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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 June 2022 (No. 3)

Commission File Number 001-37846

**QUOIN PHARMACEUTICALS LTD.**  
(Translation of registrant's name into English)

**Azrieli Center, Round Tower, 30<sup>th</sup> Floor**  
**132 Menachem Begin Blvd**  
**Tel Aviv, 6701101**  
(Address of principal executive offices)

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

Form 20-F  Form 40-F

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

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

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## EXPLANATORY NOTE

### *Business Updates*

Quoin Pharmaceuticals Ltd. (the “Company”) is an emerging specialty pharmaceutical company dedicated to developing products that help treat rare and orphan diseases for which there are currently no approved treatments. The Company’s initial focus is on the development of products, using its proprietary owned and in-licensed technology, that could help address rare skin diseases for which there are currently no approved treatments or cures. Its 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. In addition, the Company intends to pursue the clinical development of QRX003 in other rare dermatological diseases, including Peeling Skin Syndrome, SAM Syndrome, and Palmoplantar Keratoderma. The Company’s three other pipeline products in development are also targeting rare skin diseases, including Epidermolysis Bullosa, Netherton Syndrome and Scleroderma.

The Company announces material financial information to its investors using its investor relations website (<https://investors.quoinpharma.com/>), SEC filings and press releases. The Company uses these channels as well as social media to communicate with the public about the Company, its products and other issues. It is possible that the information the Company posts on social media could be deemed to be material information. Therefore, the Company encourages investors, the media and others interested in the Company to review the information the Company posts on the U.S. social media channels listed below. This list may be updated from time to time on the Company’s investor relations website.

The Company’s LinkedIn Page (<https://www.linkedin.com/company/quoin-pharmaceuticals/>)  
The Company’s Twitter Account (@Quoinpharma)

### *License and Distribution Agreement*

On June 14, 2022, Quoin Pharmaceuticals, Inc., a wholly-owned subsidiary of the Company, entered into a License and Distribution Agreement (the “License Agreement”) with WinHealth Investment (HK) Limited (“WinHealth”). Under the terms of the License Agreement, WinHealth has the exclusive rights to commercialize, upon the receipt of applicable regulatory approvals, pharmaceutical products QRX003 and QRX004 (in finished dosage form for human use) in Greater China, including Hong Kong, Macau and Taiwan.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of such License 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) and on Form F-3 (Registration Nos. 333-219614, 333-229083 and 333-265596).*

### *Exhibits*

<b>Exhibit No.</b>	<b>Exhibit</b>
<a href="#">10.1</a>	<a href="#">License Agreement, dated June 14, 2022, by and between Quoin Pharmaceuticals, Inc. and WinHealth Investment (HK) Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F)</a>

**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: June 16, 2022

**QUOIN PHARMACEUTICALS LTD.**

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

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**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**

**LICENSE AND DISTRIBUTION AGREEMENT**

This License and Distribution Agreement (this “**Agreement**”), dated as of June 14, 2022 (“**Effective Date**”), is by and between by and between Quoin Pharmaceuticals, Inc., a Delaware corporation located at 42127 Pleasant Forest Court, Ashburn, VA 20148 (“**Quoin**”) and WINHEALTH INVESTMENT (HK) LIMITED, a company incorporated under the laws of Hong Kong located at Unit 2512, 25/F., Seapower Tower, Concordia Plaza, No.1 Science Museum Road, Kowloon, Hong Kong (“**DISTRIBUTOR**”) (“**Licensee**”). Quoin and Licensee are sometimes referred to herein individually as a “**Party**,” and together as the “**Parties**.”

**Recitals**

**WHEREAS**, Quoin owns certain Product Technology with respect to the Product (as defined herein).

**WHEREAS**, Quoin wishes to grant to Licensee, and Licensee desires to accept, an exclusive license under the Product Technology for Licensee to obtain the Regulatory Approvals and Exploit the Product in the Territory, in accordance with the terms and conditions set forth herein.

**INTENDING TO BE LEGALLY BOUND**, in consideration of the foregoing and the mutual agreements contained herein and subject to the satisfaction of the terms and conditions set forth herein, the parties hereto agree as follows:

**SECTION 1. DEFINED TERMS**

Capitalized terms used in this Agreement and not specifically defined shall have their respective meanings set forth on Exhibit 1 attached hereto, which Exhibit 1 is hereby incorporated into this Agreement and made a part hereof by reference.

