, we concluded that the calculation of ADSs due to the 2020 Noteholders did not account for accrued interest due when the ADSs were issued. We reached cash settlements with two 2020 Noteholders, who are not our directors, to account for this. Based on the terms of these cash settlements, we estimate the liability to the remaining three 2020 Noteholders, including our directors, to be $1,146,000 as of December 31, 2022, and we expect to settle the remaining liability in 2023. The exercise price of the warrants held by the 2020 Noteholders was reduced to $0.00 as of July 14, 2022 as a result of the Altium Agreement discussed above. The change in the exercise price of the Noteholder Warrants resulted in a deemed dividend of approximately $65,000. From July to September 2022, the 2020 Noteholders exercised all their warrants to purchase ADSs at $0.00 per ADS exercise price, and a total of 29,388 ADSs were issued to such noteholders, of which 3,575 ADSs were issued to Mr. Langer and 3,245 ADSs were issued to Mr. Culverwell.

**Item 14. Principal Accountant Fees and Services**

The Company's shareholders appointed Friedman LLP ("Friedman") as the Company's independent registered public accounting firm for the year ended December 31, 2021. Based on information provided by Friedman, effective September 1, 2022, Friedman combined with Marcum LLP ("Marcum"). The Company's shareholders appointed Marcum as the Company's independent registered public accounting firm for the year ended December 31, 2022.

The following table sets forth the aggregate accounting fees paid by us to Marcum and Friedman for all services, including audit services, for the years ended December 31, 2022 and 2021, as applicable.

| | Year Ended December 31, 2022 | Year Ended December 31, 2021 |
|---|---|---|
| **Type of Fees** (in thousands) | | |
| **Audit Fees** | $ 258 | $ 229 |
| **Audit-Related Fees** | — | 5 |
| **Tax Fees** | — | 18 |
| **All Other Fees** | — | — |
| Total | $ 258 | $ 252 |

***Audit Fees*** refer to the aggregate fees, including expenses, billed by our principal accountant 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 during each of the fiscal years ended December 31, 2022 and 2021.

***Audit-Related Fees*** refer to the aggregate fees, including expenses, billed by our principal accountant 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 during the fiscal years ended December 31, 2022 and 2021.

***Tax Fees*** refer to the aggregate fees, including expenses, billed by our principal accountant for services rendered for tax compliance, tax advice and tax planning during the fiscal years ended December 31, 2022 and 2021.

***All Other Fees*** refer to the aggregate fees, including expenses, billed for all other products and services provided by our principal accountant during the fiscal years ended December 31, 2022 and 2021.

***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. If a type of service, that is to be provided by our auditors, has not received such general pre-approval, it will require specific pre-approval by our audit committee.

## 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.

| Exhibit No. | Exhibit Description |
|---|---|
| 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. (incorporated by reference to Exhibit 10.1 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021). |
| 2.2 | Amendment made as of 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. (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the SEC on September 27, 2021). |
| 2.3 | Amended and Restated Share Transfer Agreement, dated May 27, 2021 by and between Cellect Biotechnology Ltd. and EnCellX Inc. (incorporated by reference to Exhibit 2.2 to Registration Statement on Form F-4 filed with the Securities and Exchange Commission on June 16, 2021). |
| 2.4 | Amendment made as of 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. (incorporated by reference to Exhibit 99.3 to Form 6-K filed with the SEC on September 27, 2021). |
| 2.5 | 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 (incorporated by reference to Exhibit 10.4 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021). |
| 2.6 | 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 (incorporated by reference to Exhibit 10.6 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021). |
| 2.7 | Amendment Agreement, dated as of September 17, 2021, by and among Quoin Pharmaceuticals, Inc., Cellect Biotechnology, Ltd., and Altium Growth Fund, L.P. (incorporated by reference to Exhibit 99.1 of the Form 6-K filed with the Securities and Exchange Commission on September 17, 2021). |
| 2.8 | Letter Agreement, dated September 17, 2021, between Quoin Pharmaceuticals, Inc. and Cellect Biotechnology, Ltd. (incorporated by reference to Exhibit 99.2 of the Form 6-K filed with the Securities and Exchange Commission on September 17, 2021). |
| 2.9 | Second Amendment Agreement, dated as of March 13, 2022, by and among Quoin Pharmaceuticals, Inc., Quoin Pharmaceuticals Ltd., and Altium Growth Fund, L.P. (incorporated by reference to Exhibit 4.1 to Form 6–K filed with the SEC on March 28, 2022). |
| 2.10 | Waiver Agreement, dated June 6, 2022, by and among Quoin Pharmaceuticals Ltd., Quoin Pharmaceuticals, Inc. and Altium Growth Fund, LP (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on June 6, 2022). |
| 2.11 | Agreement, dated July 14, 2022, by and among Quoin Pharmaceuticals, Inc., Quoin Pharmaceuticals Ltd. and Altium Growth Fund, LP (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on July 15, 2022). |
| 2.12 | Letter of Agreement among Cellect Biotechnology Ltd, Dr. Shai Yarkoni and EnCellX, Inc. (incorporated by reference to Exhibit 2.5 to Registration Statement on Form F-4 filed with the Securities and Exchange Commission on July 16, 2021). |

| | |
|---|---|
| 2.13 | Form of Representative Agreement among Cellect Biotechnology Ltd, Eyal Leibovitz, as Representative, and EnCellX, Inc. (incorporated by reference to Exhibit 2.6 to Registration Statement on Form F-4 filed with the Securities and Exchange Commission on August 6, 2021). |
| 3.1 | Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on February 28, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on February 8, 2022). |
| 3.2 | Amendment to the Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on April 12, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022). |
| 3.3 | Amendment to the Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on November 3, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on September 21, 2022). |
| 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 (incorporated by reference to Exhibit 4.1 to Registration Statement on Form F-1/A as filed with the SEC on July 26, 2016). |
| 4.2 | Specimen American Depositary Receipt (included in Exhibit 2.1). |
| 4.3 | Form of Contingent Value Rights Agreement, by and among Cellect Biotechnology, Ltd., Eyal Leibovitz in the capacity of Representative and Computershare, Inc. in the capacity of Rights Agent (incorporated by reference to Exhibit 4.14 to Registration Statement on Form F-4 filed with the SEC on August 6, 2021). |
| 4.4 | Registration Rights Agreement, dated as of March 24, 2021, by and between Cellect Biotechnology Ltd. and the investors listed on the Schedule of Buyers attached thereto (incorporated by reference to Exhibit 10.5 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021). |
| 4.5 | Form of Primary Warrants for the Purchase Agreement (incorporated by reference to Exhibit B to Exhibit 10.4 to Form 6-K filed with the SEC on March 24, 2021). |
| 4.6 | Form of Exchange Warrant (incorporated by reference to Exhibit 99.1 to Form 6-K filed with the SEC on September 17, 2021). |
| 4.7 | Form of Series A Warrant (incorporated by reference to Exhibit 2.5 to Form 20-F filed with the SEC on April 13, 2022). |
| 4.8 | Form of Series B Warrant (incorporated by reference to Exhibit 2.6 to Form 20-F filed with the SEC on April 13, 2022). |
| 4.9 | Form of Series C Warrant (incorporated by reference to Exhibit 2.7 to Form 20-F filed with the SEC on April 13, 2022). |
| 4.10 | Form of Warrant Agent Agreement between Cellect Biotechnology Ltd. and Computershare Inc., as warrant agent, including the form of Warrant (incorporated by reference to Exhibit 4.6 of the Registration Statement on Form F-1 filed with the SEC on February 7, 2019). |
| 4.11 | Form of Securities Purchase Agreement, dated August 5, 2022 (incorporated by reference to Exhibit 4.11 of the Registration Statement on Form F-1/A filed with the SEC on August 4, 2022). |
| 4.12 | Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.12 of the Registration Statement on Form F-1 filed with the SEC on August 3, 2022). |
| 4.13 | Form of Common Warrant (incorporated by reference to Exhibit 4.13 of the Registration Statement on Form F-1 filed with the SEC on August 3, 2022). |
| 4.14 | Form of Amendment No. 1 to Warrant to Purchase Ordinary Shares Represented by American Depositary Shares (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the SEC on February 28, 2023). |
| 4.15 | Form of Securities Purchase Agreement, dated February 22, 2023 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on February 28, 2023). |
| 4.16 | Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on February 28, 2023). |
| 4.17 | Form of Common Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on February 28, 2023). |
| 4.18 | Placement Agency Agreement by and between A.G.P. / Alliance Global Partners and Quoin Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on February 28, 2023 |
| 10.1# | Compensation Policy for Executives and Directors of Quoin Pharmaceuticals Ltd, adopted on April 12, 2022 (incorporated by reference to Annex B included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022). |
| 10.2# | Amended and Restated Equity Incentive Plan of Quoin Pharmaceuticals Ltd., effective as of April 12, 2022 (incorporated by reference to Annex C included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022). |
| 10.3# | 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. as of April 12, 2022 (incorporated by reference to Annex D included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022). |

