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

FORM 6-K

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

For the month of December 2021 (No. 1)

Commission File Number 001-37846

QUOIN PHARMACEUTICALS LTD.

(Translation of registrant's name into English)

23 Hata'as Street

Kfar Saba, Israel 44425

(Address of principal executive offices)

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

Form 20-F Form 40-F

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

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

EXPLANATORY NOTE

Unaudited Interim Financial Statements as of, and for the period ended, September 30, 2021 and Related Management's Discussion and Analysis of Financial Condition and Results of Operations

On December 17, 2021, Quoin Pharmaceuticals, Inc. ("Quoin"), a wholly-owned subsidiary of Quoin Pharmaceuticals Ltd. (the "Company"), issued unaudited interim financial statements as of, and for the period ended, September 30, 2021, together with the related Quoin's Management Discussion and Analysis of Financial Condition and Results of Operations, attached hereto as Exhibits 99.1 and 99.2, respectively, and incorporated by reference herein.

Distribution Agreement

Quoin entered into a Distribution Agreement (the "Distribution Agreement") with Orpharm LLC ("Orpharm"), dated December 15, 2021. Under the terms of the Distribution Agreement, Orpharm has exclusive royalty-free rights to commercialize pharmaceutical product QRX003 (the "Product") in Russia and CIS region, upon the receipt of regulatory approvals in these territories. Under the Distribution Agreement, Quoin is obligated to supply the Product to Orpharm.

The foregoing description of the Distribution Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of such agreement, attached hereto as Exhibit 10.1 and incorporated by reference herein.

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

Exhibits

Exhibit No.	Exhibit
<u>10.1</u>	<u>Distribution Agreement with Orpharm LLC (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F).</u>
<u>99.1</u>	<u>Unaudited Interim Financial Statements as of, and for the period ended, September 30, 2021</u>
<u>99.2</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations as of, and for the period ended, September 30, 2021</u>

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 17, 2021

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

THE SYMBOL “[****]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

DATED DECEMBER 15, 2021

QUOIN PHARMACEUTICALS INC.

AND

ORPHARM LLC

DISTRIBUTION AGREEMENT

THIS DISTRIBUTION AGREEMENT (the «**Agreement**») is made December 15, 2021

BETWEEN:

- (1) **QUOIN PHARMACEUTICALS INC**, a company incorporated and registered in Delaware, having its principal office at 42127 Pleasant Forest Court, Ashburn, VA 20148 («**Quoin**»); and
- (2) **ORPHARM LLC**, a company incorporated in a company incorporated in Russia, whose principal place of business is at 141860, Moscow Region, Dmitrov, Iksha, Naberezhnaya street 10/B (the «**Distributor**»),

(each a «**Party**» and together the «**Parties**»).

BACKGROUND

- (A) QUOIN is a specialty pharmaceutical company focused on the development and sale of treatments for life threatening diseases.
- (B) QX003 will be approved by the EMA or FDA and indicated for the treatment of Netherton Syndrome
- (C) QUOIN has the exclusive right to sell PRODUCT in the Territory (as defined below) and to sub-license to Distributor the exclusive right to sell PRODUCT in the Territory.
- (D) The Distributor has considerable marketing experience in the Territory (as defined below) and wishes to act as QUOIN's distributor for the Product therein.
- (E) The Parties agree and understand that this Agreement supersedes and replaces all prior or contemporaneous negotiations, commitments, agreements (written or oral) and writings between the Parties with respect to the subject matter of this Agreement. All such other negotiations, commitments, agreements and writings will have no further force or effect, and the Parties will have no further rights, liabilities or obligations to any such other negotiation; commitment, agreement or writing thereunder.

THE PARTIES AGREE as follows:

1. **Definitions and Interpretation**

- 1.1. In this Agreement:
- 1.2. «**Affiliate**» as to a Party, means any corporation, firm, partnership or other entity which, directly or indirectly, controls, is controlled by, or is under common control with, such Party. For purposes of this definition, the terms «control,» «controlled by» and «under common control with» shall mean (i) in the case of a corporate entity, direct or indirect ownership of more than fifty percent (50%) of the securities having the right to vote for the election of directors, and (ii) in the case of a non-corporate entity, direct or indirect ownership of more than fifty percent (50%) of the equity interests with the power to direct the management and policies of such non-corporate entity; (b) status as a general partner in any partnership; or (c) any other arrangement where an entity possesses, directly or indirectly, the power to direct the management or policies of another entity, whether through ownership of voting securities, by contract or otherwise.
- 1.3. «**QUOIN-Owned Information and Materials**» means: (a) all reports, materials, information and documentation prepared by QUOIN during the Term related to the Product; and (b) QUOIN-Specific SOPs.
- 1.4. «**Distributor-Specific SOPs**» means standard operating procedures, specifications and instructions that are listed in Schedule 2 as amended from time to time in accordance with Section 5.2.
- 1.5. «**Applicable Local Law**» means the applicable provisions of any and all applicable national, regional, and local laws, treaties, statutes, rules, regulations, administrative codes, and ordinances, and any and all directives, and orders or administrative decisions of any governmental agency or authority (including Regulatory Authorities) having jurisdiction over or related to the subject matter in question, including Marketing Authorisation, Trade Control Laws, Anti-Bribery Laws and other Anti-Corruption Laws, which are applicable to the subject matter of this Agreement.
- 1.6. «**Business Day**» means any day (other than Saturday, Sunday or a public holiday in the US or Russia or non-working holiday in US or Russia) when clearing banks are physically open for business in Russia or the US
- 1.7. «**Change of Control**» means, with respect to an entity, the occurrence of one or more of the following: (a) the acquisition by any third party (or related group of third parties), whether by tender or exchange offer made directly to the stockholders, open market purchases or any other transaction or series of transactions, of 50% or more of the capital stock entitled to exercise voting rights or to elect the members of the Board of Directors or other analogous governing body of such entity; (b) a merger or consolidation in which such entity is not the surviving entity, except for a transaction in which the securities of such entity immediately prior to consummation of such merger or consolidation are converted by means of such merger or consolidation into securities representing more than fifty percent (50%) of the total combined voting power of the surviving entity; or (c) any reverse merger in which such entity is the surviving entity but in which the securities of such entity immediately prior to consummation of such reverse merger represent less than fifty percent (50%) of the total combined voting power of such entity's capital stock outstanding immediately after consummation of such merger; or (d) any sale of all or substantially all of the assets of the entity to any third party (or related group of third parties).
- 1.8. «**Commencement Date**» means the date of this Agreement.

- 1.9. «**Compassionate Supply**» means, the supply or the provision of Product on a compassionate use basis (as applicable).
- 1.10. «**Confidential Discounted Price**» means prices which are lower than the List Price as agreed under Clause 9.1.
- 1.11. «**Confidential Information**» shall have the meaning set out in Clause 23.1.
- 1.12. «**DAP**» means Delivered at Place as defined by Incoterms 2010.
- 1.13. «**Delivery**» has the meaning set out in Clause 6.1.
- 1.14. «**Distributor SOPs**» means written standard operating procedures, specifications and instructions that are created by Distributor for general applicability in connection with its distribution activities under this Agreement.
- 1.15. «**EMA**» means the European Medicines Agency.
- 1.16. «**FDA**» means US Food and Drug Administration.
- 1.17. «**\$USD**» means Dollars.
- 1.18. «**Facility**» means the warehouse in the Territory operated by the Distributor to store the Product provided that the facility is approved in writing by QUOIN as a storage location for the Product.
- 1.19. «**Force Majeure**» means acts of God or the public enemy, earthquakes, fire, flood, epidemic, strike, lockout, embargo, sanctions restrictions, blockade, civil insurrection or war, acts of terrorism, inability to procure raw materials, power or supplies, labour shortages or strife, and other conditions (other than financial difficulties) beyond the control of the affected Party which delay or prevent the rendition of such Party's performance under this Agreement.
- 1.20. «**KOL**» means Key Opinion Leader.
- 1.21. «**Marketing Authorisation**» means marketing approval of the Product by a Regulatory Authority as a treatment for Netherton Syndrome
- 1.22. «**Named Patient Supply**» means the supply of Product to Purchasers, whether paid for or free of charge, on behalf of a specific Patient or Patients in the Territory, under such procedures as may exist or be adopted by regulatory authorities in the Territory that permit use and purchase of the Product in the Territory.
- 1.23. «**Patient(s)**» means the patient for whom the Product has been prescribed.
- 1.24. «**Pricing Authority**» means the Regulatory Authority in the Territory responsible for prices registration, re-registration, control over compliance with the rules of pricing for pharmaceutical products in the established by national legislation of the Territory cases,
- 1.25. «**Privacy Laws**» means the applicable laws governing the use and disclosure of personal data and other information about Patients in the Territory including the General Data Protection Regulation 2016/679 and the Federal Law №152-FZ dd 27.07.2006 .
- 1.26. «**Product**» means any of the Products listed in Schedule 1.
- 1.27. «**Purchase Order**» means an order for the purchase of the Product in the form given by Distributor to QUOIN..
- 1.28. «**Purchaser**» means a purchaser of the Product in the Territory, including, but not limited to, health funds, other government agencies, private insurance companies, hospitals and Patients, to whom Distributor distributes Product under this Agreement whether this is Compassionate Supply or Named Patient Supply.
- 1.29. «**Purchaser Product Price**» means the price paid by Purchasers for the Product in accordance with Clause 9.1, being either the List Price or the Confidential Discounted Price, as applicable.
- 1.30. «**Regulatory Authority**» means the EMA or FDA, the applicable regulatory body for the Territory and any other applicable regulatory or government authority.
- 1.31. «**Regulatory Filing**» means a filing with the applicable regulatory body for the Territory for marketing approval of the Product.
- 1.32. «**Services**» means those services defined in clause 3.2.
- 1.33. «**SOPs**» means, collectively, the QUOIN-Specific SOPs and Distributor SOPs as listed in Schedule 2.
- 1.34. «**Specifications**» shall mean, with respect to Product, the physical specifications for the Product as set forth in the Marketing Authorisation, as updated, changed or amended from time to time.
- 1.35. «**Term**» has the meaning given to it in Clause 2.
- 1.36. «**Territory**» means Russia and CIS only.

- 1.37. «**Trade Control Laws**» means the export control laws and economic and political sanctions laws of the United States government and national laws of the Territory, including economic sanctions laws of the Territory. Such export controls include, but are not limited, to those of the U.S Export Administration Regulations (Title 15 of the U.S Code of Federal Regulations Part 730 et seq.) and the economic sanctions, rules and regulations implemented under statutory authority and/or President's executive orders and administered by the U.S Treasury Department's Office of Foreign Assets Control (Title 31 of the U.S Code of Federal Regulations Part 500 et seq.), which may restrict the export of the Product from the United States and/or their re-export from other countries.
- 1.38. «**Unfit**» means that the Product is unfit for supply or use in the Territory because it has (a) suffered damage in the course of shipment in advance of and up to Delivery; or (b) has not been maintained within the registered storage conditions (which are also applicable to the shipping conditions) and after investigation, the Product cannot be released for distribution to Purchasers.
- 1.39. In this Agreement the following interpretations shall apply:
- a) words importing the singular number shall import the plural and vice versa and words importing the masculine gender shall import the feminine and neuter and vice versa;
 - b) words such as «hereunder», «hereto», «hereof» and «herein» and other words commencing with «here» shall, unless the context clearly indicates to the contrary refer to the whole of this Agreement and not to any particular clause thereof;
 - c) the headings in this Agreement shall not affect or limit the intent, scope or interpretation of this Agreement;
 - d) reference to clauses and Schedules are references to the clauses of and schedules to this Agreement;
 - e) a reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or instrument as amended, consolidated, modified, extended or replaced in whole or in part, by any subsequent statute, enactment, order, regulation or instrument or as contained in any subsequent re-enactment thereof;
 - f) any phrase introduced by the terms «including», «include» and «in particular» or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.
 - g) in the event of any conflict, inconsistency, or ambiguity between the clauses and the schedules, the clauses shall prevail;
 - h) reference to «provision», «supply», «delivery» or similar or related terms in the context of the Services shall mean the supply of the Services;
 - i) reference to the Parties, or an Affiliate shall include such entities respective successors and permitted assigns;
 - j) subject to the Parties' agreement of change, reference to any document shall be construed as a reference to the document as at the Commencement Date. In addition, all documents referenced within this Agreement, shall be deemed included herein by reference;
 - k) reference to a month means a calendar month;
 - l) references in this Agreement to a «person» includes any individual, firm, body corporate, association or partnership, government or state or agency of a state, local authority or government body or any joint venture association or partnership (whether or not having a separate legal personality).

2. **Term**

This Agreement shall enter into effect on the Commencement Date and shall continue in force for a period of five (5) years (the «**Term**») unless terminated earlier by either Party as otherwise provided in this Agreement. The Term may be extended for an additional twelve (12) month period by written agreement of the Parties, to be reached at least thirty (30) days in advance of the expiry of the Term.

3. **Appointment and Scope of Appointment**

- 3.1. With effect from the Commencement Date and in consideration of the mutual promises and covenants entered into and other good and valuable consideration, the sufficiency and adequacy of which is hereby acknowledged, QUOIN appoints the Distributor as its exclusive distributor of the Product in the Territory for the duration of the Term.
- 3.2. Distributor shall, perform all activities necessary and required to fulfil the Compassionate Supply and Named Patient Supply orders in the Territory, which includes the import of Product into the Territory and its supply and distribution of Product from the point of Delivery of Product to Purchasers and Distributor shall:
- a) obtain all necessary licenses and permits to import, store at the Facility, wholesale and otherwise perform the Services and supply to Purchasers the Product in the Territory;
 - b) submit Purchase Orders to QUOIN;
 - c) provide such documentation, information and support to Purchasers, Regulatory Authorities and others involved in the supply processes as are necessary or useful to facilitate the Named Patient Supply or the provision of Product on a compassionate use basis;
 - d) provide QUOIN with the Purchaser Product Price for all Purchaser Orders in writing and in a format mutually agreed upon by the Parties;

e) engage with Purchasers and the Pricing Authority (as applicable) or other authorized bodies that are buyers of the Product to ensure effective reimbursement from the Pricing Authority or buyers to the Distributor with respect to the Product sold by the Distributor (however, for the avoidance of doubt, the reimbursement (or not) of the Distributor by a relevant Pricing Authority shall have no effect on the Distributor's obligation to discharge its invoices to QUOIN for the Purchaser Product Price in accordance with Clause 9.2;

- f) comply with all applicable SOPs, laws and regulations, and, with respect to documentation and information about the Product, shall only provide information that has been approved by QUOIN for use by Distributor in the Territory;
- g) not delegate all or any part of its obligations hereunder to any person without the prior written consent of QUOIN not to be unreasonably withheld;
- h) identify the relevant KOL's for the Territory and meet with and invite these KOL's to relevant national meetings;
- i) attend relevant national congresses and have a Product brand presence at these congresses;
- j) work in conjunction with QUOIN and be consistent with QUOIN' key educational messaging and Product goals. This includes, but is not limited to, the creation of educational materials to educate in those countries where Marketing Authorisation has not been granted including Product safety and efficacy, mapping of referring and potential treating physicians and institutions of note, specific and targeted disease state awareness programs, mapping or diagnostic pathway and diagnostic education. All educational materials are to be approved in writing by QUOIN. The procedure for the creation and distribution of key educational messaging and Product goals will be mutually agreed and in good faith by the parties;
- k) implement a program of pharmacovigilance for the Product in accordance with Applicable Local Law and present such program reports to both the local agencies in the Territory and QUOIN's global pharmacovigilance department as required. The procedure for the creation and implementation of pharmacovigilance program for the Product will be mutually agreed and in good faith by the parties;
- l) support clinical development activities such as supplying medical educational materials to QUOIN clinical trials where requested to do so, to be agreed between both Parties in case Distributor has the specified information (materials). In the absence of such information (materials), Distributor shall have the right to refuse to provide them; and
- m) must without delay inform QUOIN in the event of any suspected falsified or counterfeit product, diversion or theft.

3.3. The Parties acknowledge that the grant of exclusive distributorship is being made in order to expand the supply of the Product in the Territory.

3.4. The Distributor shall, only when Marketing Authorisation has been granted in the Territory, use its best endeavors to promote and increase sales of the Product in the Territory and in particular, but without limitation, shall:

- a) maintain a comprehensive supply network and employ such staff with such training and technical expertise as shall be necessary to maintain such network and to effect prompt delivery of the Product;
- b) purchase from QUOIN and offer for supply the full range of the Product, unless agreed in writing by QUOIN;
- c) avoid any act or omission which may in any way harm or interfere with the reputation or supply of the Product or the reputation of QUOIN; and
- d) cultivate and maintain good relations with Purchasers and potential Purchasers within the Territory in accordance with best commercial practice.

3.5. The Distributor shall refrain from making active sales or supply of the Product to Purchasers outside of the Territory. Rights to make active sales or supply in such territories are reserved to QUOIN and its other distributors. For these purposes, active sales or supply shall be understood to mean actively approaching or soliciting Purchasers, including the following actions:

- a) visits;
- b) direct mail, including the sending of unsolicited emails;
- c) advertising in media, on the internet or other promotions, where such advertising or promotion is specifically targeted at Purchasers outside of the Territory;
- d) online advertisements addressed to Purchasers outside of the Territory and other efforts to be found specifically by users outside of the Territory, including the use of territory-based banners on third party websites and paying a search engine or online advertisement provider to have advertisements or higher search rankings displayed specifically to users outside of the Territory;
- e) advertising or promotion in any form, or translation of the Distributor's website into a language other than English, that the Distributor would not reasonably carry out but for the likelihood that it will reach Purchasers outside of the Territory; and
- f) accepting a Purchase Order from a Purchaser outside the Territory.

3.6. Distributor shall only perform such other activities as are mutually agreed upon by the Parties in writing.

4. Nature of Relationship

4.1. During the Term if QUOIN and/or Distributor becomes aware that any person other than the Distributor is supplying Product in the Territory in violation of QUOIN' and/or Distributor rights under the Licensing Agreement («**Unauthorised Product Supply**») then QUOIN will use commercially reasonable efforts to exercise its rights to prevent such Unauthorised Product Supply

- 4.2. During the Term and for a period of one (1) year thereafter, Distributor shall not directly or indirectly, promote any competing products in the Netherthon Syndrome space
- 4.3. Except as specifically set forth in this Agreement, during the Term and for a period of one (1) year thereafter, Distributor shall not, directly or indirectly, manufacture, develop, prepare or file Regulatory Filings for, distribute, market, sell, supply or otherwise commercialize, the Product in any form (including any dosage form), including generic versions, substitutions, alternative presentations or anything comparable to the foregoing of the Product, in the Territory or outside the Territory. This restriction shall not apply in the event that QUOIN transfers its rights in the Product to a third party and that third party permits such activities to be undertaken by the Distributor. Without limiting the provisions of Clauses 23 (Confidentiality) and Clause 18 (Intellectual Property Rights) or any other provision of this Agreement, in no event shall Distributor: (a) use or disclose Confidential Information (as defined in Clause 23.1) of QUOIN to undertake any activities during the Term or after the Term to compete, directly or indirectly, against the Product in any manner or form, including, without limitation, the competitive activities set forth in Clauses 4.1 and 4.2; or (b) be granted, or be deemed to have been granted, any license or other rights to the Product that are not specifically set forth in this Agreement and shall not use any rights specifically granted to them in this Agreement to undertake any activities during the Term or after the Term to compete, directly or indirectly, against the Product in any manner or form, including, without limitation, the competitive activities set forth in Clauses 4.1 and 4.2.
- 4.4. Distributor shall not distribute, sell, supply or otherwise transfer, either directly or indirectly, any Product purchased under this Agreement or otherwise (i) outside the Territory; or (ii) other than on a Compassionate Supply or Named Patient Supply basis. Without limiting the foregoing, Distributor shall not knowingly sell, supply, distribute or otherwise transfer Product purchased under this Agreement or otherwise to a third party in the Territory who, either directly or indirectly, sells, supplies or distributes Product outside the Territory. In addition, Distributor shall not distribute, supply or sell any Product purchased under this Agreement or otherwise to any person listed as a 'Specially Designated National' by the United States Office of Foreign Assets Controls, or its successor agency (the «OFAC»).