**SECTION 2. LICENSE AND EXCLUSIVITY**

**2.1 License to Licensee.** Subject to the terms and conditions of this Agreement, Quoin hereby grants to Licensee an exclusive (even as to Quoin and its Affiliates) royalty-bearing license under the Product Technology to Exploit the Product in the Territory, which license shall not be sublicensable to any third party without Quoin’s prior written consent, except to its Affiliates.

**2.2 Retained Rights.** Quoin retains all rights to the Product Technology that are not licensed to Licensee hereunder, including the exclusive right to Exploit the Product outside the Territory.

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### **2.3 Non-Competition.**

**2.3.1.** During the Term, Quoin shall not, in any capacity, whether directly, indirectly or through Affiliates, for its own account or for the benefit of any person or Entity, engage in the research, development, manufacture, promotion, sale or distribution of the Product for sale in the Territory unless authorized in writing by Licensee; provided, however, that nothing herein shall restrict Quoin from performing its obligations pursuant to this Agreement or the Supply Agreement or from Exploiting the Product outside the Territory.

**2.3.2.** During the Term, Licensee shall not, in any capacity, whether directly, indirectly or through Affiliates, for its own account or for the benefit of any person or Entity, engage in the development, manufacture, supply, promotion, sale or distribution of a Competing Product for sale in the Territory unless authorized in writing by Quoin.

**2.3.3.** The Parties hereto agree that any breach by either Party of the covenants and agreements contained in this Section 2.3 may result in irreparable injury to the other Party for which money damages could not adequately compensate it and, therefore, in the event of any such breach, the non-breaching Party shall be entitled (in addition to any other rights and remedies which it or they may have at law or in equity) to seek an injunction from any competent court of equity to enjoin and restrain the breaching Party and any other person or entity involved therein from continuing such breach.

**2.3.4.** If any portion of the covenants and agreements contained herein, or the application thereof, is construed to be invalid or unenforceable, then the other portions of such covenant(s) or agreement(s) or the application thereof shall not be affected and shall be given full force and effect without regard to the invalid or unenforceable portions. If any covenant or agreement herein is held to be unenforceable because of the area covered, the duration thereof, or the scope thereof, then the court making such determination shall have the power to reduce the area and/or duration and/or limit the scope thereof, and the covenant or agreement shall then be enforceable in its reduced form.

### **SECTION 3. REGULATORY APPROVAL IN THE TERRITORY**

**3.1** Licensee shall use Commercially Reasonable Efforts to obtain all required Regulatory Approvals for the Product for the Initial Indication as soon as reasonably possible following the Effective Date.

Quoin shall be the applicant and owner of Regulatory Approvals in the Territory in the mainland China due to the restriction of the Applicable Laws and the Licensee shall serve as the domestic legal representative for the Product. Whenever and wherever Licensee or its Affiliate is allowed to hold the Regulatory Approval including the marketing authorization holder of the Product by Applicable Laws, Quoin shall support or transfer such holder of the Regulatory Approval, no matter in the application stage or being approved, to Licensee or its designated Affiliate. Notwithstanding above, in the regions where Licensee or its Affiliate is permitted to directly serve as the holder for the Regulatory Approval, including the marketing authorization holder, Quoin shall support Licensee to apply and hold such Regulatory Approval directly.

**3.2** Licensee shall be responsible for all aspects of preparing, obtaining, and maintaining throughout the Term, at Licensee's cost and expense, the Regulatory Approvals in Licensee's name, including setting the overall regulatory strategy therefor and conducting communications with Governmental Authorities. Licensee shall determine what information or documentation may be required to complete any forms or applications necessary to file for the Regulatory Approvals for the Product. For the avoidance of doubt, Licensee shall be responsible for the cost and expense associated with any further development which may be required in connection with securing the Regulatory Approvals, including any supplemental clinical trials. Subject to the foregoing, upon request from Licensee, Quoin will provide to Licensee necessary assistance and information that is in the possession of Quoin as necessary for Licensee to obtain such Regulatory Approvals as below ("Necessary Support"):