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| 10.4# | Executive Employment Agreement, dated March 9, 2018, by and between Quoin Pharmaceuticals, Inc. and Dr. Michael Myers (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on October 29, 2021). |
| 10.5# | Executive Employment Agreement, dated March 9, 2018, by and between Quoin Pharmaceuticals, Inc. and Denise Carter (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on October 29, 2021). |
| 10.6# | Service Agreement, dated November 1, 2021, by and between Quoin Pharmaceuticals, Inc. and Gordon Dunn (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on November 23, 2021). |
| 10.7 | Research Agreement, dated November 1, 2021, by and between Quoin Pharmaceuticals, Inc. and Queensland University of Technology (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on November 23, 2021). |
| 10.8 | License and Distribution Agreement, dated November 5, 2021, by and between Quoin Pharmaceuticals, Inc. and AFT Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.3 to Form 6-K filed with the SEC on November 23, 2021). |
| 10.9 | Supply Agreement, dated September 15, 2021, by and between Quoin Pharmaceuticals, Inc. and AFT Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.4 to Form 6-K filed with the SEC on November 23, 2021). |
| 10.10 | License and Distribution Agreement, dated November 7, 2021, by and between Quoin Pharmaceuticals, Inc. and GenPharm Services FZ LLC (incorporated by reference to Exhibit 10.5 to Form 6-K filed with the SEC on November 23, 2021). |
| 10.11 | Supply Agreement, dated November 7, 2021, by and between Quoin Pharmaceuticals, Inc. and GenPharm Services FZ LLC (incorporated by reference to Exhibit 10.6 to Form 6-K filed with the SEC on November 23, 2021). |
| 10.12 | Distribution Agreement, dated December 15, 2021, by and between Quoin Pharmaceuticals, Inc. and Orpharm LLC (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on December 20, 2021). |
| 10.13 | License and Distribution Agreement, dated as of January 24, 2022 between the Company and E-Log Logistica LTDA (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on January 31, 2022). |
| 10.14 | 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 (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.4 to Form 6-K filed with the SEC on March 8, 2022). |
| 10.15 | License and Distribution Agreement, dated as of February 11, 2022, by and between Quoin Pharmaceuticals Ltd. and Neopharm (Israel) 1996 Ltd. (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.5 to Form 6-K filed with the SEC on March 8, 2022). |
| 10.16 | Supply Agreement, dated as of February 11, 2022, by and between Quoin Pharmaceuticals Ltd. and Neopharm (Israel) 1996 Ltd. (incorporated by reference to Exhibit 10.6 to Form 6-K filed with the SEC on March 8, 2022). |
| 10.17 | License Agreement, dated June 14, 2022, by and between Quoin Pharmaceuticals, Inc. and WinHealth Investment (HK) Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on June 17, 2022). |
| 10.18 | License and Distribution Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on July 15, 2022). |
| 10.19 | Supply Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.3 to Form 6-K filed with the SEC on July 15, 2022). |
| 10.20 | Research Agreement, dated May 20, 2022, by and between Quoin Pharmaceuticals, Inc. and Queensland University of Technology, Australia (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on June 6, 2022). |
| 10.21 | Exclusive License Agreement, dated October 17, 2019, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.30 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.22 | Exclusive License Agreement Renewal, dated May 8, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.31 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.23 | First Amendment to the Exclusive License Agreement, dated July 31, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.32 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.24 | Second Amendment to the Exclusive License Agreement, dated September 30, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.33 to Form 20-F filed with the SEC on April 13, 2022). |

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| 10.25 | Third Amendment to the Exclusive License Agreement, dated January 27, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.34 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.26 | Fourth Amendment to the Exclusive License Agreement, dated April 19, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.35 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.27 | Fifth Amendment to the Exclusive License Agreement, dated June 14, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.36 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.28 | Quotation – Tech Transfer and Clinical Manufacture for QRX003 Topical Lotion, dated April 8, 2021, by Ferndale Contract Manufacturing to Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.37 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.29 | Development and Supply Agreement, dated January 13, 2021, by and between TopChem Pharmaceuticals Limited and Quoin Pharmaceuticals Limited (incorporated by reference to Exhibit 4.38 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.30 | Master Services Agreement, dated November 2, 2020, by and between Therapeutics, Inc. and Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.39 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.31 | Term Sheet for Agreement, dated October 29, 2019, by and between Axella Research, LLC and Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.40 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.32 | Term Sheet for Agreement, dated January 11, 2020, by and between Axella Research, LLC and Quoin Pharmaceuticals, Inc. (re: QRX003) (incorporated by reference to Exhibit 4.41 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.33 | Term Sheet for Agreement, dated January 11, 2020, by and between Axella Research, LLC and Quoin Pharmaceuticals, Inc. (re: QRX004) (incorporated by reference to Exhibit 4.42 to Form 20-F filed with the SEC on April 13, 2022). |
| 10.34# | Form of Non-Qualified Stock Option Award Agreement for directors (incorporated by reference to Exhibit 10.34 to Form F-1 filed with the SEC on August 3, 2022). |
| 10.35# | Form of Non-Qualified Stock Option Award Agreement for officers (incorporated by reference to Exhibit 10.35 to Form F-1 filed with the SEC on August 3, 2022). |
| 14.1* | Code of Ethics. |
| 21.1 | Subsidiaries of Registrant (incorporated by reference to Exhibit 8.1 to Form 20-F filed with the SEC on April 13, 2022). |
| 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. |
| 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. |
| 32.1* | Certification of Chief Executive Officer pursuant to 18 U.S.C. § 1350. |
| 32.2* | Certification of Chief Financial Officer pursuant to 18 U.S.C. § 1350. |
| 99.1* | Description of Ordinary Shares. |
| 101* | Information formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements. |
| 104* | Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101) |

* Filed herewith

# 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 15, 2023

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<br>Dr. Michael Myers | Chairman and Chief Executive Officer<br>(Principal Executive Officer) | March 15, 2023 |
| /s/ Gordon Dunn<br>Gordon Dunn | Chief Financial Officer<br>(Principal Financial Officer and Principal Accounting Officer) | March 15, 2023 |
| /s/ Denise Carter<br>Denise Carter | Director and Chief Operating Officer | March 15, 2023 |
| /s/ Joseph Cooper<br>Joseph Cooper | Director | March 15, 2023 |
| /s/ James Culverwell<br>James Culverwell | Director | March 15, 2023 |
| /s/ Dennis Langer<br>Dennis Langer | Director | March 15, 2023 |
| /s/ Natalie Leong<br>Natalie Leong | Director | March 15, 2023 |
| /s/ Michael Sember<br>Michael Sember | Director | March 15, 2023 |

**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, 2022, the related consolidated statements of operations, and stockholders' equity and cash flows for the year ended December 31, 2022, 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, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, 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 audit provides a reasonable basis for our opinion.

**Critical Audit Matters**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was 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. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

**Contracted Research & Development Cost Recognition:**

| | |
|---|---|
| *Critical Audit Matter Description* | As discussed in Note 3 to the financial statements, the Company records costs for clinical trial activities based upon estimates of costs incurred through the balance sheet date for services performed by contract research organizations, clinical study sites and other vendors.<br><br>Auditing the recognition of pre-clinical and clinical trial costs associated with contracted organizations is challenging due to the significant judgment required to determine the nature and level of services that have been received, including determining the progress to completion of specific tasks and activities conducted in relation to what has been invoiced and recorded. |
| *How We Addressed the Matter in Our Audit* | The primary procedures we performed to address this critical audit matter included:<br><br>● Obtained an understanding of the design and operating effectiveness of internal controls for pre-clinical and clinical cost recognition<br>● Tested the completeness and accuracy of the underlying data used in the estimates including, but not limited to, the estimated costs per project milestone and duration<br>● Assessed the reasonableness of the significant assumptions, corroborated the progress of the pre-clinical and clinical trials with the Company's operations personnel and to information obtained by the Company directly from third parties, and to information in contracts or statements of work including costs for those activities and project duration<br>● Examined subsequent invoicing received from such third parties |

/s/ Marcum LLP

We have served as the Company's auditor since 2020 (such date takes into account the acquisition of certain assets of Friedman LLP effective September 1, 2022)
East Hanover, New Jersey
March 15, 2023.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the 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, 2021, the related consolidated statements of operations, and stockholders' equity and cash flows for the year ended December 31, 2021, 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, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

**Consideration of the Company's Ability to Continue as a Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has a working capital deficiency, an accumulated deficit, has incurred significant losses and cash outflows from 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.

/s/ Friedman LLP

PCAOB ID 711
We have served as the Company's auditor since 2020.
East Hanover, New Jersey
April 13, 2022, except for Notes 2 and 17, as to which the date is August 2, 2022 as referenced within the financial statements filed on August 2, 2022 in Form F-1.