5. Operational Aspects

- 5.1. Distributor shall perform its obligations in accordance with the terms of this Agreement and the SOPs. Distributor shall perform its obligations under this Agreement with the skill, care and diligence that would be expected of an experienced distributor in the Territory.
- 5.2. Distributor-Specific SOPs are listed in Schedule 2. Distributor shall have in place at all times all SOPs necessary to comply with all local codes and regulations operating in the Territory, including those which govern interactions with health professionals and payments of buyers and shall provide QUOIN with copies of all relevant Distributor SOPs upon request.. In the event of any conflict between Distributor's otherwise standard practices and procedures (including those set forth in a Distributor SOP) and a QUOIN-Specific SOP, the terms of the QUOIN-Specific SOPs prevail
- 5.3. Reports
- a) Distributor shall provide information and reports to QUOIN in the format provided in Schedule 3 on a monthly basis and such further information as is reasonably required in applicable SOPs within the timeframes and upon the frequency set forth in the applicable SOPs or as otherwise mutually agreed. Upon receipt of a request for a report from QUOIN that Distributor is not already providing to QUOIN, Distributor will discuss with QUOIN in good faith if it is reasonably practicable for Distributor to provide such report and the likely timeframe for its delivery. All reports provided by Distributor to QUOIN shall be in English; and
- b) Distributor shall use commercially reasonable efforts to validate that all information included in the reports that is generated by the Distributor or from its own records is accurate and complete, and all other information provided to QUOIN under this Agreement (other than information that is provided by QUOIN) is to the best of the Distributor's knowledge accurate and complete, and that translations of documents made by or on behalf of Distributor shall be complete and accurate in all material respects.
- 5.4. Distributor shall, at its expense, use a knowledgeable team of employees to supply the Product on a Named Patient Supply or Compassionate Supply basis and QUOIN shall provide them with relevant training on a basis to be discussed and agreed between the Parties prior to submission of the first Purchase Order.

6. Product Shipment and Distribution

- 6.1. QUOIN shall deliver or procure the delivery of the Product (DAP Incoterms 2010) within thirty (30) days of the order placement by Distributor to customs located at the arrival airport of the Product in the Territory i.e. Sheremetyevo-2 airport, Sheremetievskaya customs code 10005000, customs post Sheremetyevo Airport (cargo) code 10005022 i.e. the arrival date on the air-way bill (each, a «**Delivery**»). For the avoidance of doubt, the Distributor shall be responsible for import customs clearance, customs duties, taxes and any other local governmental charges, and risk of any loss or damage to the Product shall pass to the Distributor upon Delivery. Title to and risk of Product transfers to Distributor upon Delivery. Should QUOIN not receive payment of Product by Distributor within the timeframe outlined in clause 9.3, QUOIN is entitled to claim immediate return of the Product and all associated costs of same from Distributor.
- 6.2. In relation to ordering and shipment of Product from QUOIN to Distributor:
- a) Distributor shall only purchase Product from QUOIN. The Parties shall discuss near and long-term forecasts of Product supply in the Territory at the meetings with such frequency as may be required. For planning purposes only, no later than the 5th Business Day of each month, the Distributor shall provide QUOIN with a rolling twelve (12) month forecast of anticipated purchases of Product, broken out by dosage form;
- b) Distributor shall also, immediately upon receipt of the requisite purchase documentation from a Purchaser promptly submit a firm written Purchase Order to QUOIN for the amount of Product inventory that is necessary to fulfil the order from the Purchaser. Each Purchase Order shall specify the amount of Product required, by dosage form, and the requested delivery date for Product ordered which shall not be less than one (1) month from the date of the Purchase Order; provided, however, that QUOIN shall have the right to reject any Purchase Orders that do

not contain an amount and dosage type. QUOIN shall use commercially reasonable efforts to accept all Purchase Orders except for any that it rejects in writing within forty-eight (48) hours for being non-compliant with this Clause 6.2 or where a Purchase Order is one hundred and fifty percent (150%) higher than that which was provided in the twelve (12) month rolling forecast by the Distributor to QUOIN in Clause 6.2a), and having used all reasonable efforts to accept the significantly increased Purchase Order, QUOIN cannot fulfil such a Purchase Order. QUOIN shall deliver or procure Delivery of all of the Product comprised in the Purchase Orders to Distributor, as set forth in Clause 6.1, within thirty (30) days of the date of the Purchase Order. QUOIN agrees to send the Specification to Distributor within fifteen (15) Business Days from receipt of a Purchase Order. Furthermore, QUOIN agrees to send the applicable Marketing Authorisations for the Product to Distributor promptly after the Commencement Date and shall endeavor to keep Distributor informed of any changes in Marketing Authorisation including renewals etc. The terms and conditions of this Agreement shall be controlling over any inconsistent or additional terms or conditions included in any Purchase Order, supply acknowledgment, invoice or other document, which inconsistent or additional terms shall be null and void;

- c) each shipment of Product to Distributor shall contain such quality control certificates and other documentation as are necessary to show that at the time of Delivery the Product conformed to the Specifications; Furthermore, QUOIN shall inform the Distributor of shipment of the Product within two (2) Business Days before the date of shipment of Product with an indication of description, range and quantity; cost; gross weight and net weight of the Product with copies of the following documents attached to the notice and to be sent with the Product: (i) invoice; (ii) packing list; (iii) waybill; (iv) certificate of origin of the goods; and (if required) (v) export declaration/letter justifying its non-submittal, (vi) documents confirming quality of the Product and the manufacturer (manufacturer's certificate of quality). Should any further documents be required QUOIN will use commercially reasonable endeavors to provide said documents. For the avoidance of doubt, QUOIN will provide documents in the English language, if documents are required to be translated to a language that is not English, this will be the responsibility of the Distributor, at Distributors cost.
- d) QUOIN shall supply Product to Distributor on a Named Patient Supply or Compassionate Supply basis in international packs and upon Marketing Authorisation being granted shall work with Distributor at no extra cost to QUOIN and Distributor to ensure the supply of Product contains labelling and other graphics that are compliant with the Marketing Authorisation and will discuss in good faith any possible change in Delivery times required to fulfill Purchase Orders due to the creation of new packs with labelling and other graphics that are compliant with the Marketing Authorisation.
- e) The Distributor shall be responsible for carrying out a visual inspection of the Product for any failure or defect in the Product, and for the quantitative compliance with the Purchase Order. QUOIN shall be entitled to take all necessary steps to ascertain the cause of any failure or defect, including shortage. In the event that QUOIN determines the failure or defects (including shortage) are due to loss or damage occurring before the risk of loss or damage passed to the Distributor under the Agreement the Distributor shall co-operate with QUOIN in taking whatever steps are necessary to remedy the defect and the Distributor shall promptly send to QUOIN the units of the allegedly defective Product or some other evidence of deficiency as QUOIN shall specify. If it is impossible to return (re-export) a defective Product, such Product will be destroyed by the Distributor. At the same time, QUOIN undertakes to reimburse the Distributor for the costs incurred in connection with the destruction of the Product in the manner and within the time specified in the relevant Distributor's requirement.

Credit for the defective Product shall issue only if and to the extent that QUOIN, examination shall confirm the Distributor's complaints. Should Distributor disagree (which has to be in good faith and not commercially unreasonable otherwise QUOIN's examination will be final and binding), with QUOIN's complaints, the Parties will agree in good faith to appoint an independent international expert in this field to resolve any dispute. The determination of the independent expert which will be completed within thirty (30) calendar days from appointment, will be final and binding on the Parties in the absence of manifest error. The costs of the independent expert will be shared by the parties equally, QUOIN reserves the right to, subject to receipt of a certificate of destruction of the Product in question, replace or procure the replacement of such Product with conforming Product within thirty (30) days and shall procure reimbursement of the Distributor for the pre-approved costs of destruction of the Product in question in accordance with the regulatory requirements of the Territory;

- f) QUOIN reserves the right to require the Distributor to return to QUOIN all or part of the Unfit Product at QUOIN's expense or to destroy it, or otherwise to dispose of it at QUOIN's expense and pursuant to its instructions; and
- g) within ten (10) Business days from the Delivery of Product, Distributor shall advise QUOIN in writing (a «**Rejection Notice**») if a shipment of Product does not conform to the Specifications at the time of Delivery or is Unfit at the time of Delivery. If a Rejection Notice is not received by QUOIN within ten (10) Business Days from Delivery of Product, Distributor will be deemed to have accepted the Product. Acceptance of the Product does not impose on Distributor any liability for any consequence of the Product not conforming to Specifications. If Distributor delivers a Rejection Notice in respect of all or any part of a shipment of Product, then Distributor shall, within ten (10) Business Days following such Rejection Notice, provide QUOIN with all necessary information to prove that the Product in question did not conform to the Specifications at the time of delivery to Distributor. The Parties acknowledge the implications of a Rejection Notice and shall act towards each other in good faith and with full transparency in the event that a Rejection Notice is served. Rejection of Product by Distributor, whether appropriate or not, shall not impact its obligations under Clause 6.1. The remedies provided in this Clause 6.2(g) shall be Distributor's sole and exclusive remedy for the delivery by QUOIN of non-conforming Product

6.3. In relation to shipment to the Distributor:

- a) Distributor shall, at its own expense, be responsible for obtaining any necessary import (into the Territory) permits and licenses, and for paying all customs, duties and other governmental charges related to (i) the shipment and delivery of Product from the QUOIN to Distributor (other than those costs which QUOIN will incur as required under DAP Incoterms 2010) (ii) and to the importation and supply of the Product in the Territory on a Named Patient Supply or Compassionate Supply basis, such charges include but are not limited to any taxes, charges, fees or duties related to or imposed in connection with the handling, storage, processing and/or legalization of the Product and/or any documents relating to the Product (other than those costs which QUOIN will incur as required under DAP Incoterms 2010). Importation of the Product on a charitable basis (if applicable) will be mutually agreed between the parties in a separate agreement;
- b) Distributor shall, in respect of each order for the Product to be supplied hereunder, be responsible for ensuring the accuracy of the order and for providing QUOIN with any information which is necessary in order to enable QUOIN to fulfil the order;
- c) Distributor shall distribute Product on a «first expire, first out» basis and otherwise comply with all applicable SOPs in selecting Product inventory for dispensing and distribution; and

d) except as required by applicable laws, regulations or SOPs, Distributor shall not, without QUOIN' and/or QUOIN' prior written consent, alter, make any modifications or tamper with Product packaging or trademarks used on or in relation to the Product (except to remove Product from the shipping containers) or alter, make any modifications or tamper with Product labelling.

6.4. Distributor will at all times handle, store and distribute Product in accordance with Applicable Local Laws, regulations, SOPs, label requirements and the requirements of the Territory Regulatory Authorities, and shall, upon request by QUOIN, provide evidence of compliance with such requirements. The Product is to be maintained in accordance with labelled storage conditions.

7. Recall of Product

7.1. In the event (a) any Regulatory Authority issues a directive or order that the Product be recalled, (b) a court of competent jurisdiction orders such a recall, or (c) QUOIN communicates that the Product should be recalled for any reason, the Parties shall promptly implement a recall for such Product to the extent distributed under this Agreement in accordance with applicable SOPs and QUOIN's reasonable requirements. QUOIN shall, unless the recall has been caused by the negligence of the Distributor in its handling the Product, be responsible for all reasonable costs and expenses of recalling and destroying the Product (e.g. destruction charges (upon provision of evidence of destruction), man-hours and other costs incurred by Distributor in assisting QUOIN in arranging and coordinating a recall). QUOIN or Third-Party Designee on behalf of QUOIN as appropriate will be responsible for all returns, except as set forth in the applicable SOP, and all aspects of any recall (subject to the provision by the Distributor of requested reasonable assistance). Any recalled Product will be destroyed in accordance with Applicable Local Law requirements. QUOIN shall use reasonable commercial endeavors to replace or procure in good faith and if feasible the replacement of such recalled Product with conforming Product within thirty (30) days;

7.2. Without prejudice to any other rights QUOIN as appropriate may have against the Distributor, the Distributor shall at all times maintain adequate control procedures to permit complete recall of any of the Product, including the implementation of a traceability system which allows traceability data to be retrieved within a maximum of twenty-four (24) hours.

7.3. If QUOIN determines or becomes aware that the Product fails in any respect to meet the relevant Specifications or the standards of quality and appearance required by QUOIN or applicable law, QUOIN shall be entitled by notice to the Distributor to require the Distributor to take all necessary action to recall immediately any such Product (including any such Product sold to Purchasers of the Distributor) and cease all further supply of such Product on a Named Patient Supply or Compassionate Supply basis until QUOIN can satisfy itself that the cause of the failure has been detected and rectified. The Product must be clearly marked and kept separate from other products and must be handled and disposed of in accordance with QUOIN' instructions. Save as required by law, the Distributor shall make no announcement of any kind in respect of the withdrawal of any of the Product from the market unless requested by QUOIN.

7.4. In relation to inventory processing and monitoring:

a) Distributor will record receipt of orders from Purchasers and shipments of Product in accordance with the SOPs. Distributor will supply QUOIN with reports related to Product inventory, orders and shipment that cover the information in the format set out in Schedule 3 or required by applicable SOPs, which will include reports of all inventory under the control of Distributor. All reports provided by Distributor to QUOIN as appropriate shall be in English;

b) Distributor shall at all times segregate Product inventory from other products and Product inventory shall be clearly marked as Product inventory, along with the purpose of such inventory. Distributor shall ensure the timely delivery of Product to Purchasers upon its arrival in the Territory; and

c) During the Term, QUOIN have the right to perform, during normal business hours, upon reasonable prior notice to Distributor, physical inventory counts and inspections of Product at the Facility and, if applicable, any other facility of the Distributor where Product is stored. QUOIN is obliged to notify the Distributor about the implementation of these inspections (audit) no later than ten (10) Business Days before the intended inventory (inspection, audit). QUOIN must provide an audit program within the deadline. The procedure of inventory (inspection, audit) applies to all inventories (inspection, audit).

8. Payment

8.1. The list price for the Product (the «**List Price**») shall be notified by QUOIN to the Distributor commencing on the date of the first Purchase Order. List Price is confidential and Distributor may not disclose or change the List Price unless QUOIN provides its written consent. The Distributor shall be entitled to enter into arrangements with pricing authorities whereby it may supply such Product on a Named Patient Supply or Compassionate Supply basis for prices which are lower than the List Price subject to each such arrangement being entered into upon a strictly confidential basis and having received the prior written approval of QUOIN (the «**Confidential Discounted Price**»). The Purchaser Product Price with respect to each Purchase Order shall be either the List Price or the Confidential Discounted Price, as applicable. In the event of a change in the List Price, QUOIN must send the Distributor a corresponding notice no later than thirty (30) days before the entry into force of the new List Price.

8.2. Distributor shall purchase each unit of Product from QUOIN at the applicable Purchaser Product Price which will result in a bonus (commission payment) of [****] percent ([****]%) to the Distributor.

8.3. Distributor shall remit payment for Product to QUOIN within ninety (90) calendar days of Delivery of the Product in the Territory against an invoice issued by QUOIN via wire transfer. All amounts due under this Agreement shall be paid in USD. Payment will be deemed past due if not received by the due date.

8.4. All amounts due under this Agreement and any judgment or arbitral award under this Agreement shall be paid in USD. Any Party remitting an amount other than in USD shall be required to bear the cost of converting any payment in such alternate currency into USD or that payment remitted in an alternate currency may be rejected by the receiving Party.

- 8.5. Distributor shall invoice Purchasers for the Purchaser Product Price directly on their own behalf and shall be solely responsible for collections of accounts receivables resulting therefrom.
- 8.6. Distributor shall bear all responsibility and liability for all supply, use, excise, value-added, services, consumption, and other taxes and duties, including but not limited to any withholding taxes, associated with the purchase of Product and its supply and distribution under this Agreement (other than QUOIN' income taxes based upon or measured by income). The Parties expressly agree that all payments to QUOIN pursuant to this Agreement shall be made without any deduction, withholding, retention, or set off on account of taxes or otherwise and oblige Distributor to gross-up such payments on account of any taxes, deductions or retentions under applicable laws.
- 8.7. Except as specifically set forth in this Agreement, the Parties shall each bear their own costs in connection with the distribution of Product into and within the Territory, drafting and negotiation this Agreement, and any disputes or other matters related to this Agreement, in addition, without limiting the foregoing, Distributor shall bear its own costs and expenses in coordinating and performing its activities under this Agreement.
- 8.8. For purposes of Distributors bank and currency exchange laws of the Territory only, the total value of the Agreement will be determined by the total number of invoices or other documents, which confirm the Delivery of Product (including but not limited invoices and other applicable pricing documents).
- 8.9. QUOIN Bank Details are as follows:

[****]

9. Reporting and Records

- 9.1. Distributor shall submit to all reasonable inquiries and inspections by relevant Regulatory Authorities that relate to the Product or this Agreement. Distributor shall promptly inform QUOIN and Third-Party Designee on behalf of QUOIN of all inspections or audits of Distributor to be conducted by any relevant Regulatory Authority if such inspections are directly related to the Product or this Agreement. Distributor will (a) provide QUOIN with copies of all documents, reports or communications received from or given to any Regulatory Authority associated therewith, translated into English if necessary; (b) permit QUOIN' representatives to be present on site and participate, as appropriate, based on questions or requests specific to QUOIN or the Product, and as permitted by Regulatory Authority, in such inspections and participate in the wrap-up sessions; and (c) allow QUOIN the opportunity and sufficient time (at least five (5) Business Days where possible) to review and provide comments to Distributor on communications with Regulatory Authorities, drafts of which shall be provided to QUOIN with an English translation, with respect to matters related to QUOIN or the Product, and Distributor and its Affiliates will, to the extent consistent with applicable laws and regulations, revise any such correspondence to the Regulatory Authority taking into account QUOIN' comments to the extent such are reasonable and given timely. Each Party will be responsible for its own costs in complying with the terms of this Clause 10.
- 9.2. Distributor shall notify QUOIN and Third-Party Designee on behalf of QUOIN immediately (and in no event later than two (2) Business Days) after Distributor receives any contact or communication from any Regulatory Authority related to the Product. Distributor, without being required to place itself in breach of obligations of confidentiality or applicable laws or regulations, shall provide QUOIN with copies of any such correspondence or other communication (or relevant sections thereof if the correspondence or communication relates to the Product or Services not covered by this Agreement), translated into English if necessary, within two (2) Business Days of receipt of such communication by Distributor. Distributor will consult with QUOIN regarding the response to any inquiry or observation from any Regulatory Authority relating to the Product, and shall, if permitted by applicable laws and regulations, and if not prejudicial to its own relationship with the Regulatory Authority, allow QUOIN, at its discretion, to participate in any further contacts or communications relating to the Product subject to any deadlines imposed by the Regulatory Authority. Distributor will comply with all reasonable requests and comments by QUOIN and Third-Party Designee on behalf of QUOIN with respect to all contacts and communications with any Regulatory Authority relating to the Product. Distributor will provide QUOIN with drafts, with an English translation, of any correspondence or other reports to be submitted to any Regulatory Authority concerning the Product for review prior to submission, will consider in good faith QUOIN' and/or comments that are given on a timely basis, and will provide final copies to QUOIN promptly after submission.
- 9.3. Distributor shall maintain customary books and records with respect to the Product provided pursuant to this Agreement, and shall retain such books and records for a period of five (5) years after termination or expiration of this Agreement or longer if required by applicable laws or regulations. QUOIN retains the right to inspect these books and records throughout this period.
- 9.4. Upon reasonable advance notice to Distributor, Distributor shall permit employees and/or representatives of QUOIN, to enter the Facility and conduct a reasonable inspection of the property, processes, procedures and records related to the Product during normal business hours in order to determine whether Distributor is complying with the terms of this Agreement, including, without limitation, Clause 18.4 and Clause 13. Each Party shall pay its own costs associated with the activities contemplated by this Clause 10.4.
- 9.5. Notwithstanding anything in this Agreement to the contrary, Distributor shall use commercially reasonable efforts to remedy any deficiencies or breaches that are noted by QUOIN employees or representatives or Third-Party Designee on behalf of QUOIN a Regulatory Authority during any inspection or audit. Audits or inspections that are conducted as a result of a prior deficiency or breach noted by the employees or representatives of QUOIN or may be conducted at such frequency as is reasonable to confirm that the deficiency or breach, as the case may be, has been cured in a sustained manner. QUOIN acknowledges and covenants that any person conducting any such inspection (other than an employee or agent of a Regulatory Authority) shall fully comply with the confidentiality obligations of this Agreement, and shall at all times comply with health, safety and other requirements that are posted at the applicable site and other reasonable written policies of Distributor of which QUOIN' employees or representatives or are made aware, to the extent consistent with applicable laws and regulations.