- (a) Quoin shall provide any and all necessary regulatory support to Licensee for information required by the Regulatory Authorities, which may include, but is not limited to any and all technical documents, materials, data and information of the CMC, non-clinical studies and clinical studies of the product in accordance with the requirements and format under ICH M4 provided always that Quoin will only be able to provide such information to the extent that the said items are available to Quoin. Quoin shall use its commercially reasonable effort to facilitate that the suppliers of the API, excipients and packaging materials (container closure system) of the Product will provide assistance, such as conduct DMF filing in the Territory if and as required by the Regulatory Authorities. Quoin shall assist Licensee in solving any technical issues during the IND and/or NDA review once any deficiency letter is issued by the Regulatory Authority, provided that Quoin can only provide information which it has available. Quoin shall upon Licensee's request participate in the communication meetings requested by the Regulatory Authority or other competent authorities in the Territory. Quoin shall on its cost provide all necessary samples and reference standards used for drug testing and clinical trials.
- (b) Once any deficiency letter is issued with regards to the manufacturing, specification, analytical procedure and stability of the product during IND and/or NDA review process in the Territories of Registration, Quoin shall use its commercially reasonable effort to conduct necessary manufacturing related studies in order to meet the authorities' registration requirements in case that such studies have to be performed in the manufacturing sites. Quoin shall use commercially reasonable efforts to improve the manufacture process and quality control as per the Regulatory Authorities' registration requirements accordingly.

Licensee will deliver to Quoin any data or information related to the Product generated for purposes of submission of the Regulatory Approvals, and an electronic copy of the applications for Regulatory Approvals upon submission.

**3.3** Licensee shall use Commercially Reasonable Efforts to file for the Regulatory Approvals for the Product for the Initial Indication in the Territory within eighteen (18) months following the date of Quoin receiving regulatory approval for such Initial Indication in either the United States or European Union, in the event that clinical trial waiver is issued by NMPA and the Product dossier provided by Quoin meets the requirements of NMPA. In the event that Licensee determines that the Data Package is not sufficient to obtain the Regulatory Approvals, and the additional information and documentation required makes it unlikely that the Licensee will be able to file for the Regulatory Approvals within such eighteen-month period, Licensee shall promptly notify Quoin and the Parties will discuss a reasonable timeline for Licensee to compile the necessary information and documentation and submit the filings for the Regulatory Approvals.

**3.4** If Licensee does not file for the Regulatory Approvals (in a form reasonably likely to be approved) for the Initial Indication with applicable Governmental Authorities in the Territory within eighteen (18) months following the date of Quoin receiving regulatory approval in either the United States or the European Union according to Section 3.3, or such later date as agreed upon by Quoin, Quoin may terminate this Agreement in accordance with Section 11.2.2 hereof, provided that Quoin has provided Necessary Support under Section 3.2. If the Regulatory Approvals for the Initial Indication have not been granted by the applicable Governmental Authorities in the Territory on or before such date which is [36 months] after the date of filing such Regulatory Approvals or such later date as agreed upon by Quoin, both Parties shall negotiate in good faith on the extension of such period, provided that Quoin has provided Necessary Support under Section 3.2 and WinHealth has used Commercially Reasonable Efforts to acquire the Regulatory Approval.

**3.5** In the event that Quoin obtains regulatory approval for any Additional Indication for the Product in the United States or the European Union, Licensee will use Commercially Reasonable Efforts to obtain, as promptly as practicable (but in any event within [18] months following such approval in the United State or the European Union), any Regulatory Approvals required to permit the Commercialization of the Product in the Territory for such Additional Indication. If the Regulatory Approvals for such Additional Indication have not been granted by the applicable Governmental Authorities in the Territory on or before such date which is [36 months] after the date of filing such Regulatory Approvals or such later date as agreed upon by Quoin, both Parties shall negotiate in good faith on the extension of such period, provided that Quoin has provided Necessary Support under Section 3.2 and WinHealth has used reasonable efforts to acquire the Regulatory Approval.