**QUOIN PHARMACEUTICALS LTD.**

**Consolidated Balance Sheets**

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 2,860,628 | $ 7,482,773 |
| Investments | 9,992,900 | — |
| Prepaid expenses | 516,584 | 715,474 |
| Total current assets | 13,370,112 | 8,198,247 |
| | | |
| Prepaid expenses - long term | 383,390 | 300,000 |
| Intangible assets, net | 704,561 | 808,604 |
| Other assets | — | 50,000 |
| Total assets | $ 14,458,063 | $ 9,356,851 |
| | | |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | 605,600 | $ 923,239 |
| Accrued expenses | 1,175,705 | 1,685,409 |
| Accrued license acquisition | — | 250,000 |
| Accrued interest and financing expense | 1,146,251 | 743,840 |
| Due to officers - short term | 600,000 | 600,000 |
| Warrant liability | — | 373,599 |
| Total current liabilities | 3,527,556 | 4,576,087 |
| | | |
| Due to officers - long term | 3,523,733 | 4,123,732 |
| Total liabilities | $ 7,051,289 | $ 8,699,819 |
| | | |
| Commitments and contingencies | | |
| | | |
| Shareholders' equity: | | |
| Ordinary shares, no par value per share, 500,000,000,000 ordinary shares authorized - 24,233,024,799 (4,846,605 ADS's) ordinary shares issued and outstanding at December 31, 2022 and 3,354,650,799 (670,930 ADS's) at December 31, 2021 | $ — | $ — |
| Treasury stock, 2,641,693 ordinary shares | (2,932,000) | (2,932,000) |
| Additional paid in capital | 47,855,521 | 31,659,017 |
| Accumulated deficit | (37,516,747) | (28,069,985) |
| Total shareholders' equity | 7,406,774 | 657,032 |
| | | |
| Total liabilities and shareholders' equity | $ 14,458,063 | $ 9,356,851 |

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

**QUOIN PHARMACEUTICALS LTD.**

**Consolidated Statements of Operations**

| | Years Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Operating expenses | | |
| General and administrative | $ 6,584,868 | $ 4,499,923 |
| Research and development | 2,672,836 | 1,562,927 |
| Total operating expenses | 9,257,704 | 6,062,850 |
| | | |
| Other (income) and expenses | | |
| Forgiveness of accounts payable | (416,000) | — |
| Fair value adjustment to convertible notes payable | — | 1,250,000 |
| Warrant liability (income) expense | (77,237) | 12,784,329 |
| Financing expense | — | 275,000 |
| Unrealized income | (1,307) | — |
| Interest income | (95,745) | — |
| Interest and financing expense | 714,081 | 1,090,409 |
| Total other expense | 123,792 | 15,399,738 |
| Net loss | $ (9,381,496) | $ (21,462,588) |
| Deemed dividend on warrant modification | (65,266) | — |
| Net loss attributable to shareholders | $ (9,446,762) | $ (21,462,588) |
| | | |
| **Loss per ADS** | | |
| Loss per ADS | | |
| Basic | $ (3.90) | $ (67.96) |
| Fully-diluted | $ (3.90) | $ (67.96) |
| | | |
| Weighted average number of ADS's outstanding | | |
| Basic | 2,421,916 | 315,801 |
| Fully-diluted | 2,421,916 | 315,801 |

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

**QUOIN PHARMACEUTICALS LTD.**

**Consolidated Statements of Shareholders' Equity**
**Years Ended December 31, 2022 and 2021**

| | Ordinary Shares | ADS's | No Par Value | Treasury Stock | Additional Paid in Capital | Accumulated Deficit | Total |
|---|---|---|---|---|---|---|---|
| **Balance at December 31, 2020** | 1,201,460,800 | 240,292 | $ — | $ — | $ 100 | $ (6,607,397) | $ (6,607,297) |
| Net loss | — | — | — | — | — | (21,462,588) | (21,462,588) |
| Conversion of "2020 Notes" into ordinary shares | 25,913,600 | 5,183 | | | 1,213,313 | | 1,213,313 |
| Sale of equity securities, including conversion of "Bridge Notes" | 1,710,500,800 | 342,100 | | | 17,000,000 | | 17,000,000 |
| Costs associated with sale of equity securities | | | | | (1,897,126) | | (1,897,126) |
| Merger recapitalization of Cellect | 416,775,599 | 83,355 | | (2,932,000) | 2,932,000 | | — |
| Reclassification of warrant upon issuane of Exchange warrants | | | | | 12,410,730 | | 12,410,730 |
| **Balance at December 31, 2021** | 3,354,650,799 | 670,930 | — | (2,932,000) | 31,659,017 | (28,069,985) | 657,032 |
| Net loss | — | — | — | — | — | (9,381,496) | (9,381,496) |
| Stock based compensation | | | | | 764,007 | — | 764,007 |
| Issuance of ADS and Pre-Funded Warrants, net | 16,800,000,000 | 3,360,000 | | | 14,877,332 | — | 14,877,332 |
| Cashless exercise of warrants | 3,857,439,000 | 771,488 | — | — | — | — | — |
| Settlement of accrued expenses | 220,935,000 | 44,187 | — | — | 193,537 | — | 193,537 |
| Reclassification of warrant liability upon issuance of Exchange warrant | | | | | 296,362 | | 296,362 |
| Deemed dividend on warrant modification | — | — | — | — | 65,266 | (65,266) | — |
| **Balance at December 31, 2022** | 24,233,024,799 | 4,846,605 | $ — | $ (2,932,000) | $ 47,855,521 | $ (37,516,747) | $ 7,406,774 |

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

**QUOIN PHARMACEUTICALS LTD.**

**Consolidated Statements of Cash Flows**

| | Years Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cash flows used in operating activities | | |
| Net loss | $ (9,381,496) | $ (21,462,588) |
| Fair value adjustment to convertible notes payable | — | 1,250,000 |
| Change in fair value of warrant liability | (77,237) | 12,784,329 |
| Stock based compensation | 764,007 | — |
| Forgiveness of trade payable | (416,000) | — |
| Financing expense | — | 275,000 |
| Amortization of intangibles | 104,043 | 104,043 |
| Increase in accrued interest and financing expense | 714,081 | 696,799 |
| Unrealized gain on investments | (93,779) | — |
| Changes in assets and liabilities: | | |
| Increase (decrease) in accounts payable and accrued expenses | (217,806) | 1,347,801 |
| Decrease in prepaid expenses & other assets | 123,455 | (715,474) |
| Net cash used in operating activities | $ (8,480,732) | $ (5,720,090) |
| | | |
| Cash flows used in investing activities | | |
| Purchase of investments | (9,899,121) | — |
| Payment for license acquisition | (250,000) | (625,000) |
| Net cash used in investing activities | $ (10,149,121) | $ (625,000) |
| | | |
| Cash flows provided by financing activities: | | |
| Payments of offering costs | — | 141,338 |
| Payments of deferred loan costs | 42,045 | (50,000) |
| Increase in due to officers | — | 139,285 |
| Payment of amounts due to officers | (599,999) | (304,466) |
| Proceeds from issuance of “Bridge Notes”, net | — | 3,475,000 |
| Payment of interest on “Bridge Notes” | (311,670) | — |
| Proceeds from sale of equity securities, net | 14,877,332 | 10,102,874 |
| Net cash provided by financing activities | $ 14,007,708 | $ 13,504,031 |
| | | |
| Net change in cash | (4,622,145) | 7,158,941 |
| Cash - beginning of year | 7,482,773 | 323,832 |
| Cash - end of year | $ 2,860,628 | $ 7,482,773 |
| | | |
| Supplemental information - Non cash items: | | |
| Interest paid | $ — | $ 393,611 |
| Exchange of “2020 Notes” for Ordinary shares | $ — | $ 1,213,313 |
| Exchange of “Bridge Notes” for Ordinary shares | $ — | $ 5,000,000 |
| Reclassification of warrant liability to equity upon issuance of “Exchange warrants” | $ 296,362 | $ 12,410,730 |
| Deemed dividend on warrant modification | $ 65,266 | $ — |
| Offering expenses associated with warrant modification | $ 491,601 | $ — |
| Settlement of accrued expenses | $ 193,537 | $ — |

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

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## NOTE 1 – ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

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."). On October 28, 2021, Cellect completed the business combination with Quoin Inc., in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021 (the "Merger Agreement"), by and among 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."Because Quoin Inc. was the accounting acquirer, its historical financial statements became the Company's historical financial statements and such assets and liabilities continued to be recorded at their historical carrying values. The impact of the recapitalization has been retroactively applied to all periods presented.

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

Quoin Inc. was incorporated in Delaware on March 5, 2018. Quoin Inc. is clinical stage specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently no approved treatments or cures. The Company's initial focus is on the development of products, using proprietary owned and in-licensed drug delivery technologies, that could help address rare skin diseases. The Company's first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary in-licensed Invisicare® technology, is under development as a potential treatment for Netherton Syndrome ("NS"), a rare hereditary genetic disease. QRX003 is currently being tested in two clinical studies in the United States ("U.S.") under an open Investigational New Drug ("IND") application with the Food and Drug Administration ("FDA"). Dosing of patients has commenced for the first study, and the Company is preparing to commence enrollment into the second clinical study. The Company is also developing QRX004 as a potential treatment for Recessive Dystrophic Epidermolysis Bullosa ("RDEB"). In addition, the Company has entered into Research Agreements with the Queensland University of Technology ("QUT"), which include an option for global licenses to QRX007 for the potential treatment of NS and QRX008 for the potential treatment of scleroderma. To date, no products have been commercialized and revenue has not been generated.

## NOTE 2 - LIQUIDITY RISKS AND OTHER UNCERTAINTIES

The Company has incurred net losses every year since inception and has an accumulated deficit of approximately $37.5 million at December 31, 2022. The Company has historically funded its operations through debt and equity financings. On August 9, 2022, the Company completed an offering (the "August Offering") of ordinary shares represented by ADSs and pre-funded warrants to purchase ordinary shares represented by ADSs with each ADS and pre-funded warrant accompanied by an ordinary warrant, for aggregate gross proceeds of $16.8 million, resulting in net proceeds of approximately $14.9 million (see Note 14). On February 24, 2023, the Company completed an offering (the "February Offering") of ordinary shares represented by ADSs and pre-funded warrants to purchase ordinary shares represented by ADSs with each ADS and pre-funded warrant accompanied by an ordinary warrant, for aggregate gross proceeds of $7.0 million, resulting in net proceeds of approximately $6.0 million (See Note 18). As a result of the completion of such Offerings, the Company believes that it has sufficient cash and liquidity to effect its business plan for at least one year from the issuance of these consolidated financial statements.

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

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**Other risks and uncertainties:**

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

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

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

The Company is also dependent on several third party suppliers, in some cases a single-source supplier which includes the supplier of the active pharmaceutical ingredient (API), as well as the contract manufacturer of the drug substance for the expected clinical development.