10. Data Exchange Agreement

- 10.1. The Parties agree to enter into a safety data exchange agreement prior to the first distribution of Product into the Territory («**Safety Data Exchange Agreement**»). The Safety Data Exchange Agreement shall address the issues typically and customarily covered by such agreements.

11. Compliance

- 11.1. The Distributor shall pay for and maintain in force all licences, consents, permits and approvals of all Regulatory Authorities whatsoever which are or may be necessary or advisable in connection with the carrying out by the Distributor of any of its obligations pursuant to this Agreement.
- 11.2. The Distributor shall comply with all applicable laws and regulations relating to the transportation, distribution, storage, marketing, offer for supply and supply of the Product on a Named Patient Supply or Compassionate Supply basis and the Distributor shall notify QUOIN of any changes or proposed changes that are made or proposed from time to time in such laws relating to the nature or method of manufacture, packaging or labelling of the Product as soon as reasonably practicable after the change or proposed change comes to the attention of the Distributor.
- 11.3. The Distributor shall comply with any specific storage and/or distribution requirements relating to the Product notified to the Distributor by QUOIN and the Distributor agrees that QUOIN (at its discretion) may audit the Distributor's premises for compliance with the obligations imposed under this Clause 12.
- 11.4. The Distributor will conduct its business with integrity. The Distributor shall not give any payments, services, gifts, entertainment, bribes or other advantages to any supplier employee or third party which are intended to influence the way in which QUOIN employee, or third party goes about his or her duties. The Distributor shall not engage in actual or attempted money laundering and agrees that it will comply with all applicable laws for the prevention of fraud, corruption, racketeering or terrorism (collectively, «**Anti-Corruption Laws**»). When requested to do so by QUOIN, the Distributor shall confirm in writing its compliance with this Clause 12, and agrees to immediately notify QUOIN in writing if it has discovered any act or omission which may constitute a breach by the Distributor of this Clause 12.

12. Additional Obligations, Representations and Warranties

- 12.1. Each Party represents and warrants, and covenants to the other Party that during the Term it is, and will at all times be, in compliance with all applicable laws, regulations and industry codes applicable to its business, the distribution of the Product into and within the Territory and the Services, including, without limitation, applicable anti-bribery laws including the U.S. Foreign Corrupt Practices Act, as amended (collectively the «**Anti-Bribery Laws**»), laws and regulations regulating the payments to health care professionals, prohibiting the submission of false information to Regulatory Authorities, the Pricing Authority and other government agencies, Privacy Laws, and laws and regulations on restraint of trade and competition, and U.S. anti-boycott and export control laws. Each Party shall take all action necessary and required actions to comply with all such laws, regulations and industry codes. To the extent QUOIN has disclosed to Distributor on or before the Commencement Date specific written policies to assure compliance with respect to Anti-Bribery Laws, export laws or any other applicable laws, Distributor shall comply with such QUOIN policies.
- 12.2. In addition, notwithstanding any other provision of the Agreement, neither Party be required to take, or to refrain from taking, any action where to do so would be inconsistent with or penalized under the laws of England and Wales or the Territory or any applicable foreign jurisdiction and in particular QUOIN shall not be required to act in any way that is prohibited by Trade Control Laws.
- 12.3. In addition, notwithstanding any other provision of this Agreement, QUOIN or Third-Party Designee on behalf of QUOIN shall not be required to take, or to refrain from taking, any action where to do so would be inconsistent with or penalized under the laws of England and Wales or any applicable foreign jurisdiction.
- 12.4. Each Party covenants and agrees that, as requested by the other Party and on a periodic basis, it shall certify in writing to the other Party that it is in full compliance with Clause 13.1 and has not committed any violations of the laws, regulations or codes set forth in Clause 13.1. Distributor shall also complete any surveys, and respond to information requests, made by QUOIN or Third-Party Designee on behalf of QUOIN in connection with the foregoing certification and shall require its Affiliates to do the same.
- 12.5. Each Party represents, warrants and covenants with the other Party that it, nor any of its affiliates are, and during the Term shall not be: (a) listed on any restricted parties list maintained by the OFAC, the U.S. Department of Commerce, or its successor agency, or other similar lists maintained by any agency or Regulatory Authority within the United States Government; or (b) located in or acting on behalf of governments or countries who are on OFAC's sanctioned countries list. In the event a Party or any of its Affiliates becomes listed on the lists set forth in (a) or (b) of this subsection, the Party shall immediately notify the other Party in writing.
- 12.6. Without limiting any of QUOIN' other termination rights in this Agreement or its ability to pursue other rights and remedies against Distributor or any of its Affiliates, any breach of clause 13.1 shall be considered a material breach of this Agreement and entitle QUOIN to terminate this Agreement under clause 20.3a) without the requirement to provide Distributor with the cure period set forth therein.
- 12.7. All of Distributor, its Affiliates' and/or Subcontractors' employees and agents who perform the Services shall be qualified to perform such Services, and have all professional licenses, permits, certificates and registrations required for their performance of the Services.
- 12.8. Distributor shall be responsible for the health and safety of the employees and agents of Distributor, its Affiliates and/or Subcontractors who perform the Services. Distributor, its Affiliates and/or Subcontractors shall comply with all applicable laws, rules and regulations relating to employee and Facility health and safety. Distributor, its Affiliates and/or Subcontractors shall ensure that its employees and agents at the Facilities comply with all SOPs related to safety, security, entrances, parking areas, sanitation, and other provisions for maintenance of good order.

- 12.9. Distributor represents that it now has and will maintain in full force and effect, all applicable licenses, permits and approvals required by Distributor and its Affiliates to fulfil its obligations under this Agreement.
- 12.10. Distributor represents that it has a backup and disaster recovery plan to back up all transactions, records and data related to the Services in the event of a system malfunction or in the event of a natural disaster, including Force Majeure events. Distributor shall provide QUOIN with written notice of the start and stop of any Services as a result of system malfunctions and its nature and expected duration promptly following its occurrence. In the event of a system malfunction, Distributor will continue to perform its other obligations under this Agreement and will use commercially reasonable efforts to resume performance of all its obligations under this Agreement as soon as reasonably practicable.
- 12.11. Distributor, its Affiliates and/or Subcontractors shall comply with all safety and security (including information technology) SOPs, laws and regulations that apply to the Facility and the Services. Distributor will notify QUOIN in writing of any breaches of such procedures, standards, SOPs, laws or regulations that impact the Product or the Services.
- 12.12. Distributor, its Affiliates and/or Subcontractors shall comply with all applicable quality control SOPs and all laws and regulations that apply to the Facility, the Product and the Services
- 12.13. In distributing the Product in the Territory and performing the Services, Distributor, its Affiliates and/or Subcontractors will access and collect information from Purchasers and Patients. Distributor and its Affiliates and Subcontractors shall comply with all Privacy Laws related to such information, including limitations on the use and disclosure of personally-identifiable Patient information («**Personal Data**»). Distributor, its Affiliates and/or Subcontractors shall not use or disclose Personal Data for any purpose other than to perform its obligations under this Agreement and shall not provide Personal Data to QUOIN or its Affiliates or to any third party (a) unless permitted or required under applicable laws and regulations or (b) with the express prior written approval of QUOIN, provided in the case of clause (b), such disclosure is permitted by applicable laws and regulations, including Privacy Laws, and any required consents from the relevant Patient have been obtained.
- 12.14. Any breach this Clause 13 shall be considered a material breach of the Agreement and entitle the non-breaching Party to terminate the Agreement under Clause 20.3 without the requirement to provide the other Party with the cure period set forth therein.

13. Mutual Representations and Warranties

- 13.1. QUOIN hereby warrants that the Products shall, as at the date of Delivery, conform with the Specifications and are free of defects.
- 13.2. Each of the Parties represents and warrants to the other as follows:
- a) such Party is a corporation duly organized, validly existing and in good standing under the laws of its respective jurisdiction of incorporation;
 - b) the Agreement constitutes a valid and binding obligation of such Party enforceable in accordance with its terms;
 - c) neither the execution and delivery of the Agreement nor the consummation of the transactions contemplated hereby constitutes a violation of, default under, or conflicts with (a) any terms of the articles of incorporation, bylaws or other organizational documents of such Party or (b) any order, judgment or decree of any court or governmental body binding upon or affecting such Party; and
 - d) The persons executing this Agreement on behalf of the Parties are duly authorized to do so and by so doing are bound to the terms and conditions of this Agreement.
- 13.3. Distributor and its Affiliates and QUOIN and its Affiliates and their respective employees and agents are not prohibited, prevented or limited in any manner by any applicable Regulatory Authority or applicable laws and regulations from performing the Services.

14. Indemnification, Limitation of Liability and Insurance

- 14.1. Indemnification.
- a) QUOIN, at its own expense, shall defend, indemnify and hold harmless Distributor and its officers, directors, employees, agents and successors from and against all liabilities, costs, charges, expenses (including reasonable attorneys' fees) and damages including those related to personal injury or death incurred in connection with any third party claim (collectively, «**Claims**» and individually, a «**Claim**») to the extent they resulted from, or arose out of: (a) the Product not being in accordance with the Specification as of the date of Delivery; (b) manufacturing, handling and shipping of the Product by QUOIN prior to the date of Delivery; (c) any actual or asserted infringement or violation of any patent, trademark, trade name, copyright or other intellectual or proprietary rights of any third party with respect to any Product or information relating to the Product provided by or on behalf of QUOIN; (d) any negligent or intentional misconduct of QUOIN or any of its employees, representatives or agents; (e) any breach of or default of the terms of the Agreement or the Safety Data Exchange Agreement by QUOIN or (f) any breach of any representation or warranty hereunder by QUOIN or; provided, however that QUOIN' indemnification obligations under this Clause 15.1(a) shall not apply to any liability or damages to the extent caused by the negligence or willful misconduct of Distributor or its employees or agents, or breach of the Agreement by Distributor;
 - b) Distributor, at its own expense, shall defend, indemnify and hold harmless QUOIN and their Affiliates and their respective employees, officers, directors, employees, agents and successors from and against all third party Claims that result from or are caused by (a) the negligence or intentional misconduct of Distributor or any of its Affiliates or Subcontractors or any of their respective agents or employees; (b) the supply or distribution of the Product in the Territory on a Named Patient Supply or Compassionate Supply basis; (c) any breach of or default of the terms of this Agreement or the Safety Data Exchange Agreement by Distributor or any of its Affiliates or Subcontractors or any of their respective employees or agents; or (d) any breach of any representation or warranty hereunder by Distributor; provided, however that Distributor's indemnification obligations under this Section 15.1(b) shall not apply to any liability or damages to the extent caused by the negligence or willful misconduct of QUOIN or its employees or agents, or breach of this Agreement by QUOIN.

- c) Distributor may engage specific personnel to provide consultancy services exclusively to QUOIN in relation to the Product (the «**Consultants**»). Distributor, at its own expense, shall defend, indemnify and hold harmless QUOIN and their respective employees, officers, directors, employees, agents and successors from and against all third party Claims that result from or are caused by (a) the negligence or intentional misconduct of Distributor or any of its employees, Consultants or subcontractors or any of their respective agents or employees; (b) the distribution activities of the Distributor with respect to the Product (c) any breach of or default of the terms of the Agreement by Distributor; or (d) any breach of any representation or warranty hereunder by Distributor; provided, however that Distributor's indemnification obligations under this Clause 15.1(c) shall not apply to any liability or damages to the extent caused by the negligence or willful misconduct of QUOIN or its employees or agents breach of the Agreement by QUOIN; and
- d) The Party entitled to indemnification under this Clause 15.1 (the «**Indemnified Party**») shall give prompt written notice of the Claim to the Party obligated to provide the indemnification (the «**Indemnifying Party**») and, provided that the Indemnifying Party is not contesting the indemnity obligation, shall permit the Indemnifying Party to control any litigation relating to such Claim and disposition of any such claim, provided that the Indemnifying Party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of any Claim as the settlement or disposition relates to the Parties being indemnified under this Clause and the Indemnifying Party shall not settle or otherwise resolve any claim without the prior written consent of the Indemnified Party unless the settlement completely absolves the Indemnified Party of all liability for the Claim and the settlement contains a permanent and comprehensive release of liability in favour of the Indemnified Party and its Affiliates and, as applicable, their respective employees and agents. The Indemnified Party shall cooperate with the Indemnifying Party in its defence of any claim for which indemnification is sought hereunder and is not entitled to indemnification from the Indemnifying Party for any Claim settled without the prior written consent of the Indemnifying Party.

15. LIMITATION OF CERTAIN DAMAGES: NO OTHER WARRANTIES.

- 15.1. EXCEPT FOR LIABILITY ARISING UNDER A PARTY'S INTENTIONAL MISCONDUCT OR FRAUD OR CLAUSES 4.3, 4.4, 15.1, 18 AND 23, IN NO EVENT SHALL EITHER PARTY, ITS AFFILIATES OR THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES AND AGENTS BE LIABLE FOR ANY INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS), WHETHER OR NOT CONTEMPLATED OR FORESEEABLE, WHETHER A CLAIM THEREFORE IS BROUGHT AT LAW OR IN EQUITY AND REGARDLESS OF WHETHER ANY CLAIM THEREFORE IS BASED UPON CONTRACT, TORT OR OTHER PRINCIPLES; PROVIDED THAT THIS LIMITATION ON LIABILITY SHALL NOT APPLY TO THE EXTENT PROHIBITED BY APPLICABLE LAWS OR REGULATIONS.
- 15.2. EXCEPT AS EXPRESSLY SET FORTH IN THE AGREEMENT DISTRIBUTOR MAKES NO OTHER REPRESENTATIONS, WARRANTIES OR PROMISES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS EXPRESSLY SET FORTH IN THE AGREEMENT, QUOIN MAKES NO REPRESENTATIONS, WARRANTIES OR PROMISES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND HEREBY EXPRESSLY DISCLAIMS ANY SUCH REPRESENTATIONS, WARRANTIES OR PROMISES, THAT THE PRODUCT WILL OBTAIN MARKETING AUTHORISATION OR CAN BE SUCCESSFULLY DISTRIBUTED IN THE TERRITORY.
- 15.3. NEITHER PARTY EXCLUDES OR LIMITS ITS LIABILITY IN NEGLIGENCE FOR DEATH OR PERSONAL INJURY, OR FOR FRAUD, OR WILFUL MISCONDUCT OR OTHERWISE INsofar AS ANY EXCLUSION OR LIMITATION OF ITS LIABILITY IS VOID, PROHIBITED OR UNENFORCEABLE BY LAW.

16. Insurance.

- 16.1. Distributor hereby confirms that as of the Commencement Date, Distributor has valid contracts of liability insurance of transportation of goods and stock and further agrees to maintain such insurance for the Term of this Agreement.
- 16.2. QUOIN shall maintain during the Term customary and reasonable commercial general liability insurance and product liability insurance.
- 16.3. All insurance required hereunder shall be with reputable insurance companies. If any insurance required hereunder is provided on a claims-made basis, then said insurance shall be maintained in full force and effect for at least five (5) years after the expiration of the Agreement and any renewals hereunder.

17. Intellectual Property Rights

- 17.1. Results of Services.
- a) QUOIN-Owned Information and Materials and telephone numbers, website addresses, trademarks, service marks and copyrights will be the exclusive property of QUOIN; and
- b) QUOIN shall own and be free to use, without restriction or any payments, QUOIN-Owned Information and Materials QUOIN will have the right to use and disclose the QUOIN-Owned Information and Materials, any other documents, information and materials covered by this Clause for any and all purposes.
- 17.2. Intellectual Property - Ownership; Assignment.
- a) Distributor agrees to and hereby assigns to QUOIN all of Distributor's right, title and interest in and to any and all discoveries, improvements, trademarks, processes, formulas, data, inventions, enhancements, know-how and trade secrets, whether protectable under intellectual property laws or otherwise, relating to the Product whether developed during the Term or thereafter (including, without limitation, any use thereof, any manufacturing process applicable thereto, any method of administration thereof or any method of packaging or handling thereof) (collectively,

«**Inventions**») and related intellectual property rights (collectively, «**Product Inventions**»). Distributor shall promptly disclose to QUOIN all Product Inventions;

- b) Distributor agrees to execute, at QUOIN's expense, such instruments of transfer, assignment, conveyance or confirmation and such other documents as QUOIN may request to assign to QUOIN all Product Inventions;
- c) Without the prior written consent of QUOIN, Distributor shall not, at any time file, cause to be filed, or consent to the filing of, any patent, trademark, service mark, trade name or copyright application with respect to, or claiming, any QUOIN-Owned Information and Materials; and
- d) As between Distributor and QUOIN, QUOIN shall have the sole right, but not the obligation (other than as provided below), to file, prosecute, defend, maintain and enforce (collectively, «Protect») all rights in QUOIN-Owned Information and Materials within or outside the Territory.

17.3. QUOIN Trade marks.

- a) Subject to the terms and conditions of the Agreement, QUOIN hereby grants to Distributor a license to use QUOIN owned or licensed trademarks (including PRODUCT) solely in connection with marketing and distributing the Product under the Agreement in the Territory. Distributor acknowledges QUOIN' ownership of all right title and interest in and to QUOIN trademarks, and agrees that it will do nothing inconsistent with such ownership and that all use of QUOIN trademarks by Distributor shall inure to the benefit of and be on behalf of QUOIN.QUOIN. Distributor agrees that nothing in the Agreement shall give Distributor any right, title or interest in QUOIN trademarks other than the right to use such trademarks in accordance with the Agreement; and
- b) Distributor further agrees that it will not attack, use any of the trade marks in any way which might prejudice their distinctiveness, validity or goodwill nor will it assist others in attacking, QUOIN' rights in its trademarks. The Distributor shall also not use in the Territory any trademarks or trade names so resembling any trade mark or trade names QUOIN owns or licenses which are likely to cause confusion or deception. Notwithstanding anything in the Agreement to the contrary, if, by virtue of Distributor's use of QUOIN's trademarks, Distributor acquires any equity, title or other rights in or to such trademarks, Distributor shall and hereby agree to assign and transfer same to QUOIN and to execute and deliver all requested applications and other documents, and take such other actions as QUOIN may reasonably request, to effect the assignment and transfer of Distributor's equity, title or other rights in or to such trademarks. QUOIN will reimburse Distributor for Distributor's out-of-pocket expenses incurred in connection with cooperation provided at QUOIN's request under the preceding sentence. In addition, Distributor shall comply with SOPs or other instructions provided by QUOIN to Distributor with respect to the proper use of QUOIN' trademarks.