## SECTION 4. COMMERCIALIZATION

**4.1 Launch.** So long as the Launch Quantities are delivered in accordance with the terms of the Supply Agreement, which shall be signed within twelve month before the receipt the Regulatory Approval for the Initial Indication from the Regulatory Authorities in the Territory. Licensee shall Launch the Product in the Territory within [6] months following receipt of approval of the Regulatory Approvals for the Initial Indication from the Governmental Authorities in the Territory provided that Quoin deliver the Products to the Licensee within 2 months after receipt of the Regulatory Approval in the Territory. In the event that Licensee does not Launch the Product within such time period, Quoin may terminate this Agreement in accordance with Section 11.2.2.

**4.2 Commercialization.** Licensee shall market, promote, sell, and otherwise commercialize the Product in the Territory during the Term. Licensee shall use Commercially Reasonable Efforts to maximize Net Sales in the Territory. Licensee shall not sell the Product bundled or in combination with any other product without Quoin's prior written consent.

### **4.3 Sales Efforts.**

**4.3.1.** The Licensee shall submit Annual Marketing Plan to the JSC. If, within three years following Launch of the Product in the Territory, the JSC determines with proper evidence that Licensee is not using Commercially Reasonable Efforts to maximize Net Sales in the Territory, the Parties will meet promptly following notice thereof from Quoin to discuss and approve a remediation plan for Licensee to increase its efforts to market, promote, sell, and otherwise commercialize the Product in the Territory, including sales targets. If the Parties are unable to reach an agreement with respect to the aforementioned plan according to the forecast determined by JSC for twelve (12) months, Quoin may terminate this Agreement upon written notice to Licensee.

**4.3.2.** If Licensee applies for Regulatory Approval for the Product for an indication other than for the treatment of a rare disease or condition, Licensee will prepare and deliver to Quoin, for Quoin's review, input, and approval, a commercialization plan, which plan will describe the anticipated commercialization activities for such indication in the Territory, including key tactics and specific resources for implementing those commercialization activities, a [three-year] sales forecast, and any other information necessary for the successful commercial Launch and subsequent commercialization of the Product for such indication in the Territory. Quoin will give Licensee the opportunity to consider and respond to Quoin's comments on the commercialization plan. Quoin shall not unreasonably withhold its approval of the commercialization plan.

**4.4 Supply.** The parties shall negotiate in good faith the terms of a supply agreement (which shall include applicable quality and pharmacovigilance provisions) pursuant to which Quoin will manufacture and supply, or have manufactured and supplied, to Licensee the Product for sale in the Territory during the Term (the "**Supply Agreement**"). Licensee and its affiliates shall purchase all of their requirements for the Product from Quoin.



**SECTION 5. FINANCIAL PROVISIONS**

**5.1 Royalty.**

**5.1.1. Royalty.** Commencing on the Launch of the Product in the Territory and during the Term of this Agreement, Licensee shall pay to Quoin [twenty percent (20%)] of Net Sales (the “**Royalty**”). For the avoidance of doubt, Quoin shall not be required to make any payments to Licensee to the extent Net Sales for any period is negative.

<u>Net Sales in the entire Territory during a Calendar Year:</u>	<u>Royalty Rate as a Percentage of Net Sales in the respective year</u>
[***]	[***]
[***]	[***]
[***]	[***]

**5.1.2. Payment of Royalty; Audits; Records.** Within thirty (30) business days after the expiration of each calendar quarter during the Term (including the first and last quarters during such period that may be of lesser duration), Licensee shall deliver to Quoin a statement for such quarter showing (i) the calculation of Net Sales for the Product sold by Licensee during such quarter, and (ii) the Royalty for the Product on such sales. Licensee shall pay any Royalty due to Quoin along with the delivery to Quoin of the statement showing such calculation. In order to verify quarterly reports, Quoin or its authorized representative shall be entitled, during normal business hours and upon reasonable prior written notice to Licensee, to have access to the books and records of Licensee directly related to the calculation of the Royalty. If the inspection reveals that the Royalty has been incorrectly calculated with evidence provided to Licensee, then any underpayment shall be paid by Licensee and any overpayment shall be paid by Quoin within fifteen (15) calendar days of such determination. The costs of any such inspection shall be borne by Quoin except when the inspection reveals an underpayment to Quoin of five percent (5%) or more, in which case Licensee shall reimburse Quoin for the actual out-of-pocket costs of the inspection.

**5.1.3. Manner and Place of Payment.** All payments owed by Licensee under this Agreement shall be made in United States Dollars (\$US) by wire transfer in immediately available funds to a bank and account in the United States designated in writing by Quoin.