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

*Nasdaq Listing*

On April 22, 2022, the Company received a letter from the Listing Qualifications staff (the "Staff") of The Nasdaq Stock Market, LLC ("Nasdaq") notifying the Company that it is no longer in compliance with Nasdaq Listing Rule 5550(b)(1) requiring minimum stockholders' equity of at least $2.5 million for continued listing on The Nasdaq Capital Market. Based on the Company's Form 6-K, dated August 10, 2022, the Staff has determined that the Company complies with the minimum stockholder's equity requirement, and the Company evidenced continued compliance for the year ended December 31, 2022.

On June 10, 2022, the Company received a letter from the Staff notifying the Company that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that the Company did not meet the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2). On August 15, 2022, the Staff determined that the closing bid price of the Company's ADSs was at $1.00 per ADS or greater for the preceding 10 business days, and the Company regained compliance with the minimum bid price requirement.

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

**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation:**

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"), which have been consistently applied, reflecting the operations of Quoin Inc. since inception and include the accounts of Quoin Ltd. since the date of the Merger. All intercompany accounts and transactions have been eliminated in consolidation.

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**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, fair value of debt instruments, stock-based compensation and warrants, research and development expense recognition, intangible asset estimated useful lives and impairment assessments, allowances of deferred tax assets, contingency recognition, and cash flow assumptions regarding going concern considerations.

**Reclassification:**

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

**Cash and cash equivalents:**

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

**Warrants:**

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

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

**Investments:**

Investments as of December 31, 2022 consist of U.S. Treasury Bills, which are classified as trading securities, totaling $9.9 million. The Company determines the appropriate balance sheet classification of its investments at the time of purchase and evaluates the classification at each balance sheet date. All of the Company's U.S. Treasury Bills held on December 31, 2022 matured within the subsequent one month from the balance sheet date. As of December 31, 2022, the carrying value of the Company's U.S. Treasury Bills approximates their fair value due to their short-term maturities.

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**Long-lived assets:**

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

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

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

The Company recognizes impairment when the sum of the expected undiscounted future cash flows is less than the carrying amount of the asset. Impairment losses, if any, are measured as the excess of the carrying amount of the asset over its estimated fair value. During the years ended December 31, 2022 and 2021, there were no impairment indicators which required an impairment loss measurement.

**Research and development:**

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

**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, 2022 and 2021, 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

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value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

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

**Fair value of financial instruments:**

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

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

**Earnings (loss) per share:**

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

For the year ended December 31, 2022, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 3,368,820 ADS or 16,844,100,000 Ordinary Shares and 307,142 in outstanding stock options as their inclusion in the denominator would be anti-dilutive.

For the year ended December 31, 2021, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 143,028 ADS or 715,140,000 Ordinary Shares and warrants to purchase 1,257,723 ADS or 6,288,615,000 Ordinary Shares issuable pursuant to Primary Financing as their inclusion in the denominator would be anti-dilutive.

**NOTE 4 – CONVERTIBLE NOTES PAYABLE**

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

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

The Noteholder Warrants have been determined to have equity classification. The change in the fair value of the warrants through the exchange date was included in other income (expense) in the accompanying statement of operations, and then reclassified from liability

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to additional paid in capital. On July 14, 2022, as a result of the Altium Agreement (see Note 5), the exercise price of the Noteholder Warrants was reduced to $0 and the 2020 Noteholders subsequently exercised all of their warrants. The change in the exercise price of the Noteholder Warrants resulted in a deemed dividend of approximately $65,000 recorded during the year ended December 31, 2022.

The ADSs issued to the 2020 Noteholders did not include the accrued interest which was estimated to be approximately $744,000 at December 31, 2021 of which $312,000 was paid to two of the five 2020 Noteholders during the year ended December 31, 2022. Based on the terms of the cash settlement with these two 2020 Noteholders, the Company's estimate of the liability to the remaining three 2020 Noteholders was increased to $1,146,000.

Interest expense, at the stated interest rate, recognized in the year ended December 31, 2022 and 2021 was approximately $-0- and $202,000, respectively.

**NOTE 5 – BRIDGE FINANCING AND SECURITIES PURCHASE AGREEMENT (Primary Financing)**

Bridge Financing

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

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

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

The Bridge Notes were offset against the purchase price under the Securities Purchase Agreement related to the Primary Financing and converted into 100,618 ADSs upon the closing of the Primary Financing in October 2021. Interest expense, at the stated interest rate, recognized in the year ended December 31, 2022 and 2021 was $-0- and $394,000, respectively.

Bridge Warrants

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

Following the closing date of the Merger, on each of the tenth trading day, the forty-fifth day, the ninetieth day, and the one hundred thirty-fifth day thereafter (each, a "Reset Date"), if the initial exercise price of the Bridge Warrants is greater than the arithmetic average of 85% of the three lowest weighted average prices of the post-Merger ordinary shares of the combined company during the ten trading day period immediately preceding the applicable Reset Date (the "Reset Price"), the exercise price of the Bridge Warrants will be reset to the Reset Price. Upon the occurrence of a Fundamental transaction, as defined in the Bridge Warrants, the warrant holder has the right to elect a cash settlement for the value of the warrant based on the Black Scholes options pricing model.

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The Company determined that the warrants met the criteria to be recorded as a liability instrument through the exchange date on the closing of the Primary Financing. The fair value for the total issuances of these warrants was determined by a MonteCarlo simulation model to be approximately $3.8 million at the date of issuance.

Upon the closing of the Primary Financing in October 2021, the Bridge Warrants were exchanged for warrants to purchase 99,074 ADSs at a fixed per share exercise price of $49.75 ("Investor Exchange Warrants"), as amended, which replaced the reset provisions and modified the fundamental transaction requirements of the Bridge Warrants. On July 14, 2022, the Company and the Investor entered into an agreement amending the terms of the Investor Exchange Warrants, see below agreements with Altium Growth Fund, LP and Warrant Exercises.

Primary Financing

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

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

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

Agreements with Altium Growth Fund, LP and Warrant Exercises

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

The exercise price of the Noteholder Warrants was also reduced to $0.00 as of July 14, 2022 as a result of the Altium Agreement. The change in the exercise price of the Noteholder Warrants resulted in a deemed dividend of approximately $65,000 recorded during the year ended December 31, 2022. From July to September 2022, the 2020 Noteholders exercised all their warrants to purchase ADSs at $0.00 per ADS exercise price, and the Company issued a total of 29,388 ADSs to such noteholders.

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**NOTE 6 - FAIR VALUE OF FINANCIAL INSTRUMENTS**

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

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

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

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

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

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

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis by fair value hierarchy at December 31, 2022 and 2021:

| December 31, 2022 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| US Treasury Bills | $ 9,992,900 | $ — | $ — | $ 9,992,900 |
| Total US Treasury Bills Asset | $ 9,992,900 | $ — | $ — | $ 9,992,900 |

| December 31, 2021 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| 2020 Notes warrants | $ — | $ — | $ 373,599 | $ 373,599 |
| Total Warrant Liability | $ — | — | $ 373,599 | $ 373,599 |

The following shows the movement of the warrant liability balance during the year ended December 31, 2022 and 2021.

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

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

**NOTE 7 – STOCK BASED COMPENSATION**

In March 2022, the Board of Directors of the Company approved the Amended and Restated Equity Incentive Plan (the "Amended Plan") which increased the number of ordinary shares reserved for issuance under such equity incentive plan to 15% of the Company's outstanding ordinary shares on a fully-diluted basis, or 6,391,925,000 ordinary shares, represented by 1,278,385 ADSs as of December 31, 2022. Under the Amended Plan, the Company may grant options to its directors, officers, employees, consultants, advisers and service providers. The Amended Plan was approved by the shareholders at the Company's Annual General Meeting of Shareholders held on April 12, 2022.
On April 12, 2022, the Company granted options to acquire 1,535,714,000 ordinary shares, represented by 307,142 ADSs, at $17.50 per share to management, directors and employees and 971,243 shares remained available for issuance as of December 31, 2022. Such options vest over a three or four year period. There were no further grants during the year ended December 31, 2022.

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

| | ADS Underlying Options | | Weighted Average Exercise Price | Weighted Average Contractual Terms |
|---|---|---|---|---|
| Outstanding at December 31, 2021 | 5,744 | $ | 636.74 | 0.33 |
| Granted | 307,142 | $ | 17.50 | |
| Forfeited/Cancelled | (5,744) | $ | 636.74 | |
| **Outstanding at December 31, 2022** | **307,142** | **$** | **17.50** | **9.28** |
| | | | | |
| Exercisable options at December 31, 2022 | — | $ | — | — |

The intrinsic value of outstanding options at December 31, 2022 was $0.

Stock options granted during the year ended December 31, 2022 were valued using the Black-Scholes option-pricing model with the following weighted average assumptions:

| | December 31, 2022 |
|---|---|
| Expected volatility | 106.0 % |
| Risk-free interest rate | 2.7 % |
| Expected dividend yield | 0.0 % |
| Expected life of options in years | 6.9 |
| Exercise Price | $ 17.50 |
| Fair value of ADS | $ 15.38 |
| Estimated fair value of option | $ 12.92 |

Stock based compensation expense was approximately $764,000 ($100,000 included in research and development expense and $664,000 included in general and administrative expenses) in the year ended December 31, 2022. There was no stock-based compensation in the year ended December 31, 2021.