17.4. Except as expressly set forth in the Agreement, nothing in the Agreement, nor the delivery of any information or materials from one Party to the other Party (or any third party acting on its behalf) in connection with the Agreement will be deemed to grant to any Party any right or license under any intellectual property of the other Party.

17.5. Distributor shall provide QUOIN with prompt written notice as soon as Distributor becomes aware of any actual, alleged, suspected or threatened sale or supply of a generic form of Product in the Territory, infringement of QUOIN's Product-related patents or trademarks in the Territory or misappropriation of QUOIN-Owned Information and Materials that comes to the attention of Distributor or its Affiliates or Subcontractors.

18. Additional QUOIN Obligations

- 18.1. QUOIN shall take all action necessary such that it complies with all existing and applicable laws, regulations and industry codes related to the manufacture of the Product and the responsibilities allocated to it under the Agreement and to provide full assistance and information to the Distributor such that, if QUOIN seeks to obtain Marketing Authorisation in the Territory during the Term of this Agreement then both Parties will work together to achieve this (subject to the termination right at Clause 20.1), with the Marketing Authorisation to be owned exclusively by QUOIN. Distributor acknowledges that Product will be European Union labelled product manufactured in accordance with current good manufacturing practices applicable in the United States.
- 18.2. QUOIN shall promptly notify Distributor if QUOIN becomes the subject of or becomes aware of any threatened, investigation by a Regulatory Authority in the Territory involving the Product.
- 18.3. QUOIN represents and warrants to the Distributor that it has the right to appoint the Distributor as exclusive Distributor for the Product in the Territory and that the Distributor's marketing and distribution of the Product in the Territory will not infringe the intellectual property rights of any third party.

19. Termination

- 19.1. In addition to the other clauses of the Agreement that permit QUOIN to terminate the Agreement early, QUOIN may also terminate the Agreement by giving Distributor written notice stating the grounds of termination as follows:
 - a) QUOIN may terminate the Agreement upon immediate written notice if QUOIN or Third-Party Designee on behalf of QUOIN is no longer permitted under applicable laws or regulations from shipping Product to Distributor or otherwise doing business with Distributor;
 - b) QUOIN may terminate the Agreement at any time if the Product is no longer permitted in the Territory or to be given to the Purchasers of the Product in the Territory;
 - c) QUOIN may terminate the Agreement upon immediate written notice in the event Distributor breaches Clauses 3.2, 4.2, 4.3, 4.4, 6.4, 12, 13.1, 17, 18 or Clause 26 of the Agreement;
 - d) QUOIN may terminate the Agreement if there is a Change of Control of the Distributor;

- e) QUOIN may terminate the Agreement upon immediate written notice if Distributor promotes or is involved in any competing products to that of the Product in the Netherton Syndrome or related Ichthyosis Disorders space.
- f) QUOIN may terminate upon immediate written notice if Distributor sells, supplies or promotes the Product outside of the Territory;
- g) QUOIN may terminate upon immediate written notice if Distributor fails to obtain within five (5) months from the Commencement Date the necessary permits and licenses to distribute the Product in the Territory;
- h) QUOIN may terminate the Agreement at any time if the Distributor totally or substantially discontinues operation of its pharmaceutical distribution business;

19.2. In addition to the other clauses of the Agreement that permit the Distributor to terminate the Agreement early, Distributor may also terminate the Agreement by giving QUOIN written notice stating the grounds of termination as follows:

- a) Distributor may terminate the Agreement upon immediate written notice if Distributor is no longer permitted under applicable laws or regulations from doing business with QUOIN;
- b) Distributor may terminate the Agreement at any time if the Product is no longer permitted in the Territory;
- c) Distributor may terminate the Agreement upon immediate written notice in the event QUOIN or any of its Affiliates breaches Clause 13.1; and
- d) Distributor may terminate the Agreement at any time if QUOIN totally or substantially discontinues operation of its business.

19.3. Either Party may terminate this Agreement with immediate effect by written notice to the other Party if:

- a) the other Party commits a material breach of this Agreement (for this purpose, Distributor's payment obligations shall be deemed material) and (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days of being notified in writing to do so;
- b) the other Party has entered into any composition or arrangement with its creditors or becomes subject to an examination order or goes into liquidation, (otherwise than for the purposes of amalgamation or reconstruction), shall become involved in receivership, bankruptcy, debtor relief or similar proceeding, become involved in any proceeding, voluntary or forced, whereby the Party involved is limited in the free and unrestrained exercise of its own judgement as to the carrying out of the terms of this Agreement, or a resolution is passed for the winding-up of the other Party or the other Party is struck off the register of companies;
- c) an encumbrancer takes possession of, or a receiver, manager or other similar officer is appointed in respect of, the whole or any material part of the property or assets of the other Party;
- d) the other Party ceases, or threatens to cease, to carry on business;
- e) the other Party becomes unable to pay its debts as and when they fall due or is deemed to be unable to pay its debts as they fall due;
- f) the other Party suspends or ceases, or threatens to suspend or cease, to carry on all or a substantial part of its business; and
- g) any event occurs, or proceeding is taken, with respect to the other Party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in Clause 20.3(b) to Clause 20.3(f) inclusive.

19.4. All rights and obligations of the Parties shall cease to have effect immediately upon termination of this Agreement except that termination shall not affect:

- a) accrued rights and obligations of the Parties at the date of termination; and
- b) the continued existence and validity of the rights and obligations of the Parties under those Clauses which are expressed to survive termination and any provisions of this Agreement necessary for the interpretation or enforcement of this Agreement.

19.5. Upon termination of this Agreement for whatever reason the Distributor shall forthwith:

- a) cease to represent that it is an authorised distributor of QUOIN and cease to use any QUOIN-Owned Information and Materials; and
- b) at its own risk and expense, return to QUOIN or dispose of, as QUOIN may direct, all literature, other documents and material relating to the Product supplied to the Distributor by QUOIN together with the Product held by it, title to which has not passed to the Distributor.

20. Consequences of Termination

20.1. Upon termination the following obligations shall continue to apply: all Parties shall continue with existing responsibilities and shall abide by the terms of existing agreements with respect to Purchasers under this Agreement:

- a) both Parties shall complete any tenders/Purchase Orders submitted and open at the date of termination where any such Purchasers wish to use or continue to use the Product; provided however, that if termination is a result of breach by the Distributor, the Distributor shall pay for the Purchase order in advance of shipment of Product.
- b) both Parties shall continue to abide by all clauses regarding confidentiality, Intellectual Property Rights, support, and payments;

- c) both Parties are obliged to at first possible occasion to return any Confidential Information not needed for continued service and support;
- d) Distributor shall be supported by QUOIN and assisted in performing its obligations under any proposals, tenders, offers or other contractual commitments provided to Purchasers before the date of termination and in performing and fully completing all contracts signed with Purchasers prior to the date of termination;
- e) QUOIN is not obliged to accept Purchase Orders submitted by Distributor after the Termination Date unless it is related to a tender Distributor submitted to Purchasers prior to such termination or it is related to unfulfilled contractual obligations of Distributor for contracts with Purchasers entered into prior to termination;
- f) Notwithstanding termination, QUOIN shall supply the Product to Distributor in accordance with the terms of this Agreement to fulfil any tenders, offers or proposals submitted to Purchasers prior to termination; and

20.2. Notwithstanding the termination of the Agreement, QUOIN shall, subject to the below proviso with respect to costs, continue to support Distributor to comply with any of its legal obligations under Applicable Local Law pursuant to any contracts with Purchasers with respect to the Product, and Distributor shall reimburse QUOIN for any related staff costs (including but not limited to time, travel and accommodation) incurred by QUOIN in providing support, such reimbursement to be made upon receipt of an itemised invoice.

20.3. The Parties shall be entitled to inform Purchasers and other third parties about the Termination, but not earlier than two (2) months before the effective date of Termination unless such notification may affect the payment by such Purchasers of amounts due and owing to Distributor.

20.4. Distributor shall not have a claim against QUOIN for compensation or indemnification of any kind for or arising out of the termination or non-renewal of the Agreement. In this respect, under no circumstances shall QUOIN be liable to Distributor by reason of termination or non-renewal of the Agreement inter alia for compensation, reimbursement or damages for (i) loss of agency rights; (ii) loss of prospective compensation; (iii) good will or loss thereof; or (iv) expenditure, investments, leases, or other type of commitment made in connection with the business of such Party or in reliance on the existence of the Agreement.

21. Transition Support

21.1. Upon termination or expiration of the Agreement, Distributor shall take all commercially reasonable steps to transition Purchasers to QUOIN or parties designated in writing by QUOIN. Such transition assistance shall include, but not be limited to: (a) the transfer of QUOIN-Owned Information and Materials in a format or formats to be mutually agreed upon by the Parties; (b) the transfer of quality control testing, methods and other similar information related to the Product; and (c) the transfer to QUOIN, or the cancellation of, licenses and permits in the name of the Distributor related to the Agreement or the Product, as instructed by QUOIN; and (d) information about Purchasers and reimbursement information about the Product in the Territory; and (e) information about Patients, on a de-identified basis only, in the possession of Distributor or its Affiliates or Subcontractors, subject to compliance with applicable laws and regulations. In addition, the Distributor shall de-register the Agreement in the Territory, in the event that the Agreement had to be registered, as soon as practicable and, in doing so, take all necessary and required actions to effect such de-registration, including executing all documents that are necessary or required and making all necessary and required filings and notifications.

21.2. QUOIN shall reimburse Distributor for the reasonable and documented costs and expenses of Distributor's activities under this Clause 22 unless the termination of the Agreement is the result of a material breach by Distributor under Clause 20.3(a) in which case Distributor shall be responsible for the costs and expenses of its activities under this Clause 22.

21.3. Notwithstanding any other provision of the Agreement, the rights and obligations of the Parties under Clause 2, 4.2, 4.3, 7, 8.3, 11, 13, 14, 14.3, 18, 20, 22, 23, 24, 25, 26 and 27 shall survive termination or expiration of the Agreement, subject to any time or other limitations on the survival periods set forth in the applicable clauses.

22. Confidentiality

22.1. Each Party (the «Receiving Party») shall keep strictly private and confidential all information and documentation disclosed by the other Party before or after the Commencement Date (the «Disclosing Party») to the Receiving Party which relates to any trade secrets of the Disclosing Party (including, without limitation, proprietary processes of manufacture, know-how or methods of carrying on business) or which is identified by the Disclosing Party as confidential (the «Confidential Information») and will not use any of the Disclosing Party's Confidential Information for any purpose other than the performance of its obligations or the exercise of its rights under this Agreement or other than as provided, copy or disclose any of the Disclosing Party's Confidential Information to any third party whatsoever.

22.2. During the term of this Agreement the Receiving Party may disclose the Disclosing Party's Confidential Information to its employees and sub-contractors to the extent that it is reasonably necessary for the purposes of this Agreement. The Receiving Party shall procure that its employees and sub-contractors at all times are bound by this Clause 23.

22.3. The obligations contained in Clauses 23.1 and 23.2 shall not apply to any of the Disclosing Party's Confidential Information which:

- a) is at the Commencement Date of this Agreement already in, or at any time after the Commencement Date comes into, the public domain other than through breach of this Agreement or any other agreement between the Parties by the Receiving Party;

- b) can be shown by the Receiving Party to the reasonable satisfaction of the Disclosing Party to have been known by the Receiving Party before disclosure by the Disclosing Party to the Receiving Party;
- c) is required to be disclosed by law or pursuant to the order of a court of competent jurisdiction or the rules of any stock exchange on which a Party's shares (or those of any group Quoin) are listed; or
- d) subsequently comes lawfully into the possession of the Receiving Party from a third party with the right to disclose the information free of any obligation of confidentiality and who is not providing such information on behalf of the Disclosing Party or in connection with this Agreement.

22.4. No public announcement, communication or circular (other than to the extent required by law or by the rules of any stock exchange on which a Party's shares (or those of any group Quoin) are listed) concerning this Agreement shall be made or dispatched by the Distributor during the term of this Agreement without the prior written consent of QUOIN.

22.5. This Clause 23 shall survive termination of this Agreement for whatever cause.

23. Non-Disclosure

23.1. During the Term of the Agreement and for a period of ten (10) years thereafter, except as specifically permitted under the Agreement, the Receiving Party shall keep the Disclosing Party's Confidential Information in the strictest confidence (whether such Confidential Information was disclosed to the Receiving Party before, on or after the Commencement Date) and shall not disclose, or permit the disclosure of, any Confidential Information of the Disclosing Party to any third party without the prior consent of the Disclosing Party. The Receiving Party shall not use, or permit the use of, any Confidential Information of the Disclosing Party, without the prior consent of the Disclosing Party, for any purpose other than in connection with the proper performance of the Receiving Party's obligations under the Agreement and, in the case of QUOIN as Receiving Party, in connection with its related activities.

23.2. The Receiving Party shall use all reasonable efforts to prevent any inadvertent disclosure or unauthorized reproduction or use of the Confidential Information of the Disclosing Party that are consistent with the level of effort the Receiving Party uses to protect its own Confidential Information, but not less than commercially reasonable efforts. The Receiving Party will immediately advise the Disclosing Party in writing if the Receiving Party becomes aware of any disclosure in violation of this Clause 24 or misappropriation or misuse by any person of the Disclosing Party's Confidential Information.

23.3. Notwithstanding the foregoing, (a) QUOIN may use the Confidential Information of Distributor and/or disclose such Confidential Information to a third party for use, after the Term to the extent that such Confidential Information is included in the information and documentation required to be transferred to QUOIN under Clause 22.1 to the extent it is necessary to transition the Purchasers to QUOIN or any third party and, to the extent provided to a third party (other than a Regulatory Authority) by QUOIN, the third party is subject to confidentiality and non-use obligations as stringent as those imposed on QUOIN in this Clause 24; and (b) the Receiving Party may disclose the Confidential Information of the other Party to the extent such Confidential Information is required to be disclosed pursuant to a requirement of a Regulatory Authority or law, provided that, except with respect to Product-related filings made by or on behalf of QUOIN to a Regulatory Authority: (i) the Receiving Party has given the Disclosing Party prior written notice of such disclosure and takes all available steps to maintain the confidentiality of the information disclosed; and (ii) the Disclosing Party has been afforded a reasonable opportunity to contest the necessity and scope of such disclosure.

23.4. The Receiving Party acknowledges and agrees that the Disclosing Party considers the Confidential Information to be valuable and confidential. Unless otherwise required by law and for one copy of such information which may be retained by the Receiving Party for its records, the Receiving Party, upon the termination or expiration of the Agreement or at any other time upon the reasonable request of the Disclosing Party, shall promptly delete or return, as specified by the Disclosing Party, to the Disclosing Party, in good order, the originals and all hard (non-electronic) copies of the Disclosing Party's Confidential Information, and delete all electronic copies of the Disclosing Party's Confidential Information, except for any automatically created copies maintained on the Receiving Party's systems or back-up media and except that QUOIN will have no obligation to return or destroy the Confidential Information of Distributor incorporated into any documents, data or reports which have been provided to QUOIN under the Agreement or are required to be provided to QUOIN under Clause 22.3 or that have been incorporated into any Regulatory Filing.

23.5. Each Party acknowledges that any breach of the provisions of this Clause 24 by the other Party may result in serious and irreparable injury to the non-breaching Party for which monetary damages may not be adequate. As a result, each Party agrees that, in addition to any other remedy it may have, the other Party will be entitled to seek specific performance of these provisions and to seek injunctive relief without the need to post a bond or to show harm.

24. Publicity

Except as set forth in this Clause 25, neither Party nor their respective Affiliates will:

- a) make any public announcements concerning the Agreement or its terms without first obtaining the written consent of the other Party, except with respect to information which has already been approved in a prior public announcement;
- b) issue any press release or make any public announcement which includes the name of the other Party or its Affiliates or will otherwise use the name of the other Party or its Affiliates in any public statement, publicly released document, advertising or promotional literature without first obtaining the written consent of the other Party, except with respect to information which has already been approved in a prior press release or public announcement; or
- c) notwithstanding anything to the contrary in this Clause 25, either Party or its Affiliates may make any disclosure required by applicable securities laws (provided that if the Agreement is required to be filed as an exhibit to a securities filing, the disclosing Party will request

confidential treatment to the extent allowed by applicable law), without prior approval of the other Party. If such disclosure is required, the disclosing Party will provide the other Party with drafts of the filings, including all exhibits and appendices, for review at least five (5) Business Days prior to submission, will consider in good faith such Party's comments, and will provide final copies to such Party promptly after submission.

25. Communications about Product and Related Matters.

- 25.1. Distributor shall not promote or market the Product unless and until Marketing Authorisation is obtained with respect to the Product.
- 25.2. Subject to the requirements of all Applicable Laws, and strictly subject to the receipt of the Marketing Authorisation with respect to the Product, the Distributor shall, at its own cost and expense upon Marketing Authorisation being granted, use commercially reasonable efforts to market, promote and supply the Product in the Territory.
- 25.3. Distributor shall not promote or recommend any off-label or unapproved use of the Product.
- 25.4. Distributor shall not, in any form or medium, disparage Product or otherwise publish or communicate comparisons of Product to other products.
- 25.5. Distributor represents that it now has and will maintain in full force and effect, all applicable licenses, permits and approvals required by Distributor to fulfil its obligations under the Agreement.
- 25.6. Distributor shall comply with all safety and security (including information technology) SOPs, laws and regulations that apply to the Facility. Distributor will notify QUOIN in writing of any breaches of such procedures, standards, SOPs, laws or regulations that impact the Product.
- 25.7. Distributor shall comply with all applicable quality control SOPs and all laws and regulations that apply to the Facility and the Product.
- 25.8. In distributing the Product in the Territory, Distributor will access and collect information from Purchasers. Distributor shall comply with all Privacy Laws related to such information, including limitations on the use and disclosure of personally-identifiable Patient information («**Personal Data**»). Distributor shall not use or disclose Personal Data for any purpose other than to perform its obligations under the Agreement and shall not provide Personal Data to QUOIN or to any third party (a) unless permitted or required under applicable laws and regulations or (b) with the express prior written approval of QUOIN, provided in the case of clause (b), such disclosure is permitted by applicable laws and regulations, including Privacy Laws.

26. General

26.1. No Partnership

Nothing in this Agreement and no action taken by the Parties pursuant to this Agreement shall constitute, or be deemed to constitute, a partnership, association, joint venture, principal-agent relationship, or other co-operative entity between any of the Parties.

26.2. Force Majeure

If either Party is prevented or delayed from or in performing any of its obligations under this Agreement (other than an obligation to make payment) by Force Majeure, then:

- a) that Party's obligations under this Agreement shall be suspended for so long as the Force Majeure continues and to the extent that that Party is so prevented, hindered or delayed;
- b) as soon as reasonably possible and in any event within five (5) Business Days after commencement of the Force Majeure, that Party shall notify the other Party in writing of the occurrence of the Force Majeure, the date of commencement of the Force Majeure and the effects of the Force Majeure on its ability to perform its obligations under this Agreement;
- c) that Party shall use all reasonable efforts to mitigate the effects of the Force Majeure upon the performance of its obligations under this Agreement; and
- d) as soon as reasonably possible and in any event within five (5) Business Days after the cessation of the Force Majeure, that Party shall notify the other Party in writing of the cessation of the Force Majeure and shall resume performance of its obligations under this Agreement.

26.3. If any Force Majeure prevails for a continuous period in excess of two (2) months, either Party shall be entitled to terminate this Agreement by giving not less than fourteen (14) Business Days' notice in writing to the other Party.

26.4. Entire Agreement

This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof, supersedes all previous agreements (whether written or oral) and understandings between the Parties with respect thereto. There are no representations, agreements, arrangements or understandings, oral or written, between or among the Parties hereto relating to the subject matter of the Agreement that are not fully expressed herein.

26.5. Assignment

- a) The Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns;
- b) Distributor shall not assign any of its respective rights or delegate or subcontract any of its respective duties under the Agreement without the prior written consent of QUOIN. QUOIN. Any such assignment, delegation or subcontracting consented to by QUOIN shall not relieve the Distributor of its responsibilities and liabilities hereunder and the Distributor shall remain liable to the other Party for the conduct and performance of each permitted assignee, delegate and subcontractor hereunder.

- c) Any attempt by Distributor to assign, transfer, delegate or subcontract any of the rights, duties or obligations in violation of this Clause 27.5 will be void.

26.6. Severability

Each clause, subsection and sentence of the Agreement shall be considered severable, and if for any reason any Clause (or part thereof) is determined to be invalid under current or future law, such invalidity shall not impair the operation of or otherwise affect the valid portions of the Agreement. If any section or subsection is declared invalid under this Clause 27.6, the Parties agree to negotiate in good faith an amendment to the Agreement that would be equivalent in substance to the invalidated section or subsection.

26.7. Amendment

No alteration, amendment, waiver, cancellation or other changes in any term or condition of this Agreement shall be valid or binding on either Party unless the same has been agreed to in writing by both Parties.

26.8. Waiver

The terms, covenants and conditions of the Agreement may be waived only by a written instrument executed by the Party waiving compliance. The failure of any Party at any time or times to require performance of any provision of the Agreement shall in no manner affect the right at a later date to enforce the same or to enforce any future compliance with or performance of any of the provisions hereof. No waiver by any Party of any condition or other breach of any provision, term or covenant in the Agreement whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such condition or the breach of any other provision, term or covenant of the Agreement.

26.9. No Third-Party Beneficiaries.

The Agreement is intended for the benefit of the Parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

26.10. Variation

This Agreement may only be varied in writing excluding electronic methods of writing signed by each of the Parties.

26.11. Costs and Expenses

Each Party shall pay its own costs and expenses in relation to the negotiation, preparation, execution and implementation of this Agreement.

26.12. Counterparts

This Agreement may be executed in any number of counterparts, and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Agreement, but all the counterparts shall together constitute but one and the same instrument.

26.13. Notices

- a) Any notice or other communication which the Distributor or QUOIN is required or authorised by the Agreement to serve on the other shall be sufficiently served if sent to the other at the address set out at the head of this Agreement for each Party:
- i. By hand; or
 - ii. By prepaid post,
- b) Notices sent by prepaid post shall be deemed to be served three (3) Business Days following the day of posting;
- c) Email may be used by either Party for informal, day-to-day, operational requests, approvals and notifications under this Agreement, but email is not a permitted method by which to send any formal notices under this Agreement unless such notice is acknowledged by email expressly stating to be sufficient as notice for the purpose of this Clause 27.13 of the Agreement;
- d) All notices and other communications that may be or are required to be given under the Agreement shall be in writing and shall be deemed to have been duly given on the date of delivery if personally delivered or one day after mailing if sent by independent overnight courier, and shall be addressed as follows:

If to Distributor:

Orpharm LLC
141860, Moscow Region, Dmitrov, Iksha, Naberezhnaya street 10/B
Attention: Pavel Shestiporov

If to QUOIN:

Quoin Pharmaceuticals
42127 Pleasant Forest Court, Ashburn, VA 220148, USA
Attention: Chief Executive Officer

- e) Either Party may change its address for purposes of notice pursuant to the Agreement by notifying the other Party of such change of address in the manner set forth above, except that notices for changes of address are effective only upon receipt by the other Party.

26.14. Independent Contractor

It is expressly acknowledged by the Parties hereto that each of them is independent of the other and nothing in the Agreement is intended, nor shall be construed to create, an employer-employee relationship, a joint venture relationship, or landlord tenant relationship between the Parties. The Agreement does not create a relationship of contracts agency or proxy, commercial agency or any other agency relationship between the Parties under any law, regulation or theory.

26.15. Interpretation

- a) The Parties each acknowledge, represent and agree that they have negotiated the Agreement over a period of time, that they have read the Agreement and the attached Schedules, that they fully understand the terms thereof, that they have consulted with and have been fully advised by independent legal counsel, accountants and other advisors with respect thereto, and that therefore, for purposes of interpreting the Agreement, neither Party shall be considered the author or drafter, and the Agreement shall not be construed against either Party on that basis; and
- b) The Parties each acknowledge, represent and agree that English is the controlling language of the Agreement and that the English version of the Agreement is controlling and supersedes any translations of the Agreement. In addition, the Parties each acknowledge, represent and agree that the controlling language of any disputes under the Agreement shall be English.

26.16. Governing Law and Jurisdiction

This Agreement shall be governed by and construed in accordance with the laws of England and Wales. Each of the Parties to this Agreement irrevocably agrees that the courts of England and Wales are to have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement and, for such purposes, irrevocably submits to the exclusive jurisdiction of such courts. Any proceeding, suit or action arising out of or in connection with this Agreement shall therefore be brought in the courts of England and Wales.

INWITNESS WHEREOF this Agreement is executed on the day and year set out on the first page hereof.

SIGNED by

/s/ Michael Myers

Director for and on behalf of

QUOIN

SIGNED by

/s/ Pavel Shestiperov

for and on behalf of

ORPHARM LLC

SCHEDULE 1

The Product

As at the Commencement Date the Products are:

1. QRX003 for Netherton Syndrome

Product will be supplied in International Packs, i.e. a three (3) language pack written in the English, German and Dutch languages.

SCHEDULE 2

Distributor SOPS



№	Document Name EN	Document Name RU	Document ID	Date	Ver.
1	Quality manual	Руководство по качеству	РК	2020	1
2	Quality policy	Политика о качестве	ПК	2020	1
3	Credit policy	Кредитная политика	КрП	2021	2
4	Marketing policy	Маркетинговая политика	МП	2021	2
5	Guidelines for storage and transportation	Методические рекомендации по хранению и транспортировке	МР	2021	2
6	Information security policy	Политика информационной безопасности	ПИБ	2020	1
7	Documentation management	Управление документацией	СТО-01	2020	1
8	Records management	Управление записями	СТО-02	2020	1
9	Internal audit	Внутренний аудит	СТО-03	2020	1
10	Managing nonconforming services and products	Управление несоответствующими услугами и продукцией	СТО-04	2020	1
11	Corrective and preventive actions (CAPA)	Корректирующие и предупреждающие действия (CAPA)	СТО-05	2020	1
12	Development and presentation of QMS documents	Порядок разработки и оформления документов СМК	СТО-06	2020	1
13	Procedure for subcontractor or partner due diligence and contractual work	Порядок Организации договорной работы	СТО-07	2021	2
14	Procedure for the organization of claim related work	Порядок организации претензионно-исковой работы	СТО-08	2020	1
15	Procedure for creating a Counterparty card in 1С	Порядок создания карточки Контрагента в ИС 1С	СТО-09	2020	1
16	Power of attorney management procedure	Порядок организации работы с доверенностями	СТО-10	2020	1
17	Procedure for preparing complaints to the federal antimonopoly service (FAS) on the actions (omissions) of customers under 44-FZ, 223-FZ	Порядок подготовки жалоб в ФАС на действия (бездействия) заказчиков в рамках 44-ФЗ, 223-ФЗ	СТО-11	2020	1
18	Corporate anti-corruption program	Корпоративная программа по противодействию коррупции	СТО-12	2020	1

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ORPHARM LLC – RELEVANT SOP INDEX. OCTOBER 2021

19	Regulations on the Credit Committee	Положение о Кредитном комитете	СТО-13	2020	1
20	Assortment management procedure	Порядок работы по ассортименту в Обществе	СТО-14	2020	1
21	Processing manufacturers' requests	Порядок работы с производителем по запросам	СТО-15	2020	1
22	Procedure for ensuring information security when providing antivirus protection	Порядок обеспечения информационной безопасности при обеспечении антивирусной защиты	СТО-16	2020	1
23	Procedure for ensuring the security of the local computer network	Порядок обеспечения безопасности локальной вычислительной сети	СТО-17	2020	1
24	The procedure for ensuring information security in the management domain	Порядок обеспечения информационной безопасности при управлении доменом	СТО-18	2020	1
25	Procedure for ensuring information security when working with corporate email	Порядок обеспечения информационной безопасности при работе с корпоративной электронной почтой	СТО-19	2020	1
26	Procedure for ensuring information security when working with the Internet	Порядок обеспечения информационной безопасности при работе с сетью интернет	СТО-20	2020	1
27	Procedure for ensuring information security when working with software	Порядок обеспечения информационной безопасности при работе с программным обеспечением	СТО-21	2020	1
28	Procedure for ensuring information security of file exchange	Порядок обеспечения информационной безопасности файлового обмена	СТО-22	2020	1
29	Procedure for ensuring information security when using portable mobile devices	Порядок обеспечения информационной безопасности при эксплуатации портативных мобильных устройств	СТО-23	2020	1
30	Procedure for ensuring information security when working with information resources	Порядок обеспечения информационной безопасности при работе с информационными ресурсами	СТО-24	2020	1
31	Information security procedures for data archiving, backup, and recovery	Порядок обеспечения информационной безопасности при архивировании, резервном копировании и восстановлении данных	СТО-25	2020	1

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32	Procedure for ensuring information security when recording, storing and using key information carriers	Порядок обеспечения информационной безопасности при учете, хранении и использовании носителей ключевой информации	СТО-26	2020	1
33	Procedure for purchasing goods (medicines and medical devices)	Порядок закупки товара (лекарственные средства и изделия медицинского назначения)	СТО-28	2020	1
34	Procedure for receiving goods from the supplier to the warehouse	Порядок приемки товара от поставщика на склад	СТО-29	2020	1
35	Procedure for claims processing when accepting goods from a supplier	Порядок претензионной работы при приемке товара от поставщика	СТО-30	2020	1
36	Procedure for claims handling when shipping goods to the customer	Порядок претензионной работы при отгрузке товара клиенту	СТО-31	2020	1
37	The procedure for making claims of transport companies in the delivery of goods	Порядок выставления претензий транспортным компаниям при доставке товара	СТО-32	2020	1
38	Procedure for making changes to the architecture and algorithms of 1C	Порядок внесения изменений в архитектуру и алгоритмы ИС 1С	СТО-33	2020	1
39	Procedure for managing accounts receivable	Порядок управления дебиторской задолженностью	СТО-34	2020	1
40	Operating procedure for switching and network equipment, LAN	Порядок работы коммутационного и сетевого оборудования, ЛВС	СТО-35	2020	1
41	Procedure for providing and working with personal computers	Порядок предоставления и работы с персональными компьютерами	СТО-36	2020	1
42	Fault tolerance and data backup	Порядок обеспечения отказоустойчивости и резервного копирования	СТО-37	2020	1
43	Order of technical support for users	Порядок технической поддержки пользователей	СТО-38	2020	1
44	Server infrastructure organization	Порядок организации серверной инфраструктуры	СТО-39	2020	1
45	Procedure for handling medicinal products that require special temperature storage conditions	Порядок обращения с лекарственными препаратами, требующими особого температурного режима хранения	СТО-40	2020	1
48	Procedure for accounting storage and use of the Company's seals	Порядок учета хранения и использования печатей Общества	К-1	2020	1
51	Procedure for receiving and shipping goods	Порядок приемки и отгрузки ТМЦ	СТО-43	2020	1

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52	Regulation on establishing, updating and storing information about beneficial owners	Положение об установлении, обновлении и хранении информации о бенефициарных владельцах	СТО-44	2020	1
53	Inventory management and product movement from the moment of its planning, purchase and sale by the client	Управление товарным запасом и движение товара с момента его планирования, закупки и реализации клиентом	СТО-45	2020	1
54	Risk management	Управление рисками	СТО-46	2021	2
55	Change control	Управление изменениями	СТО-47	2020	1
56	The QMS analysis by the management	Анализ СМК со стороны руководства	СТО-48	2020	1
57	Policy on the processing of personal data	Политика в отношении обработки персональных данных	СТО-П 12	2020	1
58	Violation reporting policy	Политика сообщений о нарушениях	СТО-ПСН	2020	1
59	Code of corporate ethics	Кодекс корпоративной этики	СТО-ККЭ	2020	1
60	Procedure for payment of claims received from contractors under government contracts	Порядок работы по оплате претензий, поступивших от контрагентов в рамках исполнения государственных контрактов	СТО-49	2020	1
61	Monitoring of IT infrastructure and software	Мониторинг ИТ инфраструктуры и программного обеспечения	СТО-50	2020	1
62	Corporate antitrust compliance program (antitrust policy)	Корпоративная программа соблюдения антимонопольного законодательства (антимонопольная политика)	СТО-АМП	2020	1
63	Regulations on employee certification	Положение об аттестации работников	СТО-П13	2020	1
64	corporate training procedure	Об обучении	СТО-51	2020	1
65	Procedure for receiving products from the supplier to the warehouse	Порядок приемки продукции от поставщика на склад	СТО-Л 001	2020	1
66	Product placement and storage system in a warehouse	Система размещения и хранения продукции на складе	СТО-Л 002	2020	1
67	Monitoring and control of product storage conditions in the warehouse	Мониторинг и контроль условий хранения продукции на складе	СТО-Л 003	2020	1
68	Procedure for handling products that require special temperature storage conditions. Cold chain management.	Порядок обращения с продукцией, требующей особого температурного режима хранения. Управление "холодовой цепью".	СТО-Л 004	2020	1

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69	Management of non-conforming products	Управление несоответствующей продукцией	СТО-Л 005	2020	1
71	Managing product returns	Управление возвратами продукции	СТО-Л 007	2020	1
72	Procedure for decommissioning and destruction of products	Порядок списания и уничтожения продукции	СТО-Л 008	2020	1
74	Transportation of goods and materials	Транспортировка ТМЦ	СТО-Л 010	2020	1
75	Maintenance of warehouse premises and equipment. Calibration and verification of measuring instruments.	Техническое обслуживание помещений и оборудования склада. Калибровка и поверка средств измерений.	СТО-Л 011	2020	1
76	Qualification and validation	Квалификация и валидация	СТО-Л 012	2020	1
77	Ensuring sanitary and hygienic conditions in the warehouse	Обеспечение санитарногигиенического режима на складе	СТО-Л 013	2020	1
78	Emergency Plan	План мероприятий при чрезвычайных ситуациях	СТО-Л 014	2020	1
79	Management of deviations	Управление отклонениями	СТО-Л 015	2020	1
80	Internal inspection of the warehouse	Внутренние инспекции склада	СТО-Л 016	2020	1

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SCHEDULE 3

Reports and Meeting

1. Distributor will provide QUOIN with data and reports covering (but not limited to) the following topics:
 - a. Monthly supply information;
 - b. supply by country in the Territory;
 - c. inventory;
 - d. pseudonymised information on Patients;
 - e. near and long-term Product supply forecasts; and
 - f. reports of payments to medical personnel.
2. The Parties shall meet on at least a quarterly basis in person or by telephone, to discuss and review, among other things, each Party's performance under the Agreement and other matters related to their relationship.

QUOIN PHARMACEUTICALS, INC.

Financial statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020 (Unaudited)

QUOIN PHARMACEUTICALS, INC.

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QUOIN PHARMACEUTICALS, INC.

Condensed Balance Sheets (Unaudited)

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Assets		
Current assets		
Cash	\$ 652,792	\$ 323,832
Deferred offering costs	305,917	141,338
Total current assets	958,709	465,170
Intangible assets, net	834,615	912,648
Deferred loan costs	50,000	
Total assets	\$ 1,843,324	\$ 1,377,818
Liabilities and Stockholder's deficit		
Current Liabilities		
Accrued expenses	\$ 905,168	\$ 960,847
Accounts payable	517,795	-
Accrued license acquisition	500,000	875,000
Accrued interest	563,318	47,042
Due to officers	4,873,733	4,888,913
Bridge note payable	5,000,000	-
Convertible notes payable	1,213,313	1,213,313
Total current liabilities	13,573,327	7,985,115
Warrant liability	4,522,844	-
Total liabilities	18,096,171	7,985,115
Commitments and Contingencies		
Stockholders' deficit		
Common stock, par value \$0.01 per share, 10,000,000 shares authorized - 1,000,000 shares issued and outstanding at September 30, 2021 and December 31, 2020	100	100
Accumulated deficit	(16,252,947)	(6,607,397)
Total stockholders' deficit	(16,252,847)	(6,607,497)
Total liabilities and stockholders' deficit	\$ 1,843,324	\$ 1,377,818

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS, INC.

Condensed Statements of Operations and Changes in Stockholders' Deficit (Unaudited)
Nine months ended June 30,

	2021	2020
Operating Expenses		
General and administrative	\$ 2,525,366	\$ 949,143
Research and development	556,064	127,922
Total operating expenses	3,081,430	1,077,065
Other Expenses		
Fair value adjustment to bridge note payable	1,250,000	
Warrant liability expense	4,522,844	
Financing expense	275,000	
Interest expense	516,276	-
Total other expenses	6,564,120	
Net loss before income taxes	(9,645,550)	(1,077,065)
Provision for income taxes	-	-
Net loss	(9,645,550)	(1,077,065)
Accumulated deficit - beginning of period	(6,607,397)	(4,512,033)
Accumulated deficit - end of period	\$ (16,252,947)	\$ (5,589,098)
Loss per share: Basic and diluted	\$ (9.65)	\$ (1.08)
Weighted average shares outstanding:		
Basic	1,000,000	1,000,000
Fully-diluted	1,000,000	1,000,000

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS, INC.