At December 31, 2022, the total unrecognized compensation expense related to non-vested options was approximately $3,205,000 and is expected to be recognized over the remaining weighted average service period of approximately 3.07 years.

**QUOIN PHARMACEUTICALS LTD.**
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**NOTE 8 – PREPAID EXPENSES**

Prepaid expenses are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Prepaid R&D costs | $ 383,390 | $ 329,033 |
| Prepaid insurance | 508,084 | 684,191 |
| Prepaid expense | 8,500 | 2,250 |
| Total | $ 899,974 | $ 1,015,474 |
| Less: Short-term portion | (516,584) | (715,474) |
| Long-term portion | $ 383,390 | $ 300,000 |

**NOTE 9 – ACCRUED EXPENSES**

Accrued expenses are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Research contract expenses (note 13) | $ 105,071 | $ 193,537 |
| Payroll (note 12) | 788,169 | 557,937 |
| Payroll taxes (note 12) | 159,593 | 199,582 |
| Investor Relation firm fees (note 13) | 56,000 | 584,000 |
| Professional fees | 44,278 | 144,377 |
| Other Expenses | 22,594 | 5,976 |
| Total | **$ 1,175,705** | **$ 1,685,409** |

**NOTE 10 –IN-LICENSED TECHNOLOGY**

**Polytherapeutics:**

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

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

**Skinvisible:**

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 a 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

**QUOIN PHARMACEUTICALS LTD.**
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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.

**NOTE 11 - INTANGIBLE ASSETS**

Intangible assets are as follows:

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Acquired technology – Polytherapeutics | $ 40,433 | $ 40,433 |
| Technology license – Skinvisible | 1,000,000 | 1,000,000 |
| Total cost | 1,040,433 | 1,040,433 |
| Accumulated amortization | (335,872) | (231,829) |
| **Net book value** | **$ 704,561** | **$ 808,604** |

The Company recorded amortization expense of approximately $104,000 and $104,000 in the years ended December 31, 2022 and 2021, respectively. The annual amortization expense expected to be recorded for existing intangible assets for the years 2023 through 2026, and thereafter, is approximately $104,000, $104,000, $104,000, 104,000 and $288,000, respectively.

**NOTE 12 – RELATED PARTY TRANSACTIONS**

**Employment Agreements and Due to Officers/Founders:**

Due to the limited funding of Quoin Inc. prior to the consummation of the Merger, the compensation, including salary, office and car allowances and other benefits, due to Dr. Myers and Ms. Carter under their respective employment agreements, as well as reimbursement of expenses and other amounts paid by Dr. Myers and Ms. Carter to third parties on behalf of Quoin Inc., were not paid by Quoin Inc. to Dr. Myers and Ms. Carter, and were accrued as indebtedness to Dr. Myers and Ms. Carter. Following the closing of the Merger, Quoin Inc. began making payments of $25,000 per month to each of Dr. Myers and Ms. Carter to repay the above-described non-interest-bearing indebtedness. The Company repaid $300,000 and $125,000 of such indebtedness to Dr. Myers and $300,000 and $160,000 to Ms. Carter in the year ending December 31, 2022 and 2021, respectively. As of December 31, 2022, approximately $2,259,000 and $1,865,000 of such indebtedness was outstanding to Dr. Myers and Ms. Carter, respectively.

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

| | December 31, 2022 | December 31, 2021 |
|---|---|---|
| Salaries and other compensation | $ 4,108,500 | $ 4,108,500 |
| Invoices paid on behalf of the Company | 15,232 | 615,232 |
| Total | $ 4,123,732 | $ 4,723,732 |
| Less: Short-term portion | (600,000) | (600,000) |
| Long-term portion | $ 3,523,733 | $ 4,123,732 |

**Expenses:**

In 2021, the Company paid $100,000 of consulting expenses to a company controlled by Dennis Langer, our director, and approximately $48,000 and $8,000 were paid during the years ended December 31, 2022 and 2021, respectively, to Dr. Myers' son, who has been consulting for the Company on research and development matters from time to time.

**QUOIN PHARMACEUTICALS LTD.**
**Notes to Consolidated Financial Statements**
**December 31, 2022 and 2021**

## NOTE 13 – RESEARCH, CONSULTING AGREEMENTS AND COMMITMENTS

**Research and consulting agreement**

Quoin Inc. entered into a research and consulting agreement (the "Research Agreement") which commits it to pay the former owner of Polytherapeutics (the "Consultant" or "Seller") to transfer the technical know-how of Polytherapeutics with respect to (i) good manufacturing practices ("GMP"), clinical and commercial manufacturing of the Company's PolyDur polymer and (ii) formulation development of products utilizing the Company's PharmaDur polymer (See Note 10). The agreement required monthly consulting payments of $20,833 beginning on July 31, 2018 and ending February 28, 2021 (the "Post-Closing Period") for a total of $666,667 over the consulting period. Pursuant to an amendment, the Post-Closing Period was revised to terminate on December 31, 2020.

Through December 31, 2022 and the financial statement issuance date, the Company has not made any payments, the Consultant has not performed any services and the Company has not incurred or accrued for any expenses. See Note 16 for Consultant's notification of breach of contract.

**Other research consulting agreements**

Quoin Inc. entered into three consulting agreements with Axella Research LLC ("Axella") to provide regulatory and pre- clinical/clinical services to the Company with respect to QRX003 and QRX004. The combined fees of the three agreements are approximately $270,000, payable as milestones were met. The Company incurred accrued expenses of approximately $194,000 in relation to Axella consulting agreements as of December 31, 2021. In August 2022, the Company issued 44,187 ADSs to one of Axella's principals to settle the outstanding liability in full. To date the Company has incurred no research and development expenses in connection with these agreements, as no services have been provided.

In November 2020, Quoin Inc. entered into a Master Service Agreement for an initial term of three years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. A work order was entered into in June 2022 for the first QRX003 clinical study at an expected estimated cost of approximately $4.4 million through 2024. A further work order was entered into in December 2022 for the second QRX003 clinical study at an expected estimated cost of approximately $830,000 through 2024. For the years ended December 31, 2022 and 2021, the Company incurred a research and development expense under these agreements of approximately $1.2 million and $340,000 respectively.

In November 2021, the Company entered into a commitment with Queensland University of Technology for research related services associated with Netherton Syndrome of approximately $250,000 for an expected period of eighteen months. For the years ended December 31, 2022 and 2021, the Company incurred research and development costs related to this agreement of approximately $77,000 and $25,000, respectively.

In May 2022, the Company entered into a commitment with Queensland University of Technology for research related services associated with Scleroderma of approximately $610,000 for an expected period of eighteen months. The Company incurred research and development expenses of approximately $276,000 for the year ended December 31, 2022.

**Consulting agreement:**

Quoin Inc. entered into a consulting agreement with an Investor Relations (IR) firm, which provides for a monthly fee of $14,000. The agreement had an automatic annual renewal clause and has been in effect since November 2017. The Company owed the IR firm $584,000 as of December 31, 2021, which was included in accrued expenses in the accompanying balance sheet. In March 2022, the Company entered into a settlement agreement with the IR firm reducing the liability to $168,000 and recognized $416,000 as other income in the accompanying consolidated statement of operations. For the years ended December 31, 2022 and 2021, the Company incurred expenses of $112,000 and $70,000, respectively.

**QUOIN PHARMACEUTICALS LTD.**
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**Performance milestones and Royalties**

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

**Merger agreement commitment**

In consideration for the Share Transfer disclosed in Note 1, the pre-closing Cellect shareholders received a contingent value right ("CVR") entitling the holders to earnouts during the Payment Period (as such term is defined in the Share Transfer Agreement), comprised mainly of payments upon sale, milestone payments, license fees and exit fees realized by the business spun out of Cellect prior to the Merger.

Cellect entered into a CVR Agreement with Mr. Eyal Leibovitz, in the capacity of Representative for the holders of CVRs, and Computershare Trust Company, N.A., a federally chartered trust company (the "Rights Agent"). Under the terms of the CVR Agreement, the holders of the Cellect ADSs immediately prior to the Merger had the right to receive, through their ownership of CVRs, their pro-rata share of the net Share Transfer consideration, making such holders of CVRs the indirect beneficiaries of the net payments under the Share Transfer. CVRs were recorded in a register administered by the Rights Agent but were not certificated.

Since the Company will not receive any net proceeds from the CVRs, there is no asset or liability recorded in the consolidated financial statements.

**NOTE 14 – SHAREHOLDERS' EQUITY AND SHARE OWNERSHIP AND RIGHTS**

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

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

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

The Bank of New York Mellon, as depositary, has registered and delivered American Depositary Shares, also referred to as ADSs. Following an ADS ratio adjustment effective August 1, 2022, each ADS represents five thousand (5,000) ordinary shares (or a right to receive five thousand (5,000) ordinary shares). Each ADS will also represent any other securities, cash or other property which may be held by the depositary. 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.

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On August 9, 2022, the Company completed an offering (the "August Offering") of 11,050,000,000 ordinary shares represented by 2,210,000 ADSs at a purchase price of $5.00 per ADS and pre-funded warrants (the "August Pre-Funded Warrants") to purchase 5,750,000,000 ordinary shares represented by 1,150,000 ADSs at a per pre-funded warrant price of $4.9999, with each ADS and August Pre-Funded Warrant accompanied by an ordinary warrant (the "August Common Warrant"), for aggregate gross proceeds of $16.8 million, resulting in net proceeds of approximately $14.9 million. Each August Common Warrant had an exercise price of $5.00 per ADS and was to expire on the fifth anniversary of the Closing Date. On the Closing Date, the holder of August Pre-Funded Warrants sold in the August Offering exercised its Pre-Funded Warrants in full. The August Common Warrant exercise price and expiration date were subsequently amended for investors who participated in both the August Offering and February Offering, see Note 18.