Condensed Statements of Operations and Changes in Stockholders' Deficit (Unaudited)
Three months ended September 30,

	2021	2020
Operating Expenses		
General and administrative	\$ 1,042,783	\$ 302,123
Research and development	259,996	26,010
Total operating expenses	1,302,779	328,133
Other Expenses		-
Warrant liability expense	(146,808)	-
Interest expense	248,165	-
Total other expenses	101,357	
Net loss before income taxes	(1,404,136)	(328,133)
Provision for income taxes	-	-
Net loss	(1,404,136)	(328,133)
Accumulated deficit - beginning of period	(14,848,811)	(5,260,965)
Accumulated deficit - end of period	\$ (16,252,947)	\$ (5,589,098)
Loss per share: Basic and diluted	\$ (1.40)	\$ (0.33)
Weighted average shares outstanding:		
Basic	1,000,000	1,000,000
Fully-diluted	1,000,000	1,000,000

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows (Unaudited)
Nine months ended June 30,

	2021	2020
Cash flows used in operating activities:		
Net Loss	\$ (9,645,550)	\$ (1,077,065)
Fair value adjustment to bridge note payable	1,250,000	
Warrant liability expense	4,522,844	-
Financing expense	275,000	-
Amortization of intangibles	78,032	78,032
Changes in assets and liabilities:		
Increase in accounts payable and accrued expenses	462,117	203,515
Increase in accrued interest	516,276	-
Net cash used in operating activities	(2,541,281)	(795,518)
Cash flows used in investing activities		
Payment for license acquisition	(375,000)	-
Net cash used in investing activities	(375,000)	-
Cash flows provided by financing activities:		
Increase in deferred offering costs	(164,578)	-
Increase in deferred costs	(50,000)	-
Increase in due to officers	139,285	795,518
Payment of amounts due to officers	(154,466)	-
Proceeds from issuance of Bridge Notes, net	3,475,000	-
Net cash provided by financing activities	3,245,241	795,518
Net change in cash	328,961	-
Cash - beginning of period	323,832	-
Cash - end of period	\$ 652,792	-

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

NOTE 1 - ORGANIZATION AND BUSINESS

Quoin Pharmaceuticals, Inc. (“Quoin” or the “Company”) was incorporated in Delaware on March 5, 2018 (“Inception”) and established in 2017 as an Irish entity. The Irish entity did not have any operations, was merged into a wholly-owned subsidiary of Quoin which was then dissolved in 2018.

The Company was established as a specialty pharmaceutical company dedicated to developing products that treat rare and orphan diseases for which there are currently no approved treatments. The first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome (NS). In addition, the Company intends to pursue the clinical development of QRX003 in additional rare dermatological diseases including Peeling Skin Syndrome, SAM Syndrome and Palmoplantar Keratoderma.

To date, the Company has not commercialized any products and has not generated any revenue. The majority of the Company’s operating expenses since inception have been associated with completing due diligence on various technologies, asset technology acquisitions, negotiating and finalizing potential funding agreements, and building its pipeline of preclinical product candidates. The founders of the Company funded all Company related expenditures through September 2020.

On March 24, 2021, the Company and Collect Biotechnology Ltd. (“Collect”), a corporation organized under the laws of Israel and Nasdaq Capital Market listed company, announced that the Boards of Directors of the two companies unanimously approved an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) pursuant to which a wholly owned subsidiary of Collect will merge with and into Quoin (the “Merger”), with Quoin surviving as a wholly-owned subsidiary of Collect, and the operating business of Collect will be spun out into a new entity. Each share of Quoin Common Stock outstanding immediately prior to the Effective Time, as defined will be converted solely into the right to receive a number of Collect Ordinary Shares equal to the Exchange Ratio, as defined which will trade in the United States in the form of American Depositary Shares (“ADS’s,” each ADS representing 400 Ordinary Shares which reflects Collect’s 4:1 ratio change of their ADS’s as of September 24, 2021) and constitutes the “Merger Consideration”.

The Merger was completed on October 28, 2021. See Note 14- Subsequent Events.

NOTE 2 - LIQUIDITY AND ABILITY TO CONTINUE AS GOING CONCERN

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company has incurred net losses every year since inception and had an accumulated deficit of approximately \$16.3 million at September 30, 2021. The Company will require substantial additional capital for its contemplated research and development activities. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

On March 24, 2021, in connection with entering into Merger Agreement, the Company also entered into a Bridge Purchase Agreement related to Bridge Financing and a Securities Purchase Agreement related to Primary Financing (See Notes 1 and 5). The Merger and the Primary Financing were completed on October 28, 2021 (See Note 14 – Subsequent Events). The Company is also in the process of negotiating a line of credit with a bank.

Obtaining additional financing to support the research and development of the Company's therapeutic targets and its other operating requirements are necessary for the Company to continue operations. If the Company is unable to obtain additional funding, the development of its product candidates will be impacted and the Company would likely be forced to delay, reduce, or terminate some or all of its development programs, all of which could have a material adverse effect on the Company's business and the financial statements.

These condensed financial statements do not include any adjustments related to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result from the outcome of this uncertainty.

NOTE 3 - SUMMARY OF SIGNIFICANT POLICIES

Basis of presentation:

The unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying unaudited condensed financial statements reflect all adjustments (consisting only of normal recurring items) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented. The accompanying unaudited condensed Balance Sheet as of December 31, 2020 has been derived from the audited financial statements for the year ended December 31, 2020, initially filed with the U.S. Securities and Exchange Commission ("SEC") on Form F-4 on June 16, 2021. The unaudited condensed financial statements and related disclosures should be read in conjunction with the Company's audited financial statements and related notes.

Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: fair value of debt instruments 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.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

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 U.S. Food and Drug Administration ("FDA") prior to commencing commercial sales in the United States. There can be no assurance that the Company's products will receive all of the required approvals or clearances. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products.

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

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

A novel strain of coronavirus ("COVID-19") created a global pandemic 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 of COVID 19 with respect to the Company's access to API and drug substance, the potential disruption in global freight networks, as well as our ability to safely and efficiently conduct planned clinical trials.

Cash and cash equivalents:

For purposes of the statement of cash flows, 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. 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.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

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 three and nine months ended September 30, 2021 there were no impairment indicators which required an impairment loss measurement.

Deferred Offering Costs:

Deferred offering costs are expenses directly related to the expected Primary Financing. These costs consisted of legal, accounting, printing, and filing fees that the Company capitalized which will be offset against the proceeds upon completion of the Primary Financing.

Research and development:

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

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

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 also accounts for uncertain tax positions using the more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. As of September 30, 2021 and December 31, 2020, 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.

Notes to Financial Statements
September 30, 2021 and December 31, 2020

NOTE 3 - SUMMARY OF SIGNIFICANT POLICIES (CONTINUED)

Fair value:

The Company considers its cash, accounts payable, accrued expenses and the convertible and bridge notes payable to meet the definition of financial instruments. The convertible and bridge notes payable are recorded at fair value, see Notes 4 and 6. The warrants are recorded at fair value, see Notes 5 and 6. The carrying amounts of the remaining financial instruments approximated their fair values due to the short maturities.

The Company measures fair value as required by ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. 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 earnings (loss) per share in accordance with Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("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 stockholders 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 loss per share gives effect to common stock equivalents; however, potential common shares are excluded if their effect is anti-dilutive.

For the three and nine month periods ended September 30, 2021, the number of shares issuable upon the conversion of both the Convertible Notes Payable and the Bridge Notes as well as the warrants issued in connection with both of these convertible instruments are not included in the denominator since their inclusion would be anti-dilutive. See Note 14.

Recently issued accounting pronouncements:

The Company has evaluated all recent accounting pronouncements and believes that none of them will have a material effect on the Company's financial position, results of operations or cash flows except as discussed below.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*" which replaces the existing guidance in ASC 840 - *Leases*. This ASU requires a dual approach for lessee accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases, the lessee would recognize a straight-line total lease expense. This ASU is effective for fiscal years beginning after December 15, 2021 and for interim periods within those fiscal years. The Company will evaluate the impact of adoption of this ASU when it enters into a lease arrangement.

QUOIN PHARMACEUTICALS, INC.

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September 30, 2021 and December 31, 2020

The FASB recently issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470- 20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, to reduce complexity in applying GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer’s own stock and classified in stockholders’ equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in ASC 260, *Earnings Per Share*, to require entities to calculate diluted earnings per share (EPS) for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for public entities that meet the definition of an SEC filer, excluding smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact this standard will have on its financial statements.

Subsequent events:

The Company has evaluated subsequent events through December 17, 2021, which is the date the financial statements were available to be issued.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements September 30, 2021 and December 31, 2020

Note 4 – Convertible Notes Payable

On October 2, 2020, the Company commenced an offering of promissory notes (the “2020 Notes” or “Convertible Notes Payable”) and warrants.

The 2020 Notes were issued at a 25% original issue discount and bear interest at a rate of 20% per annum. Each Note Payable will automatically convert at the first closing of a Primary Financing, as defined (See Note 5) into the securities offered in such financing at the price paid by the investors in the Primary Financing. The 2020 Notes are due one year from their respective dates of issuance.

In October through December 2020, the Company received an aggregate of approximately \$910,000 pursuant to this offering, resulting in the issuance of 2020 Notes with an aggregate face value of \$1,213,333 and an original issue discount of \$303,333. Approximately 23% of such financing was received from parties who are related to or affiliated with members of the Company’s board of directors. No additional funding from the 2020 Notes was received in the three and nine months ended September 30, 2021.

Based upon the terms agreed to in March 2021 in the Primary Financing (see Notes 5 and 14), the 2020 Notes will be mandatorily convertible into ADS’s based upon the terms of the Primary Financing - see Note 14. The Company has elected to account for the convertible notes payable using the fair value model, which requires the Company to record changes in fair value as a component of other income or expense. Management elected to use the fair value model due to the short maturity of the convertible notes payable and likely conversion at the date of the Merger. The fair value of the convertible promissory notes was estimated by management to be approximately \$1.2 million at the date of issuance, resulting in an increase in the fair value of the convertible notes payable of \$378,000 which was recognized in the fourth quarter of 2020. As the Company had not yet consummated the Merger or Primary Financing, management has estimated that the fair value had not significantly changed from issuance to September 30, 2021.

The noteholders also received warrants exercisable at any time after the issuance date for a number of shares of the Company’s common stock that equates 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). The exercise price is to be based on a valuation equal to the valuation of the next financing round that is prior to or immediately after the closing of the Merger, as defined upon the issuance of any shares of Common Stock or securities convertible into shares of Common Stock below the then-existing exercise price. Since the amount of warrants and exercise price of the warrants were not knowable until the next round of financing, they were not accounted for as of December 31, 2020 as the warrant holders could not exercise the warrant at date of issuance and through December 31, 2020 since the exercise price and number of warrants had not been determined. Such determination was made in the first quarter of 2021 in connection with the Bridge Financing noted below.

The warrants will be exercisable for 300,485 (as adjusted for the Merger exchange ratio) ADS’s at an initial exercise price of \$3.98 per share, subject to adjustment, see Note 14. Upon closing of the Primary Financing, each holder agrees to submit this warrant in exchange for the Series A warrants issued in the Primary Financing with the same amount of warrant shares and the same exercise price under this warrant and have a contractual term of 5 years.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements September 30, 2021 and December 31, 2020

The Company determined that these warrants met the criteria to be recorded as a liability instrument. The fair value of warrants was determined by a Black Scholes model to be approximately \$0.8 million at the date of issuance. The significant estimates used in such calculation were as follows:

• Stock price	\$3.98 (post exchange ratio)
• Initial exercise price	\$3.98 (post exchange ratio)
• Contractual Term	5.0
• Volatility	98%
• Discount rate	.81%

The fair value of the warrants are included in warrant liability expense in the accompanying statement of operations for the three and nine months ended September 30, 2021. See Note 6. The change in the fair value from issuance to September 30, 2021 was de-minimus.

Interest expense, at the stated interest rate, recognized in the three and nine months ended September 30, 2021 was approximately \$61,000 and \$182,000, respectively. Accrued interest at September 30, 2021 was approximately \$229,000.

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), the Company entered into a “Bridge Purchase Agreement” on March 24, 2021 with an investor (the “Investor”), pursuant to which the Investor has agreed to purchase, and the Company agreed to issue 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 \$3,750,000 together with warrants. The Bridge Notes were purchased in three closings: (i) the first closing for \$2,000,000 in aggregate principal amount of Bridge Notes closed on March 25, 2021 (the Company received proceeds of \$1.5 million less fees of \$90,000); (ii) the second purchase of \$1,666,666 in aggregate principal amount closed in April 2021 (the Company received proceeds of \$1.25 million) ; and (iii) a third purchase of \$1,333,333 closed in May 2021 (the Company received proceeds of \$1.0 million less fees of \$185,000). The Bridge Notes are secured by a lien on the Company’s current and future assets, are senior to all other outstanding and future indebtedness of the Company and include covenants limiting future indebtedness, among others.

The Bridge Notes were issued with a 25% original issue discount, bear interest at a rate of 15% per annum and have a maturity date of the earliest to occur of: (i) December 25, 2021 (ii) the Public Company Date and (iii) the time immediately prior to the consummation of the Securities Purchase Agreement.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements September 30, 2021 and December 31, 2020

The Bridge Note holder (the “Holder”) and the Company agreed that if the Securities Purchase Agreement is consummated, the Holder may, at its election, offset the purchase price otherwise payable by the Holder to the Company pursuant to the Securities Purchase Agreement, 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 hereunder shall be deemed to be fully satisfied without any further obligations on, or liability to, the Company. If the Holder elects to offset the purchase price under the Securities Purchase Agreement, the purchase price payable by the Holder to the Company pursuant to the Securities Purchase Agreement shall be reduced by the outstanding amount so deemed satisfied. The Bridge Notes were offset against the purchase price under the Securities Purchase Agreement and converted into up to 1,257,721 ADS’s (as adjusted for the Merger exchange ratio, and including shares held in escrow for the benefit of the investor) upon closing of the Securities Purchase Agreement.

The Company has elected to account for the Bridge Notes using the fair value model, which requires changes in fair value to be included in the Statement of Operations. Management elected to use the fair value model due to the short maturity and likely conversion at the date of the Merger. The fair value of the Bridge Notes was estimated by management to be approximately \$5.0 million at the date of issuances, resulting in an increase in the fair value of approximately \$500,000 upon the first issuance and an aggregate of \$750,000 upon the April and May closings. \$275,000 of debt issuance costs was also immediately recognized as a component of other expense. Management has determined that the fair value had not significantly changed from issuance to September 30, 2021. See Note 6.

At September 30, 2021, the face amount of Bridge Notes outstanding was \$5,000,000. Interest expense, at the stated interest rate, recognized in the three and nine months ended September 30, 2021 was approximately \$187,000 and \$334,000, respectively. Accrued interest at September 30, 2021 was approximately \$334,000.

Warrants

Upon the funding of each Bridge Note tranche described above, the Investor received warrants to purchase a number of shares of Company common stock equal to the aggregate principal amount of the Bridge Notes issued divided by the initial per share exercise price of \$3.98 (the “Bridge Warrants”) or a total of 1,238,429 (as adjusted for the Merger exchange ratio) shares, subject to adjustments, as defined including certain reset mechanics. The Bridge Warrants shall have a term of five years from the date all of the shares underlying the Bridge Warrants are freely tradable. The Bridge Warrants also contain certain rights with regard to asset distributions and fundamental transactions. At the effective time of the Merger, each Bridge Warrant will automatically be exchanged for warrants to purchase ordinary shares, with share amounts and share prices adjusted to reflect the Exchange Ratio (as defined in the Merger Agreement) of the combined company’s ordinary shares. In connection with the first closing on March 25, the Company issued 495,374 Bridge warrants, and 743,055 (as adjusted for the Merger exchange ratio) were issued in the three months ended June 30, 2021 in connection with the following two closings.

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

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

The Company determined that the warrants met the criteria to be recorded as a liability instrument. The fair value of warrants was determined by a MonteCarlo simulation model to be approximately \$1.6 million at the date of issuance of the 495,374 warrants in connection with the first closing and an aggregate of \$2.2 million at the date of issuance of the 743,055 (post exchange ratio) in connection with the second and third closing of the Bridge Notes. The significant estimates used in such calculation were as follows:

The fair value of the warrants are included in other expense in the accompanying statement of operations for the three and nine months ended September 30, 2021. The change in the fair value from issuance to September 30, 2021 was de-minimus. See Note 6.

In September 2021, the Company and note holders agreed that when the warrants are exchanged for the Exchange Warrants the reset provisions will be replaced by a fixed number of shares and exercise price of \$3.98. See Note 14.

Securities Purchase Agreement (Primary Financing)

The Company, Collect and the Investor signed a Securities Purchase Agreement (the “Purchase Agreement” or the “Primary Financing”) on March 24, 2021, pursuant to which the Investor agreed to purchase immediately prior to the closing of the Merger (i) \$17.0 million of Quoin common stock (including the set off of the \$5.0 million Bridge Notes), which will be exchanged for Collect ADS’s in the Merger.

In connection with the Purchase Agreement, the Investor will also receive Series A, Series B and Series C warrants (the Primary Warrants, as amended) exercisable into shares of the combined company, to be issued 136 days after closing of the Purchase Agreement. An amendment to the Primary Warrants was consummated in September 2021 which replaced the reset provisions with a fixed number of shares and exercise price. The Series A Warrants, Series B Warrants and Series C Warrants each allow the holder to acquire 4,276,252, 4,276,252 and 2,389,670, respectively of ADS’s. The warrant exercise price for the Series A, B and C Warrants is \$3.98 per ADS. Upon the exercise of the Series C Warrant in full, the Investor will be granted an additional Series A Warrant to purchase 2,389,670 ADSs and an additional Series B Warrant to purchase 2,389,670 ADSs.

Notes to Financial Statements
September 30, 2021 and December 31, 2020

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 Company determined the estimated fair value of the convertible notes payable based on a qualitative evaluation of the credit worthiness of the Company and the probability of outcomes under the possible scenarios.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis by fair value hierarchy at September 30, 2021 and December 31, 2020:

	Level 1	Level 2	Level 3	Total
September 30, 2021				
Bridge warrants	-	-	\$ 3,682,727	\$ 3,682,727
Convertible note warrants	-	-	840,117	840,117
Total Warrant Liability	-	-	\$ 4,522,844	\$ 4,522,844
Bridge note payable	-	-	5,000,000	5,000,000
Convertible notes payable	-	-	1,213,333	1,213,333
Total notes payable	-	-	6,213,333	6,213,333
Total Liabilities	\$ -	-	\$ 10,736,177	\$ 10,736,177
December 31, 2020				
Convertible notes payable	\$ -	\$ -	\$ 1,213,333	\$ 1,213,333
Total Liabilities	\$ -	-	\$ 1,213,333	\$ 1,213,333

In 2020, the convertible notes payable were entered into and their initial fair value was determined to be \$1,213,333. The fair value adjustment from December 31, 2020 to September 30, 2021 was de-minimus.

In March 2021, the Bridge notes and the bridge note warrants were issued and the convertible note warrant terms were set. See Note 5. Their initial fair value were determined to be approximately \$2,000,000, \$1,552,400 and \$894,113, respectively. In the quarter ended June 30, 2021, additional Bridge notes and bridge note warrants were issued. Their initial fair value were determined to be approximately \$3,000,000 and \$2,230,679, respectively. There were no additional notes issued.

The fair value adjustment to the Bridge notes, bridge note warrants, and the convertible note warrants from issuance through September 30, 2021 was de-minimus.

NOTE 7 - ASSET ACQUISITION AND IN-LICENSED TECHNOLOGY

Polytherapeutics:

On March 24, 2018, the Company 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 the Company 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, received by Quoin 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 PHARMACEUTICALS, INC.

Notes to Financial Statements

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The Seller has the right to repurchase the intellectual property for \$100,000 if there are no products in clinical development using such technology through February 28, 2021. As of September 30, 2021, there are no products utilizing this technology in clinical development. However, the Seller has not communicated any intention to repurchase the intellectual property.

The Company also entered into a research and consulting agreement which commits the Company to pay the former owner of Polytherapeutics for additional research and development consulting services (See Notes 11 and 13).

Skinvisible:

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

The development milestones required payments upon achieving development milestones for the first Rare Skin Disease drug product developed using the licensed technology and the first two Ketamine products, as defined. Payments are due upon successful completions of certain clinical milestones (\$7.5 million) and obtaining US and EU regulatory approval (\$15 million). The Sales milestones required for every licensed product commercialized by the Company are \$10 million upon achievement of \$100 million in sales being achieved in the annual period; \$25 million upon achievement of \$250 million in sales and \$50 million upon the achievement of \$400 million in sales in an annual period. No development milestones, sales milestones or royalty payments were due in 2020 or through June 30, 2021.

On January 27, 2021, the Company and Skinvisible entered into amendment number 3 to its license agreement. This amendment modified the clinical milestone payment requirements such that \$750,000 would be payable to Skinvisible upon achievement of specified clinical milestones, and \$21.75 million upon regulatory approval in the U.S. and EU respectively.

The license fee was originally due in two equal installments of \$500,000 payable no later than December 31, 2019 and June 30, 2020, which were not paid and the agreement was amended for payment due on July 31, 2020. On July 31, 2020, the agreement was amended to further extend the payment until September 30, 2020. On September 30, 2020, the agreement was further amended, requiring payment of the license fee only when outside financing is received, as defined.

The agreement has a termination clause that is triggered if no product has commenced clinical testing 12 months after the date of the agreement or the latest subsequent amendment. On April 19, 2021, the Company and Skinvisible entered into amendment number 4 which established the development deadline as December 31, 2022. Should the Company not commence clinical testing as defined by the development deadline, the license agreement will terminate immediately except in certain circumstances as specified in the agreement.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

On June 21, 2021, the parties entered into amendment number 5 which modified the payment terms of the initial license fee - which required a payment of \$107,500 (paid on June 26, 2021), a payment of \$250,000 within 10 days of the Primary Financing, and the remaining \$250,000 upon the earlier of approval of an Investigatory New Drug application by the FDA or December 31, 2021. This amendment also eliminated the \$750,000 clinical milestone payments specified in amendment number 3 and reduced the milestone payment upon regulatory approval of product containing the Skinvisible technology in either the U.S. or E.U., whichever happens first to a total of \$5,000,000.

At September 30, 2021 and December 31, 2020, the license acquisition liability due was \$500,000 and \$875,000 respectively. In November 2021, the Company made a payment of \$250,000 against such payable.

NOTE 8 - INTANGIBLE ASSETS

Intangible assets are as follows:

	September 30, 2021	December 31, 2020
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	(205,818)	(127,785)
Net book value	\$ 834,615	\$ 912,648

The Company recorded amortization expense of \$26,011 in the three months ended September 30, 2021 and 2020. The Company recorded amortization expense of \$78,032 in the nine months ended September 30, 2021 and 2020. Amortization expense for each of the next 5 years is expected to be approximately \$104,000, and then approximately \$315,000 thereafter.

NOTE 9 - ACCRUED EXPENSES

Accrued expenses are as follows:

	September 30, 2021	December 31, 2020
Professional fees	\$ 85,720	\$ 173,095
Investor Relation firm fees (note 11)	528,000	528,000
Payroll taxes (note 10)	168,241	148,899
Research contract expenses (note 11)	85,292	105,052
Other expenses	-	5,802
Total	\$ 867,253	\$ 960,847

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements
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NOTE 10 - RELATED PARTY TRANSACTIONS

Employment agreements and Due to Officers/Founders:

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

Amounts due to the officers/founders consists of amounts specified in the employment agreements since inception to December 31, 2020 and September 30, 2021 as well as reimbursable travel and other amounts paid to third parties on behalf of the Company. The Company repaid \$154,466 and \$0 of such amounts due to officers/founders in the nine months ended September 30, 2021 and 2020, respectively.

Amounts due to officers at September 30, 2021 and December 31, 2020 consisted of the following:

	September 30, 2021	December 31, 2020
Salaries and allowances	\$ 3,973,500	\$ 3,984,000
Invoices paid on behalf of the Company	859,800	864,480
Purchase of Polytherapeutics assets	40,433	40,433
Total	\$ 4,873,733	\$ 4,888,913

See Note 4 for related party debt and Note 11 for employment agreements.

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

NOTE 11 – RESEARCH, CONSULTING AGREEMENTS AND OTHER COMMITMENTS

Research and consulting agreement:

The Company entered into a research and consulting agreement (the “Research Agreement”) which commits the Company to pay the former owner of Polytherapeutics (the “Consultant”) 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 7). 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.

Notes to Financial Statements
September 30, 2021 and December 31, 2020

NOTE 11 – RESEARCH, CONSULTING AGREEMENTS AND OTHER COMMITMENTS (CONTINUED)

Research and consulting agreement: (continued)

If the Company fails to make monthly payments under the Research Agreement and the Acquisition Agreement or the royalty payments described in Note 7, the Seller has the option to buy back all the intangible assets included in the agreement for \$1.00. Further, if the Company fails to enter a product covered by the Acquisition Agreement into clinical development by the end of the Post-Closing Period, the Seller has the option to buy the rights to commercialize said products for \$100,000. As of September 30, 2021 there are no products utilizing this technology in clinical development. The Seller has not communicated any intent to buy the product from the Company as of the financial statement issuance date.

Through September 30, 2021 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 13 for Consultant's notification of breach of contract.

Other research consulting agreements:

The Company entered into three consulting agreements with Axella Research LLC to provide regulatory and pre-clinical/clinical services to the Company with respect with QRX 003 and QRX004. The combined fees of the three agreements are approximately \$270,000, payable as milestones under the three agreements are met. Further, the Company has two options to pay the milestones due 1) one half in equity of the Company (at a pre-negotiated valuation) and one-half in cash or 2) entirely in cash, in which case a discount of approximately 20% would be applicable. The Company recognized research and development expenses for services provided and milestones met of \$34,690 and \$49,890 for the three months ended September 30, 2021 and 2020, respectively. The Company has accrued expenses of \$85,292 and \$105,052 at September 30, 2021 and December 31, 2020, respectively.

Consulting agreements:

The Company entered into a consulting agreement with an Investor Relations (IR) firm, which provides for a monthly fee of \$14,000. The agreement has an automatic annual renewal clause and has been in effect since November 2017. The Company continues to receive services from the IR firm, and owes the IR firm \$528,000 as of September 30, 2021 and December 31, 2020, which is included in accrued expenses in the accompanying balance sheet.

In November 2020 the Company entered into a Master Service Agreement for an initial term of 3 years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement requires the execution of individual work orders. The Company may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. The first work order was entered into in late 2020 for an expected estimated cost of approximately \$3.5 million. For the three and nine months ended September 30, 2021, the Company incurred approximately \$26,000 and \$200,000 of research and development costs from such vendor.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements September 30, 2021 and December 31, 2020

Employment agreements:

The employment agreements entered into by the Company with its two founders/officers provides for a combined base salary, including monthly allowances, of \$996,000 per annum, a discretionary bonus and certain allowances and benefits. In the event of termination of the two founders/officers for reason other than cause, as defined in the employment agreements, the founders shall be entitled to two years of based salary and bonus. See Note 10-related party transactions.

Performance milestones and Royalties:

See Note 7 for asset and in-licensed technology commitments.

NOTE 12 - COMMON STOCK

The Company's authorized capital stock consists of 10,000 shares of common stock. On March 5, 2018, in connection with the incorporation as a Delaware corporation, the Company issued 100 shares for a consideration of \$100 split equally between the two founders and officers of the Company. In February 2021, the Board of Directors of the Company approved an amendment to the articles of incorporation to authorize 10 million shares of common stock and to effectuate a 10,000 - 1 forward stock split. All share and per share numbers in the financial statements have been retroactively reflected in all periods presented.

The Company's common stock is entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock that are present in person or represented by proxy, subject to any voting rights granted to holders of any preferred stock. A vote by the holders of a majority of the Company's outstanding shares is required to effectuate certain fundamental corporate changes such as a liquidation, merger or an amendment to the Company's articles of incorporation.

The holders of shares of common stock will be entitled to such cash dividends as may be declared from time to time by the Company's board of directors from funds available therefor.

In the event of any merger or consolidation of the Company with or into another company in connection with which shares of the Company's common stock are converted into or exchangeable for shares of stock, other securities or property (including cash), all holders of the Company's common stock will be entitled to receive the same kind and amount of shares of stock and other securities and property (including cash). Holders of the Company's common stock have no pre-emptive rights, no conversion rights and there are no redemption provisions applicable to the Company's common stock.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements September 30, 2021 and December 31, 2020

NOTE 13 - 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 the Company threatening litigation for non-payment and related breach of contract and immediate payment of all monthly payments in the amount of \$666,667. See Notes 7 and 11. The Consultant has not provided any services and other technical requirements under the agreements, 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 14 - SUBSEQUENT EVENTS

Completion of Merger

On October 28, 2021, Quoin Pharmaceuticals Ltd., formerly known as Collect Biotechnology Ltd., completed the business combination with Quoin, in accordance with the terms of the Merger Agreement, by and among the Collect, Quoin and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Collect (“Merger Sub”), pursuant to which Merger Sub merged with and into Quoin, with Quoin surviving as a wholly-owned subsidiary of the Company. Immediately after completion of the Merger, Collect changed its name to “Quoin Pharmaceuticals Ltd.” (“Quoin Ltd.”), and began trading on the Nasdaq Capital Market under the symbol “QNRX” on October 29, 2021.

Under the terms of the Merger Agreement, Collect issued ADS’s to the holders of common stock of Quoin. Immediately after the Merger, there were approximately 8,386,627 ADS’s issued and outstanding which include 64,784 (subject to adjustment – see below) ADS’s from the conversion of the Convertible Promissory Notes, 3,003,652 for the Quoin shareholders, 1,041,939 for the Collect shareholders immediately prior to the merger, and an aggregate of 4,276,252 for the Investor, consisting of 2,433,773 delivered to the Investor on or after the Merger closing and 1,842,479 held in an escrow account for the benefit of the Investor (such shares were eligible to be released to the investor in the 4th quarter of 2021) as per the terms of the Securities Purchase Agreement. The Company has not yet issued ADS’s and warrants to the 2020 Noteholders for the accrued interest portion of amounts due.

The former holders of common stock of Quoin (including shares delivered to the Investor and the escrow account for the Investor) owned, in the aggregate, approximately 88% of the ADS’s, with Collect’s stockholders owning approximately 12% . The number of ADS’s issued to the holders of Quoin common stock outstanding immediately prior to the Merger was calculated using an exchange ratio (the “Exchange Ratio”) of approximately 12.0146 ADS’s for each share of Quoin common stock.

QUOIN PHARMACEUTICALS, INC.

Notes to Financial Statements

September 30, 2021 and December 31, 2020

In addition, pursuant to the terms of the Purchase Agreement, Quoin Ltd. issued to the Investor warrants to purchase 1,238,429 ADS's (the "Exchange Warrants") at an exercise price of \$3.98 per ADS, in exchange of Warrants issued by Quoin to the Investor in connection with the Bridge Financing. The Exchange Warrants and ordinary shares underlying the Exchange Warrants were registered with the SEC on the Registration Statement on Form F-4.

In addition, pursuant to the terms of the 2020 Notes, the Company is obligated to exchange the existing warrants for warrants on the same terms as the Investor Series A Warrants, exercisable for 300,485 ADS's at an initial exercise price of \$3.98 per ADS, subject to adjustment, see 2020 Notes Post-Merger Adjustment below.

Private Placement Transaction

On October 28, 2021, the private placement transaction with the Investor for an aggregate purchase price of approximately \$17.0 million (comprised of (x) conversion of approximately \$5 million principal amount of Bridge Notes (see Note 5), and (y) approximately \$11.5 million in cash from the Investor, net of Bridge Note accrued interest and expenses) was closed.

In addition, Quoin Ltd. will issue to the Investor, on the 136th day following the consummation of the Merger (i) Series A Warrant to purchase ADS's (the "Series A Warrant") (ii) Series B Warrant to purchase ADS's (the "Series B Warrant") and (iii) Series C Warrant to purchase ADS's ("Series C Warrants" and, together with the Series A Warrant and Series B Warrant, the "Investor Warrants").

Employment and Other Agreements

In November 2021, the Board of Directors of the Company approved amendments to the employment agreements disclosed in Note 11 setting base level compensation and bonus terms. Further, a transaction bonus related to the Merger aggregating approximately \$324,000 was paid to the two founders in November 2021.

In November 2021 the Company appointed and entered into an employment agreement with its Chief Financial Officer which provides for a base salary of \$360,000 per annum, a discretionary bonus and certain allowances and benefits.

In November and December 2021, the Company entered into three license and supply agreements, whereby the Company will receive a royalty or other proceeds from the sale of specified product revenues in select non-US markets from the licensor, if and when the underlying products are approved and commercialized.

In November 2021, the Company entered into a pre-clinical commitment for research related services associated with Netherton Syndrome of approximately \$250,000 for an expected period of eighteen months. This agreement provides the Company with an option to enter into an exclusive global license to the related intellectual property upon completion of the pre-clinical program. The option, if executed, does not require any up-front license or milestone payments but would require a single digit royalty on sales if there is a commercial approval.

QUOIN MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis is intended to help the reader understand our results of operations and financial condition and should be read in conjunction with Quoin financial statements and related notes included elsewhere in this Form 6-K, as well as in Form 6-K of Quoin Pharmaceuticals Ltd. ("Quoin Ltd."), formerly known as Collect Biotechnology Ltd. ("Collect"), dated August 13, 2021 ("August 6-K"). Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and are presented in U.S. dollars. Unless context indicates or suggests otherwise, "we", "our", "us", "Quoin" and the "Company" in this section refers to the consolidated operations of Quoin Pharmaceuticals, Inc.

Forward-Looking Statements

The following discussion contains forward-looking statements. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as "expect," "intend," "plan," "anticipate," "believe," and "will," among others. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Quoin's expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties. More detailed information about the risks and uncertainties affecting Quoin is contained under the heading "Risk Factors" included in the August 6-K and in other filings Quoin Pharmaceuticals Ltd. has made and may make with the Securities and Exchange Commission in the future. One should not place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Quoin undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as may be required by law.

Overview

We are an emerging 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. Quoin's first lead product, QRX003, is a once daily topical lotion which is under development as a potential treatment for Netherton Syndrome, a rare hereditary skin disease. We are targeting initiating clinical development of QRX003 in Netherton Syndrome patients in the first half of 2022. In addition to Netherton Syndrome, we intend to pursue the clinical development of QRX003 in other rare dermatological diseases including Peeling Skin Syndrome, SAM Syndrome, Palmoplantar Keratoderma and Epidermolysis Bullosa.

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 Canada, Australia, the Middle East and Asia; 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.

The ultimate impact of the COVID-19 pandemic is still uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with all of our employees and consultants working remotely. We will continue to actively monitor the continually evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

Key and Recent Events

Completion of Merger

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

Under the terms of the Merger Agreement, Collect issued ADS’s to the holders of common stock of Quoin. Immediately after the Merger, there were approximately 8,386,627 ADS’s issued and outstanding which include 64,784 ADS’s from the conversion of the Convertible Promissory Notes, 3,003,652 for the Quoin shareholders as of September 30, 2021, 1,041,939 for the Collect shareholders immediately prior to the merger, and an aggregate of 4,276,252 for the Investor, consisting of 2,433,773 delivered to the Investor on or after the Merger closing and 1,842,479 held in an escrow account for the benefit of the Investor as per the terms of the Securities Purchase Agreement. On each Reset Date, if the Initial Primary Price Per Share is less than the Reset Price, the Investor will receive shares from escrow such that the effective price per share of all Primary Financing Shares received by such Investor will be equal to the Reset Price, as such terms are defined in the Securities Purchase Agreement.

As of the second Reset Date which occurred in December 2021, the Investor is entitled to receive all of the ADS’s held in the escrow account. The Company has not yet issued ADS’s and warrants to the 2020 Noteholders for the accrued interest portion of amounts due.

Upon the completion of the Merger, former holders of common stock of Quoin (including shares delivered to the Investor and the escrow account for the Investor) owned, in the aggregate, approximately 88% of the ADS’s, with Collect’s stockholders owning approximately 12%. The number of ADS’s issued to the holders of Quoin common stock outstanding immediately prior to the Merger was calculated using an exchange ratio (the “Exchange Ratio”) of approximately 12.0146 ADS’s for each share of Quoin common stock.

In addition, pursuant to the terms of the Securities Purchase Agreement, dated as of March 24, 2021, Quoin Ltd. issued to the Investor warrants to purchase 1,238,429 ADS’s (the “Exchange Warrants”) at an exercise price of \$3.98 per ADS with full ratchet protection, in exchange of Bridge Warrants issued by Quoin to the Investor in connection with the second bridge financing described below. The Exchange Warrants and ordinary shares underlying the Exchange Warrants were registered with the SEC on the Registration Statement on Form F-4. Terms of the Exchange Warrants were amended in September 2021, and the reset provisions were replaced with a fixed number of shares and exercise price as set out below.

In addition, pursuant to the terms of the 2020 Notes, the Company is obligated to exchange the existing warrants for warrants on the same terms as the Investor Series A Warrants, exercisable for 300,485 ADS’s at an initial exercise price of \$3.98 per ADS, subject to adjustment, see Prior Financing Arrangements—Initial Bridge Financing.

Completion of Private Placement Transaction or “Primary Financing”

On October 28, 2021, the private placement transaction with the Investor for an aggregate purchase price of approximately \$17.0 million (comprised of (x) approximately \$5 million of senior secured notes issued in connection with the bridge loan that the Investor made to Quoin at the time of the execution of the Merger Agreement (the “Bridge Financing”), and (y) approximately \$11.5 million in cash from the Investor) was closed. In addition, Quoin Ltd. will issue to the Investor, on the 136th day following the consummation of the Merger (i) Series A Warrant to purchase ADS’s (the “Series A Warrant”) (ii) Series B Warrant to purchase ADS’s (the “Series B Warrant”) and (iii) Series C Warrant to purchase ADS’s (“Series C Warrant” and, together with the Series A Warrant and Series B Warrant, the “Investor Warrants”). The terms of the Investor Warrants were amended in September 2021, and the reset provisions were replaced with a fixed number of shares and exercise price. The Series A Warrant, Series B Warrant and Series C Warrant each allows the Investor to acquire 4,276,252, 4,276,252 and 2,389,670, respectively, of ADSs, at the adjusted ratio of 400 ordinary shares per ADS. The warrant exercise price for the Investor Warrants is \$3.98 per ADS. Upon the exercise of the Series C Warrant in full, the Investor will be granted an additional Series A Warrant to purchase 2,389,670 ADSs and an additional Series B Warrant to purchase 2,389,670 ADSs.

Prior Financing Arrangements

Initial bridge financing

On October 2, 2020, the Company commenced an offering of up promissory notes (the “2020 Notes”) and warrants. From October through December 2020, the Company received an aggregate of approximately \$910,000 in the initial bridge financing, and issued 2020 Notes with an aggregate face value of \$1,213,333. Approximately 22% of the initial bridge financing was received from parties who are related to or affiliated with members of the Company’s board of directors.

The 2020 Notes had a 25% original issue discount and interest rate of 20% per annum. In April and May 2021, each of the holders of the 2020 Notes signed waivers agreeing to waive their rights to receive Series A, B, and C warrants issuable by Collect. Each 2020 Note was maturing one year from the date of issuance. Upon the completion of the Merger, based upon the terms agreed to in March 2021 in the Primary Financing, described above, the 2020 Notes converted into 64,784 ADS (as adjusted for the Merger-exchange ratio) based on the valuation of \$3.98 per share (as adjusted for the Merger exchange ratio) negotiated in the Primary Financing, subject to adjustment, see below.

The above referenced warrants are exercisable for a number of shares of the Company’s common stock that equates to 100% of the “as if converted” shares as if the 2020 Notes 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). Upon completion of the Primary Financing, the Company is obligated to exchange the warrants for warrants on the same terms as the Investor Series A Warrants, as described above and subject to adjustment. The Company has not yet issued ADS’s and warrants to the 2020 Noteholders for the accrued interest portion of amounts due.