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

Warrants

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

| | ADSs Underlying Warrants | Weighted Average Exercise Price Per Share |
|---|---|---|
| Outstanding at December 31, 2020 | 107,894 | $ 56.92 * |
| Granted | 29,388 | 49.75 * |
| Outstanding at December 31, 2021 | 137,282 | $ 55.39 * |
| Granted | 5,385,374 | 11.21 ** |
| Terminated | (232,349) | 49.75 * |
| Exercised – Cashless and Pre Funded Warrants | (1,921,487) | — |
| Outstanding and exercisable at December 31, 2022 | 3,368,820 | $ 5.35 ** |

As of December 31, 2022, outstanding warrants expire in 2024 and 2027, and have an intrinsic value of $0.

* Note that the exercise price of certain warrants was reduced from $49.75 to $0 on July 14, 2022 and to refer to Note 5

** Note that the exercise price of certain warrants were reduced from $5.00 to $1.10 on February 24, 2023 and refer to Note 18

**QUOIN PHARMACEUTICALS LTD.**
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**NOTE 15 – INCOME TAXES**

Significant components of the Company's deferred tax assets and liabilities at December 31, 2022 and December 31, 2021 are as follows:

| (table in thousands) | 2022 | 2021 |
|---|---|---|
| Net operating losses | $ 3,334 | $ 1,945 |
| Due to Officers | — | 1,411 |
| Accrued Expenses and Other | 189 | 212 |
| R&D Credit Carryforward | 76 | 102 |
| Debt related activities | — | 375 |
| Stock Compensation | 178 | — |
| R&D Capitalization | 581 | — |
| Intangibles | 34 | — |
| ***Total gross deferred tax assets/(liabilities)*** | **$ 4,392** | **$ 4,045** |
| Less valuation allowance | (4,392) | (4,045) |
| ***Net deferred tax assets/(liabilities)*** | **$ —** | **$ —** |

The income tax benefit for the years ended December 31, 2022 and December 31, 2021 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.

| (table in thousands) | 2022 | 2021 |
|---|---|---|
| Federal Statutory Rate | $ (1,970) | $ (4,641) |
| Permanent Differences | 153 | 2,876 |
| Research and Development | (76) | (102) |
| State Income Tax | 388 | 196 |
| Change in Valuation Allowance | 347 | 1,671 |
| Deferred True Up | 1,158 | — |
| Effect of Tax Act | — | — |
| Effective Tax | $ — | $ — |

A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of the available evidence, both positive and negative, the Company determined that valuation allowances of $4,392,000 and $4,045,000 at December 31, 2022 and December 31, 2021 were necessary to reduce the deferred tax assets to the amount that will more likely than not be realized.

At December 31, 2022 and 2021, the Company had gross U.S. Federal income tax net operating loss ("NOL") carryforward of approximately $12,951,000 and $6,482,000, respectively that may be used to offset future taxable income. The NOL was generated after 2017 and can be carried forward indefinitely under the Tax Cuts and Jobs Act. The company also had gross $12,951,000 of state net operating losses that will begin to expire in 2038. At December 31, 2022, the Company had approximately $76,000 of federal Research and Development (R&D) tax credit carry-forwards. If not utilized, the federal R&D credits will begin to expire in 2042.

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.

The income tax benefit for the years ended December 31, 2022 and 2021 differed from the amounts computed by applying the US federal income tax rate of 21% primarily because of the increase in the valuation allowance and the tax impact of other permanent items, which resulted in an effective tax rate of zero for both years.

**QUOIN PHARMACEUTICALS LTD.**
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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 must now 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 $2,256,000.

**NOTE 16 - CONTINGENCIES**

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

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

**NOTE 17 – LICENSE AGREEMENTS**

During the years ended December 31 2022 and 2021 the Company entered into three and six license and supply agreements, respectively, whereby the Company will receive a royalty or other proceeds from the specified product revenues in select non-US markets from the licensor, if and when the underlying products are approved and commercialized. No royalty revenues have been received through December 31, 2022 under any of these agreements.

**QUOIN PHARMACEUTICALS LTD.**
**Notes to Consolidated Financial Statements**
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**NOTE 18 - SUBSEQUENT EVENTS**

On February 24, 2023 (the "February Closing Date"), the Company completed an offering (the "February Offering") of 24,750,000,000 ordinary shares represented by 4,950,000 ADSs at a purchase price of $1.00 per ADS and a pre-funded warrant (the "February Pre-Funded Warrant") to purchase 10,250,000,000 ordinary shares represented by 2,050,000 ADSs at a per pre-funded warrant price of $0.9999, with each ADS and February Pre-Funded Warrant accompanied by an ordinary warrant (the "February Common Warrant") for aggregate gross proceeds of $7.0 million, resulting in net proceeds of approximately $6.0 million, after deducting the placement agent's fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the subsequent exercise of the February Common Warrants. Each February Common Warrant has an exercise price of $1.00 per ADS and expires on the fifth anniversary of the February Closing Date. On the February Closing Date, the holder of the February Pre-Funded Warrant exercised its Pre-Funded Warrant in full.

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

In connection with the February Offering, the Company entered into an Amendment No. 1 to Warrant to Purchase Ordinary Shares Represented by American Depositary Shares, dated February 24, 2023 (collectively, the "Warrant Amendments"), with each of the purchasers (the "2022 Purchasers") who participated in both the August Offering and February Offering. The Warrant Amendments amended certain terms of the August Common Warrants issued to such 2022 Purchasers. Specifically, the Warrant Amendments reduced the exercise price of such warrants to $1.10 and extended the term during which those warrants could remain exercisable until February 24, 2028.

**Exhibit 14.1**

**QUOIN PHARMACEUTICALS LTD.**

**CODE OF ETHICS AND BUSINESS CONDUCT**

## I. INTRODUCTION

This Code of Ethics and Business Conduct (this "Code") contains general guidelines for conducting the business of Quoin Pharmaceuticals Ltd. and its subsidiaries (collectively, the "Company" or "Quoin") and applies to all of the Company's directors, officers and employees. We refer to all officers and other employees covered by this Code as "Company employees" or simply "employees," unless the context otherwise requires. In this Code, we refer to our principal executive officer, principal financial officer, principal accounting officer and controller, or persons performing similar functions, as our "principal financial officers." This Code, as applied to the Company's principal financial officers, shall be the Company's "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder.

This Code is designed to deter wrongdoing and to promote:

- honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the "SEC") and in other public communications made by the Company;
- compliance with applicable governmental laws, rules and regulations;
- the prompt internal reporting to an appropriate person, or persons identified in the Code, of violations of the Code; and
- accountability for adherence to the Code.

While this Code provides general guidance for appropriate conduct and avoidance of conflicts of interest, it does not supersede specific policies that are set forth in other Company policy statements. Violations of law, this Code or other Company policies or procedures can lead to disciplinary action up to and including termination of service.

**Seeking Help and Information**

Each day, you are faced with making decisions that will affect the Company's business. You are obligated to comply with the Code guidelines and should avoid even the appearance of unethical or unprofessional behavior. This Code is not intended to be a comprehensive rulebook and cannot address every situation that you may face. If you feel uncomfortable about a situation or have any doubts about whether it is consistent with the Company's ethical standards, please reach out to your immediate supervisor.

**Reporting Violations of the Code**

In addition to seeking guidance, you are expected to report any known or suspected violations of our Code, Company policies or applicable law. We have provided several channels for speaking up without fear of retaliation. Choose whichever reporting option is most comfortable for you:

- You can report a known or suspected violation to your immediate supervisor.
- You may also make a complaint by contacting the Chairman of Quoin's Audit Committee by phone (844)-722-0576 or via Web portal URL: https://www.whistleblowerservices.com/QNRX.

We will promptly and fairly review and/or investigate reports of any known or suspected violations of our Code, Company policy or applicable law in accordance with our legal and ethical obligations. We expect employees to cooperate fully and honestly in Company investigations. Some concerns may require an in-depth investigation, which could include interviews and reviews of documents. A violation of the Code or a Company policy may result in disciplinary action, up to and including termination of service, regardless of an employee's title or tenure. The Company will keep investigations confidential to the extent possible consistent with the need to conduct a thorough investigation and to resolve the concern.

**Policy Against Retaliation**

You should feel comfortable reporting perceived violations of our Code, Company policy or applicable law. It is not always easy to speak up, but doing so ensures that our Company continues to have a safe and respectful work environment. We prohibit any retaliation against anyone who, in good faith, seeks help or reports known or suspected violations. If you feel that you or any of your colleagues are being retaliated against, report it immediately. Quoin takes all allegations of retaliation seriously and will promptly and thoroughly investigate. If the Company finds that retaliation occurred, appropriate disciplinary action will be taken.

**Nothing in this Code or any other Company policy limits the ability of an employee, officer, or director to communicate with or provide information to any governmental agency or commission, including the SEC, regarding possible legal violations without disclosure to the Company, as protected under applicable whistleblower laws. The Company prohibits retaliation for any of these activities.**

**Waivers and Amendments of the Code**

Any waiver of this Code for our directors and officers, including principal financial officers, may be made only by Quoin's Board of Directors, or a designated committee of the Board of Directors, and will be disclosed to the public as required by law or the rules of the SEC and The Nasdaq Stock Market LLC. Waivers of this Code for any other employee may be made only by the Company's Chief Operating Officer. We reserve the right to amend or supplement our Code and other Company policies without prior notice.

## II. HONEST AND ETHICAL CONDUCT

The Company expects and requires ethical behavior from its directors and employees. You are expected to act in the best interests of the Company. Further, you must engage in and promote honest and ethical conduct, including handling actual or apparent conflicts of interest in an ethical manner, and act with honesty and integrity. In the best interests of the Company, you must avoid even the appearance of impropriety.

**Conflicts of Interest**

As an employee or director of the Company, you should avoid situations where a conflict of interest might occur or appear to occur. A conflict of interest occurs when our private interests or actions interfere—or appear to interfere—with the interests of the Company. We must always be transparent about outside activities and relationships. Many times, conflicts can be avoided or resolved through open and honest discussion.

Without limiting the general scope of this policy, conflicts of interest may arise when you:

- Engage in activities that compete with, or appear to compete with, the Company's interests.
- Obtain personal benefits, gifts or favors because of your position with the Company.
- Have a significant financial interest in one of the Company's vendors or competitors.
- Allow your decisions at work to be influenced, or appear to be influenced, by personal or family interests or relationships.
- Divert a business opportunity away from the Company for personal benefit.
- Engage in outside employment or service on a board of directors that interferes with your job performance or responsibilities to the Company.
- Use Company property, information or resources for personal benefit or the benefit of others.

It is not always easy to identify conflicts of interest. They can take many forms and arise in a wide variety of contexts. All actual and potential conflicts of interest must be disclosed by directors and officers, including principal financial officers, to the Audit Committee. Other employees must make their disclosure to the Chief Operating Officer. When an actual or potential conflict of interest is identified, the Chief Operating Officer, or in the case of directors and officers, including principal financial officers, the Audit Committee, in consultation with the Chief Operating Officer as appropriate, must determine whether and what mitigating controls are required.

**Corporate Opportunities**

As an employee or director of the Company, you have an obligation to advance the Company's interests when the opportunity to do so arises. If you discover or are presented with a business opportunity through the use of corporate property or information or because of your position with the Company, you should first present the business opportunity to the Company before pursuing the opportunity in your individual capacity. No employee or director may use corporate property, information or his or her position with the Company for personal gain or should compete with the Company while employed by us or while serving as a director to us. If you are a director or officer, including a principal financial officer, you should disclose to the Audit Committee the terms and conditions of the opportunity, and you may only pursue such opportunity if the Audit Committee or the Board of Directors declines to pursue such opportunity. If you are an employee (other than an officer), you should disclose to the Chief Operating Officer the terms and conditions of each business opportunity covered by this Code that you wish to pursue in order to determine whether the Company wishes to pursue the business opportunity. If the Company waives its right to pursue the business opportunity, you may pursue the business opportunity on the same terms and conditions as originally proposed and consistent with the other ethical guidelines set forth in this Code; provided that any pursuit of such business opportunity shall not interfere in any way with or otherwise interrupt your work, duties and responsibilities as an employee or director of the Company.

**Confidential Information**

Directors and employees have access to a variety of confidential information regarding the Company. Confidential information includes all non-public information that, if improperly disclosed, might be useful to competitors, or detrimental to the Company, our vendors or other third parties. Regardless of the source of confidential information or whether such information is about our Company or a third party, directors and employees must maintain the confidentiality of information entrusted to them. For reputational as well as legal reasons, it is important that directors and employees not disclose such information except in the performance of assigned duties, when the release of such information is authorized by the appropriate Company officer, or when the release of such information is legally mandated. An employee's obligation

to protect confidential information continues after he or she leaves the Company. Unauthorized disclosure of confidential information could cause competitive harm to the Company and could result in legal liability to you and the Company. Any questions or concerns regarding whether disclosure of Company information is legally mandated should be promptly referred to the Company's Chief Operating Officer. This provision is not intended to infringe on the statutory rights of employees, including but not limited to under the National Labor Relations Act.

For additional guidance, please see the Company's Insider Trading Policy.

**Protection of Corporate Assets**

Quoin depends on you to use Company assets honestly and efficiently, and to safeguard them against loss, theft, carelessness and misuse. To the extent that the Company has furnished you with equipment, you must care for that equipment and use it responsibly for Company business purposes. Company assets include items such as computers and other electronic devices, among other things. Limited personal use of Company computers and phones is acceptable provided such equipment is primarily used for business purposes and any personal use does not interfere with your ability to perform your job responsibilities or violate Company policies or applicable law. The Company reserves the right to monitor, record, disclose, audit and delete without prior notice, all usage of our network and technological equipment, to the extent permitted by local law.

Intellectual property, such as patents, copyrights, trademarks and trade secrets, are highly valuable assets and we are committed to ensuring our proprietary assets are not infringed upon or misappropriated by others. Our ongoing research and development activities, as well as our intellectual property, are confidential information and should not be disclosed to anyone outside of the Company, or to anyone internally without a legitimate business reason. This type of disclosure can seriously reduce the value of our intellectual property and potentially destroy our commercial advantage.

**Business Gifts and Entertainment**

Business gifts and entertainment are often customary courtesies in developing and maintaining strong working relationships with vendors and other providers. However, gifts and entertainment are one area where there is a significant risk for the appearance of a conflict of interest, an actual conflict of interest, or even concerns about bribery or corruption. You are expected to be transparent and exercise good judgment when giving and receiving gifts and to comply with application laws and regulations, as discussed in Section IV of this Code.

In general, you are discouraged from accepting gifts or entertainment from our vendors and other providers. Inexpensive gifts, infrequent business meals, celebratory events and entertainment, provided that they are not excessive or create an appearance of impropriety, do not violate this policy. Any gifts or entertainment in excess of $50.00 USD, whether or not reimbursed by the Company, must be reasonable and customary under the circumstances. Questions regarding whether a particular payment or gift violates this policy are to be directed to our Chief Operating Officer.

Gifts given by the Company to vendors or received from vendors should always be appropriate to the circumstances and should never be of a kind that could create an appearance of impropriety. The nature and cost of such gifts must always be accurately recorded in our books and records.

**Charitable Contributions and Political Activities**

The Company encourages our employees to become involved in community activities and charitable organizations. However, no employee may bring undue pressure on another employee to contribute to a charitable organization. The Company respects the rights of our employees to participate in the political process. Indeed, engaging in the process builds a stronger community and a better political system. However, you must at all times make clear that your views and actions are your own, and not those of the Company. Additionally, employees may not use Company time or resources to support personal political activities or use their position to coerce or pressure employees to make contributions or support a candidate or political cause.

**Fair Employment Practices**

Fair employment practices are an essential part of our business and help contribute to a culture of respect. We have a collective responsibility to foster a culture of fairness, respect, and inclusion that drives us to value and embrace differences. We prohibit any form of unlawful employee harassment or discrimination based on an individual's age, race, color, national origin, ancestry, citizenship, religion, gender, sexual orientation, gender identity, pregnancy, physical or mental disability, medical condition, requests or approved protected medical leaves, genetic information, veteran status, uniformed servicemember status, domestic violence victim status, political affiliation, or any other status protected by federal, state, or local laws.

To meet our responsibilities to employees and investors, the Company must maintain a safe and productive workplace. Violence or the threat of violence will not be tolerated, whether committed by or against a co-worker, supervisor, vendor or visitor. The unlawful use, possession, purchase, sale, distribution, or being under the influence of any illegal drug and/or the misuse of legal drugs while on Company premises or while performing services for the Company is strictly prohibited. Quoin also prohibits reporting to work or performing services under the influence of alcohol. All employees have the opportunity and responsibility to contribute to a safe work environment by using common sense rules and safe practices and by notifying management when any health or safety issues are present.

## III. ACCURACY OF FINANCIAL REPORTS AND OTHER PUBLIC COMMUNICATIONS

**Financial Reports**

As a public company we are subject to various securities laws, regulations and reporting obligations. Both federal law and our policies require the disclosure of accurate and complete information regarding the Company's business, financial condition and results of operations. The Company's financial statements are relied upon both internally and externally by individuals making business or investment decisions. Accuracy and candor are critical to the financial health of the Company. Reports and other documents the Company files or submits to the SEC as well as other public communications must contain full, fair, accurate, timely and understandable disclosure. Inaccurate, incomplete or untimely reporting will not be tolerated and can severely damage the Company and result in legal liability. All employees responsible for the preparation of the Company's public disclosures, or who provide information as part of that process, have a responsibility to assure that such disclosures and information are complete, accurate and fairly reflect the Company's assets, liabilities and material transactions engaged in by the Company.

If you become aware of inaccuracies contained in the financial statements, reports and other documents the Company filed or submitted to the SEC as well as other public communications made by the Company (collectively, "SEC Reports and Public Documents"), or material omissions from the SEC Reports and Public Documents, you should immediately report such inaccuracies or omissions to the Chairman of the Company's Audit Committee pursuant to the procedures set forth in Section I of this Code.

**Company Records**

Accurate and reliable records are crucial to our business. Our records are the basis of our earnings statements, financial reports and many other aspects of our business and guide our business decision-making and strategic planning. Company records include booking information, payroll, travel and expense reports, e-mails, accounting and financial data, measurement and performance records, electronic data files, personnel records, records relating to our intellectual property, product development and collaborations and all other records maintained in the ordinary course of our business. All Company records must be complete, accurate and reliable in all material respects. No false, artificial or misleading entries in the books and records of the Company shall be made for any reason whatsoever. No fund or asset that is not fully and properly recorded, and no accounting entries or books of account that do not truly reflect the transactions to which they relate, shall be created or maintained.