Second bridge financing

On March 24, 2021, Quoin and the Investor entered into the Bridge Securities Purchase Agreement (“Bridge SPA”), pursuant to which, among other things, the Investor agreed to purchase from Quoin notes in an aggregate principal amount of \$5.0 million (“Bridge Notes”) (in exchange for an aggregate purchase price of \$3.75 million). Pursuant to the terms of the Bridge SPA, the Investor agreed to purchase the Bridge Notes in three closings: (i) the first closing for \$2.0 million in aggregate principal amount (in exchange for an aggregate purchase price of \$1.50 million), which closed on March 25, 2021; (ii) the second closing for \$1,666,666.67 in aggregate principal amount (in exchange for an aggregate purchase price of \$1.25 million), which closed on April 23, 2021; and (iii) a third closing for \$1,333,333.34 in aggregate principal amount (in exchange for an aggregate purchase price of \$1.0 million), which closed on May 24, 2021. The Bridge Notes bore interest at a rate of 15% per annum (25% premium upon the occurrence of an event of default thereunder) and were repayable upon the earlier of (i) December 25, 2021, (ii) the date on which Quoin’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 Notes are secured by a lien on all of Quoin’s assets.

The Bridge Notes were offset against the purchase price under the Securities Purchase Agreement and converted into up to 1,257,721 ADS’s (as adjusted for the Merger exchange ratio, and including shares held in escrow for the benefit of the investor) upon closing of the Securities Purchase Agreement.

Warrants

Pursuant to the Bridge SPA, the Investor was entitled to Bridge Warrants to purchase Quoin shares of common stock having an aggregate value of \$5.0 million and with an initial exercise price reflecting a \$56.25 million fully-diluted pre-Merger valuation of Quoin, subject to certain downward adjustments. Pursuant to the Merger Agreement, the Bridge Warrants were exchanged for Exchange Warrants, as described above.

Commercial bank financing arrangement

The Company has entered into a non-binding letter of intent for a venture loan from a commercial bank. Draw downs on this facility will be dependent upon the Company meeting certain clinical and financing milestones and entering into a binding definitive agreement with the bank. No draw downs have occurred through the date of issuance of these financial statements.

Licensing agreements

Quoin entered into (i) a License and Distribution Agreement, dated as of November 5, 2021 (the “AFT License Agreement”), and (ii) a Supply Agreement, dated as of September 15, 2021 (the “AFT Supply Agreement”), with AFT Pharmaceuticals Ltd., a New Zealand company (“AFT”). Under the terms of the AFT License Agreement, AFT has exclusive rights to commercialize pharmaceutical product QRX003 (the “Product”) in Australia and New Zealand, upon the receipt of regulatory approvals in both territories. Upon approval and launch of the Product, Quoin will be entitled to a 20% royalty on net sales of the Product in Australia and New Zealand. Under the AFT Supply Agreement, Quoin is obligated to manufacture and supply the Product to AFT.

Quoin entered into (i) a License and Distribution Agreement (the “Genpharm License Agreement”) and (ii) a Supply Agreement (the “Genpharm Supply Agreement”), each dated as of November 7, 2021, with Genpharm Services FZ LLC, a United Arab Emirates company (“Genpharm”). Under the terms of the Genpharm License Agreement, Genpharm has exclusive royalty-free rights to commercialize the Product in the Middle East and North Africa region, upon the receipt of regulatory approvals in both territories. Under the Genpharm Supply Agreement, Quoin is obligated to manufacture and supply the Product to Genpharm.

Quoin entered into a Distribution Agreement (the “Distribution Agreement”) with Orpharm LLC (“Orpharm”), dated December 15, 2021. Under the terms of the Distribution Agreement, Orpharm has exclusive royalty-free rights to commercialize the Product in Russia and CIS region, upon the receipt of regulatory approvals in these territories. Under the Distribution Agreement, Quoin is obligated to supply the Product to Orpharm.

Going Concern

Our financial statements have been presented on the basis that the Company is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have not generated any revenues from operations since inception, and do not expect to do so in the foreseeable future. We have experienced operating losses and negative operating cash flows since inception, and expect to continue to do so for at least the next few years. We have financed our working capital requirements to date by our founders personally paying for Company expenses, the issuance of the bridge notes and the Private Placement transaction discussed above. On September 30, 2021, we had cash totaling approximately \$653,000 and an accumulated deficit of approximately \$16.3 million. Management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern for at least one year from the date the accompanying financial statements were issued.

Our ability to continue as a going concern is dependent on our ability to raise additional capital to fund our business activities, including our research and development programs. Our objective is to develop and commercialize therapeutic products that treat rare and orphan diseases, but there can be no assurances that we will be successful in this regard. As a result of the Merger, we may raise capital through additional issuances of ordinary shares or notes of Quoin Ltd. In addition, we may negotiate and draw down on the commercial bank financing arrangement. However, we may not be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund our future operating requirements. If we are unable to obtain sufficient capital to fund our operations, we may be forced to reduce or discontinue our operations entirely. Our financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Because we are currently engaged in research at a relatively early stage, it will take a significant amount of time and resources to develop any product or intellectual property capable of generating sustainable revenues. Accordingly, our business is unlikely to generate any sustainable operating revenues in the next several years, and may never do so. In addition, to the extent that we are able to generate operating revenues, there can be no assurances that we will be able to achieve positive earnings and operating cash flows.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, valuation allowance on deferred tax assets and valuation of intangible assets. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Form 6-K.

Financial Operations Overview

Since our incorporation, our operations have primarily been limited to licensing assets and seeking financing required for our clinical programs. We did not raise any external financing until October 2020.

The following table sets forth our results of operations for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020:

Nine months ended September 30,

	2021	2020	Change
Operating Expenses			
General and administrative	\$ 2,525,366	\$ 949,143	\$ 1,576,223
Research and development	556,064	127,922	428,142
Total operating expenses	3,081,430	1,077,065	2,004,365
Other Expenses			
Fair value adjustment to bridge note payable	1,250,000		1,250,000
Warrant liability expense	4,522,844		4,522,844
Financing expense	275,000		275,000
Interest expense	516,276		516,276
Total other expenses	6,564,120		6,564,120
Net loss	(9,645,550)	(1,077,065)	(8,568,485)

The following table sets forth our results of operations for the three months ended September 30, 2021, compared to the three months ended September 30, 2020:

Three months ended September 30,

	2021	2020	Change
Operating Expenses			
General and administrative	\$ 1,042,783	\$ 302,123	740,660
Research and development	259,996	26,010	233,986
Total operating expenses	1,302,779	328,133	974,646
Other Expenses			
Fair value adjustment to bridge note payable	-	-	-
Warrant liability expense (income)	(146,808)	-	(146,808)
Financing expense	-	-	-
Interest expense	248,165	-	248,165
Total other expenses	101,357		101,357
Net loss	(1,404,136)	(328,133)	(1,076,003)

Revenue

We have not generated, and we do not expect to generate, any revenue from the sale of any products unless or until we obtain regulatory approval of and commercialize any of our products.

Research and development expenses

Research and development expenses include the use of 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 CROs and clinical investigators, based on its estimates of service performed and costs incurred.

Our research and development expenses during the nine months ended September 30, 2021 and September 30, 2020 were approximately \$556,000 and \$128,000, respectively, representing an increase of \$428,000, or approximately 230%. Our research and development expenses during the quarter ended September 30, 2021 and September 30, 2020, were approximately \$260,000 and \$26,000, respectively, representing an increase of approximately \$234,000, or approximately 890%. The increase in both periods was primary due to increased expenditures on our development programs. We expect to significantly increase our research and development efforts by conducting the remaining studies necessary for the development and approval of QRX003. We entered into a \$3,500,000 commitment with a vendor for research and development services in November 2020. 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 two founders who have an aggregate fixed combined salary and benefits of approximately \$1.0 million per year and professional fees, and other corporate expenses. General and administrative expenses were approximately \$2.5 million and \$0.9 million, in the nine months ended September 30, 2021 and September 30, 2020, respectively, representing an increase of \$1.6 million, or 166%. General and administrative expenses were approximately \$1.0 million and \$302,000 in the quarter ended September 30, 2021 and September 30, 2020, respectively, representing an increase of \$741,000 or 245%. The increases in both periods were primarily related to professional fees associated with the Merger.

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.

Amortization of intangible assets

We amortize licensed or acquired intellectual property over its expected useful life. The license from Skinvisible was obtained in October 2019. Amortization of intangible assets was \$78,000 in each of the nine months ended September 30, 2021 and September 30, 2020. Amortization of intangible assets was \$26,000 in each of the three months ended September 30, 2021 and September 30, 2020.

Interest expense

In the fourth quarter of 2020, we issued convertible promissory notes in an initial bridge financing with an aggregate face value of \$1,213,333 (the “2020 Notes”) with a 20% coupon interest and in the nine months ended September 30, 2021 we issued additional convertible promissory notes in a subsequent bridge financing (the “Bridge Notes”) with an aggregate face value of \$5,000,000 with a 15% coupon interest. Interest expense was \$516,000 and \$248,000 in the nine and three months ended September 30, 2021, respectively. We did not have any interest expense in the nine months ended September 30, 2020.

Fair value adjustment to convertible notes payable

The Company elected to value the 2020 Notes and the Bridge Notes at fair value, which will be remeasured at each reporting period. In the nine months ended September 30, 2021 and in the quarter ended September 30, 2021 we incurred a fair value adjustment of \$1,250,000 and \$0, respectively, related to the Bridge Notes. We did not have any such expense in the three and nine months ended September 30, 2020.

Warrant liability expense

The Company records its warrants at fair value, which will be remeasured at each reporting period. In nine months ended September 30, 2021 and the quarter ended September 30, 2021, we incurred a fair value adjustment of \$4,523,000 and \$(147,000), respectively, related to the warrants associated with the 2020 Notes and Bridge Notes. We did not have any such expense in the nine months and the quarter ended September 30, 2020.

Equity-Based Compensation Expense

We have not issued stock options to purchase our common stock to employees and consultants. We expect to approve a stock option plan and issue stock options in 2022.

Income Taxes

For the nine and three months ended September 30, 2021 and 2020, no income tax expense or benefit was recognized. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Net Loss

We recorded a net loss of \$9.6 million in for the nine months ended September 30, 2021, as compared to a net loss of \$1.1 for the nine months ended September 30, 2020, representing an increase of \$8.6 million. We recorded a net loss of \$1.4 million in the quarter ended September 30, 2021, as compared to a net loss of \$328,000 for the quarter ended September 30, 2020, representing an increase of \$1.1 million. The increase in net loss in each period was primarily due to financing related charges aggregating \$6.6 million and \$101,000 in the nine and three month periods ended September 30, 2021, as well increases in research and development expense and general and administrative expense in both the nine and three month periods as the Company used more resources to develop and implement its business plan.

Liquidity and Capital Resources

Overview

For the period from inception through September 30, 2021, we had an accumulated deficit of \$16.3 million. As of September 30, 2021, we had cash of \$653,000. We do not expect to have positive cash flow for the foreseeable future. On October 28, 2021 we completed the Merger and the Primary Financing providing for up to \$25.25 million in funding from the Investor, inclusive of the convertible Notes issued under the Bridge SPA that were converted and assuming the mandatory exercise of Series C Warrants. Management estimates that actual funding received to date under the Bridge SPA and Purchase Agreement will provide funding for our ongoing business activities into the third quarter of 2022, unless the warrants are exercised or the Company is able to execute and draw down on its expected banking facility. However, we have based this estimate on assumptions that may change and we may deplete our capital resources sooner than we expect. Obtaining additional financing to support the research and development of the Company’s therapeutic targets and its other operating requirements are necessary for the Company to continue operations. If the Company is unable to obtain additional funding, the development of its product candidates will be impacted and the Company would likely be forced to delay, reduce, or terminate some or all of its development programs, all of which could have a material adverse effect on the Company’s business and the financial statements. For these reasons, there is substantial doubt about our ability to continue as a going concern for at least twelve months from the date the accompanying financial statements are issued and filed.

We expect to continue to incur significant and increasing operating losses at least for the foreseeable future. We do not expect to generate product revenue unless and until we successfully complete development of and obtain regulatory approval for QRX003, or any other future products. 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 increase substantially in 2022 as we advance the clinical development of QRX003 and begin to operate as a publicly traded company.

Future Funding Requirements

We will need to obtain further funding through other 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, 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 equity or convertible debt securities of Quoin Ltd., the ownership interest of equityholders of Quoin Ltd. will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of equityholders of Quoin Ltd. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting Quoin Ltd.'s 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

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2021 and 2020.

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	\$ (2,541,281)	\$ (795,518)
Net cash used in investing activities	(375,000)	—
Net cash provided by financing activities	3,245,241	795,518
Net increase in cash and cash equivalents	\$ 328,961	\$ -

Cash Flows from Operating Activities

Net cash used in operating activities was \$2.5 million and \$796,000 for the nine months ended September 30, 2021 and 2020, respectively, representing an increase of \$1.7 million or approximately 219%. The increase was primarily due to payment of professional fees and payment of salaries to the two founders.

Cash Flows used in Investing Activities

Net cash used in investing activities was \$375,000 for the nine months ended September 30, 2021, and represents payments under the Skinvisible license agreement. We did not have any cash flows from investing activities for the nine months ended September 30, 2020.

Cash Flows from Financing Activities

Net cash from financing activities was \$3.2 million and \$796,000 during the nine months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021, such amounts represent proceeds from the issuance of Bridge Notes, offset in part by payment of deferred offering costs and other deferred costs. In the nine months ended September 30, 2020, the founders of the Company funded the business through advances made by the founders to the Company of \$796,000. For the nine months ended September 30, 2021, the Company has begun to make partial payment of amounts due to Company officers, with a net decrease in the due to founders of \$15,000.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

Regarding our contractual obligations and commitments under our agreement with Skinvisible, see Note 7 to the financial statements.

Research consulting agreements:

The Company entered into two consulting agreements with Axcella Research LLC to provide regulatory and pre-clinical/clinical services to the Company with respect with QRX003 and QRX004. The combined fees of the two agreements are approximately \$270,000, payable as milestones under the two agreements are met. Further, the Company has two options to pay the milestone due (i) one half in equity of the Company (at a pre-negotiated valuation) and one-half in cash or (ii) entirely in cash, at a discount of approximately 20%. The Company recognized research and development expenses for services provided and milestones met of \$34,690 and \$49,890 for the three months ended September 30, 2021 and 2020, respectively. The Company recognized research and development expenses for services provided and milestones met of \$85,292 and \$80,112 for the three months ended September 30, 2021 and 2020, respectively. The Company accrued expenses of \$85,292 and \$105,052 at September 30, 2021 and December 31, 2020, respectively.

In November 2021, the Company entered into a commitment for research related services of approximately \$250,000.

The Company entered into a consulting agreement in November 2020 for clinical and pre-clinical services aggregating \$3,500,000, payable as specified services are incurred. The agreement is cancellable upon 90-day notice. For the three and nine months ended September 30, 2021, the Company incurred approximately \$26,000 and \$200,000 of research and development costs from such vendor.

Other Consulting agreements:

The Company entered into a consulting agreement with an investor relations firm, which provides for a monthly fee of \$14,000. The agreement has an automatic annual renewal clause and has been in effect since November 2017. The Company continues to receive services and make monthly payments, but owed such firm \$528,000 as of September 30, 2021 and December 31, 2020, which is included in accrued expenses in the Company balance sheet.

Employment agreements:

The employment agreements entered into by the Company with its two founders and executive officers provides for a combined base salary, including monthly allowances, of \$996,000 per annum, a discretionary bonus and certain allowances and benefits. In the event of termination of the two founders and executive for reason other than cause, as defined in the employment agreements, the founders are entitled to two years of base salary and bonus. In November 2021, the Board of Directors of the Company approved amendments to the employment agreements disclosed in Note 11 setting base level compensation and bonus terms. Further a transaction bonus related to the Merger aggregating approximately \$324,000 was paid to the two founders in November 2021.

In November 2021, the Company appointed and entered into an employment agreement with its Chief Financial Officer which provides for a base salary of \$360,000 per annum, a discretionary bonus and certain allowances and benefits.

Other Research and consulting agreement:

The Company entered into a research and consulting agreement (the "Research Agreement") which requires the Company to pay the former owner of Polytherapeutics (the "Consultant") to transfer the technical know-how of Polytherapeutics with respect to (i) good manufacturing practices ("GMP"), clinical and commercial manufacturing of the Company's PolyDur polymer and (ii) formulation development of products utilizing the Company's PharmaDur polymer. The agreement required monthly consulting payments of \$20,833 beginning on July 31, 2018 and ending February 28, 2021 (the "Post-Closing Period") for a total commitment of \$666,667 over the consulting period. Pursuant to an amendment to such agreement, the Post-Closing Period was revised to terminate on December 31, 2020. The Company will not be required to make the monthly payments under the consulting agreement if the Consultant does not provide or stops providing consulting services as described in the research consulting agreement.

If the Company fails to make monthly payments under the Consulting Agreement or royalty payments, the Consultant has the option to buy back all the rights to certain products covered by the Acquisition Agreement for \$1.00, and the Company is no longer required to make the remaining payments during the Post-Closing Period. Further, if the Company fails to enter a product covered by the Acquisition Agreement into clinical development by the end of the Post-Close Period, the Consultant has the option to buy the rights to commercialize said products for \$100,000.

As of September 30, 2021, there were no products utilizing this technology in clinical development. The Consultant has not communicated any intent to buy the product from the Company as of the financial statement issuance date. Through September 30, 2021 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.

In February 2020, the Consultant and seller of the equity interests in Polytherapeutics communicated with the Company threatening litigation for non-payment and related breach of contract and immediate payment of all monthly payments in the amount of \$666,667. The Company believes that the Consultant has not provided any services and other technical requirements under the Agreements, and therefore is 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 no revised agreements have yet been reached and no legal proceedings have been commenced as of the date hereof. The Company believes that its maximum exposure is the full amount of the payments under the Consulting Agreement (i.e. \$667,000), although the timing of such payments and the commencement date and number of months that the Consultant may have to work may be subject to re-negotiation. Should a lawsuit be filed, the Company believes it has meritorious defenses.

Recently Issued Accounting Pronouncements

Accounting Pronouncements Yet to be Adopted

The Company has evaluated all recent accounting pronouncements and believes that none of them will have a material effect on the Company's financial position, results of operations or cash flows except as discussed below.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*" which replaces the existing guidance in ASC 840 - *Leases*. This ASU requires a dual approach for lessee accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset and for operating leases, the lessee would recognize a straight-line total lease expense. This ASU is effective for fiscal years beginning after December 15, 2021 and for interim periods within those fiscal years. The Company will evaluate the impact of adoption of this ASU when it enters into a lease arrangement.

The FASB recently issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470- 20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, to reduce complexity in applying GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in stockholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in ASC 260, *Earnings Per Share*, to require entities to calculate diluted earnings per share (EPS) for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for public entities that meet the definition of an SEC filer, excluding smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact this standard will have on its financial statements.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Market Risk Considerations

As of September 30, 2021, we had cash of \$653,000.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2021 and 2020.

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

We were a private company and our common stock was not listed or traded on any public market as of September 30, 2021. Immediately after the completion of the Merger, Collect changed its name to "Quoin Pharmaceuticals Ltd." and began trading on the Nasdaq Capital Market under the symbol "QNRX" on October 29, 2021.