**Company Spokespersons**

As a public company, it is critical that all external communications with investment analysts, the media, and investors be consistent and accurate. Specific policies have been established regarding who may communicate information to the public. Public statements on our Company's behalf must be made only by the appropriate sources within the Company.

All media, financial analyst and investor inquiries must be referred to our Chief Financial Officer. For additional guidance, please see our Regulation FD Policy.

## IV. COMPLIANCE WITH LAWS AND REGULATIONS

Each employee and director has an obligation to comply with all laws, rules and regulations applicable to the Company's operations. These include, without limitation, laws covering bribery and kickbacks, copyrights, trademarks and trade secrets, information privacy, insider trading, illegal political contributions, antitrust prohibitions, foreign corrupt practices, offering or receiving gratuities, environmental hazards, employment discrimination or harassment, occupational health and safety, false or misleading financial information or misuse of corporate assets. You are expected to understand and comply with all laws, rules and regulations that apply to your job position. If any doubt exists about whether a course of action is lawful, you should seek advice from your supervisor or the Company's Chief Operating Officer. The Company's continued and current success largely depends upon its reputation for engaging in its business in an ethical and legal manner. Therefore, directors and employees must comply with both the letter and spirit of federal, state and local laws, rules and regulations applicable to the Company's business.

**Insider Trading**

Under federal securities laws, no director, officer or employee can trade in the Company's securities on the basis of material non-public information, nor can they "tip" material non-public information to others who use it to trade in the Company's securities. The Company's directors, officers and other employees designated by the Company are subject to additional restrictions on buying and selling Company's securities, such as pre-clearance trading authorization. For additional guidance, please see our Insider Trading Policy. All directors, officers and employees shall comply with the Company's Insider Trading Policy.

**Fair Competition**

We compete vigorously and honestly based on the quality of our products and services, and are committed to never engaging in, or supporting, unfair or illegal business practices. Most countries around the world

have competition laws (known in the U.S. as antitrust laws) designed to encourage competition in business for the benefit of consumers. While these laws vary around the world, their general purpose is to prevent a company or a group of companies from dominating or monopolizing the market, or using their market power to unreasonably restrain competition. When we interact with competitors, we must be especially vigilant to ensure our discussions comply with applicable competition laws. No employee or director may be involved, directly or indirectly, in any contracts, agreements or activities that might be construed as an attempt to violate these competition laws and regulations. Illegal business practices can include informal as well as formal agreements, and implied as well as express understandings or agreements between competitors, and can be evidenced by virtually any type of business conduct. Therefore, even in casual conversations, you must be careful not to give even the appearance of intent to violate competition laws. The consequences of a violation of competition laws are severe.

**Bribery and Corruption**

Bribery and corruption are not only against our Company values but are illegal and can expose both the employee and the Company to fines and other penalties, including imprisonment. Bribery refers to the offering, giving, soliciting or receiving of any item of value as a means of influencing the actions of an individual holding public or legal duty. We are committed to never offering or accepting bribes, kickbacks or other improper payments, whether directly or indirectly. All employees and directors, whether located in the United States or abroad, must comply with the U.S. Foreign Corrupt Practices Act (FCPA) and all other applicable anti-bribery and anti-corruption laws. Corruption refers to dishonest or illegal behavior, an inducement to do wrong by improper or unlawful means. We may not accept or offer corrupt payments directly and we may not do so through third parties (e.g., agents, representatives, and consultants). We should select such third parties carefully, as we personally and our Company may be held responsible for their actions.

Anti-bribery and anti-corruption laws require the Company and its employees to be diligent in how we operate. It is critically important we remain in compliance with all anti-corruption laws. Violating these laws can severely harm our Company's reputation as an ethical business and result in civil and criminal penalties for the Company and individuals involved.

**Environmental Protection**

The Company is committed to being an environmentally responsible corporate citizen. Each director and employee of the Company has a responsibility to protect the environment and human life and health. It is, therefore, imperative that each of us accepts responsibility for compliance with laws and regulations governing the protection of the environment. We encourage employees to minimize the impact of the Company's business operations on the environment with methods that are socially responsible and economically sound.

## V. DISCIPLINARY ACTIONS

Violations of our Code, Company policies or applicable laws have serious consequences for both the Company and the individuals involved. Failure to comply with our Code, Company policies or applicable laws can result in disciplinary action. Disciplinary actions may include, but not be limited to, suspension or termination of service, and such other action, including legal action, as the Company believes to be appropriate under the circumstances.

Adopted: March 14, 2023

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**

**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**

**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Dr. Michael Myers, certify that:

1. I have reviewed this Annual Report on Form 10-K for 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 these 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 15, 2023

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**

**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**

**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Gordon Dunn, certify that:

1. I have reviewed this Annual Report on Form 10-K for Quoin Pharmaceuticals Ltd. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us, by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Gordon Dunn
Name: Gordon Dunn
Title: Chief Financial Officer
Date: March 15, 2023

**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 of Quoin Pharmaceuticals Ltd. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Dr. Michael Myers
Name: Dr. Michael Myers
Title: Chief Executive Officer
Date: March 15, 2023

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

**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 of Quoin Pharmaceuticals Ltd. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Gordon Dunn
Name: Gordon Dunn
Title: Chief Financial Officer
Date: March 15, 2023

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

**Exhibit 99.1**

***The following description of our securities registered pursuant to the Securities Exchange Act of 1934 is a summary of the material terms of our articles of association, Israeli corporate law and such securities. This description contains all material information concerning such securities but does not purport to be complete.***

**DESCRIPTION OF ORDINARY SHARES**

**Ordinary Shares**

As of March 10, 2023, our authorized share capital consisted of 500,000,000,000 ordinary shares, no par value. As of March 10, 2023, there were 59,233,024,799 ordinary shares, no par value per share, outstanding (which excludes 2,641,693 ordinary shares held in treasury), and 11,846,532 ADSs outstanding, with each ADS representing five thousand (5,000) ordinary shares. All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. 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 Israeli Companies Law, as amended (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 a general or special 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***

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

***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 of our directors or one quarter of the directors then in office; or (2) one or more shareholders holding, in the aggregate either (a) 5% of our issued share capital and 1% of our outstanding voting rights, or (b) 5% of our outstanding voting rights.

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 forty 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 or termination of our auditors;
- appointment and dismissal of External Directors, if and to the extent any are required to be appointed;
- 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
- authorizing the Chairman of the board of directors or his relative to serve as the company's Chief Executive Officer or be vested with such authority; or authorizing the company's Chief Executive Officer or his relative to serve as the Chairman of the board of directors or be vested with such authority.

Under the Companies Law and our articles of association, notice of any annual or special shareholders meeting be provided at least 14 days prior to the meeting, and if the agenda of the meeting includes the appointment or removal of directors, the approval of office holders' compensation or transactions with office holders or interested or related parties, approval of a merger, or authorization of the Chairman of the board or his relative to serve as or be vested with authorities of the Chief Executive Officer, or of the Chief Executive Officer to serve as or be vested with authorities of the Chairman of the board, notice must be provided at least 35 days prior to the meeting.

***Quorum***

Our current articles of association provide that the quorum required for our general meetings of shareholders consists of two or more shareholders present in person, by proxy or by other voting instrument in accordance with the Companies Law and our articles of association, who hold or represent, in the aggregate, at least 25% of the total outstanding voting rights, within half an hour from the time the meeting was designated to start.

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.

Our Board approved to place the adoption of an amendment to the quorum requirements in our articles of association on the agenda of our next general meeting of shareholders, which will provide, in part, that one or more shareholders present in person or by proxy holding shares conferring an aggregate of at least thirty-three and one-third per cent (33⅓%) of the voting power of our company shall constitute a quorum at our general meeting.

***Resolutions***

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by applicable law. 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 a controlling shareholder has a personal interest, or any transaction regarding the terms of employment or other engagement of a controlling shareholder or a controlling shareholder's relative, other than certain exceptions as provided by regulatory relief - all as described in "*Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions*" *of the Annual Report on Form 10-K*, (ii) matters related to the compensation of our Chief Executive Officer, other than special circumstances under which our compensation committee can exempt such transactions from shareholder approval, as described in "*Compensation Committee*" *of the Annual Report on Form 10-K*, (iii) the adoption of a compensation policy, as described in "*Compensation Committee*" *of the Annual Report on Form 10-K*, (iv) compensation arrangements or grants that are exceptions to the guidelines under our compensation policy, and (v) authorization of our Chief Executive Officer to serve as or be vested with the authorities of the Chairman of our board of directors, or for the Chairman of our board of directors to serve as or be vested with the authorities of our Chief Executive Officer.

The Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the company and its other shareholders, must act in good faith and in a customary manner, and avoid abusing his or her power.

***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.

Under regulations enacted pursuant to the Companies Law, the above special tender offer requirements may not apply to companies whose shares are listed for trading on a foreign stock exchange if, among other things, the relevant foreign laws or the rules of the stock exchange include provisions limiting the percentage of control which may be acquired, or provide that the purchaser is required to make a tender offer to the public. However, the opinion of the Israeli Securities Authority (the "**ISA**") is that such exemption does not apply with respect to companies whose shares are listed for trading on stock exchanges in the United States,

including Nasdaq, which, in the ISA's opinion, do not provide for sufficient legal restrictions on obtaining control or an obligation to make a tender offer to the public.

*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 five thousand (5,000) ordinary shares (or a right to receive five thousand (5,000) 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.