**5.1.4. Late Payments.** If Quoin does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of prime plus two (2) percentage points or the maximum rate allowable by Applicable Laws, whichever is less.

**5.2 Taxes.** The amounts paid by Licensee to Quoin hereunder shall be paid without any reduction or setoff and without reduction for any withholding taxes. Quoin shall be solely responsible for paying any and all of its own taxes.

**5.3 Currency.** All dollar amounts stated in this Agreement are stated in United States' currency, and all payments required under this Agreement shall be paid in United States' currency.

## SECTION 6. INTELLECTUAL PROPERTY

**6.1 Ownership.** The Product Technology shall at all times be and remain the sole property of Quoin subject to the rights granted herein. All Inventions generated, developed, conceived or reduced to practice by Licensee or on the behalf of Licensee related to *[insert the name of the active ingredient]* are hereby assigned to Quoin. Nevertheless, Quoin hereby grants WinHealth an exclusive, royalty-free, perpetual, irrevocable license to use such IP in the Territory. Licensee shall execute all documents necessary or reasonably requested to effect the assignment of the entire right, title and interest to such Inventions to Quoin.

**6.2 Product Patents.** Quoin shall have the sole right to enforce the Product Patents in the Territory, and shall retain any damages or other amounts collected in connection therewith. Licensee will not take any actions that would challenge Quoin's ownership in the Product Patents, or contest the validity of the Product Patents. Such actions would be considered a breach of the Agreement.

**6.3 [Product Trademarks.]** Quoin shall maintain the Product Trademark registration in the Territory throughout the Term. All Product sold by Licensee in the Territory shall bear the Product Trademark and Licensee will commercialize the Product in the Territory under the Product Trademark. Furthermore, Licensee shall only use the Product Trademark in connection with Product supplied by Quoin. The nature and quality of the Product advertised or sold by Licensee on which a Product Trademark appears shall conform to quality standards and the specifications specified by Quoin in the Data Package. Licensee agrees to cooperate with Quoin to enable Quoin to verify the nature and quality of the use of the Product Trademarks and that the use of the Product Trademarks is consistent with the agreed quality standards and specifications. Licensee agrees that in using the Product Trademark in its activities under this Agreement, it will not represent in any way that it has any right or title to the ownership of the Product Trademark or the registration therefor. Licensee shall not use the Product Trademark in any way that would diminish, tarnish, disparage, or damage the goodwill in and to the Product Trademark. When using the Product Trademark, Licensee shall comply with all Applicable Laws. Licensee will not take any actions that would challenge Quoin's ownership in the Product Trademark, or contest the validity of the Product Trademark. Such actions would be considered a breach of the Agreement. All goodwill accruing to the Product Trademark as a result of the use of the Product Trademark shall belong solely to Quoin. Licensee shall provide to Quoin prompt written notice of any actual or threatened infringement of the Product Trademark in the Territory and of any actual or threatened claim that the use of the Product Trademark in the Territory violates the rights of any Third Party, of which Licensee becomes aware. Quoin shall the sole right to such action as Quoin deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademark by a Third Party in the Territory at its sole cost and expense and using counsel of its own choice. Quoin shall retain any damages or other amounts collected in connection therewith.]

## SECTION 7. REGULATORY

**7.1** Throughout the Term, Licensee shall maintain at its sole cost and expense the Regulatory Approvals for the Product in full force and effect. Licensee will be responsible for interacting with the relevant Governmental Authorities regarding the Regulatory Approvals. Licensee will provide Quoin with copies of any material correspondence with any Governmental Authority regarding the Product or Regulatory Approvals in the Territory within five (5) business day of receipt of such correspondence. Licensee shall notify Quoin in advance of any meetings with or communications with any Governmental Authority related to the Product to the extent they may impact the Quoin's rights or obligations under this Agreement.

**7.2** The Parties' obligations with respect to exchanging and reporting adverse events and other safety information relating to the Product will be set forth in a Pharmacovigilance Agreement, which will be executed by the Parties at the same time the Supply Agreement is executed.

**7.3** Licensee will comply with all Applicable Laws in the Exploitation of the Product in the Territory and the performance of its obligations under this Agreement. Licensee will maintain all Permits necessary to perform its obligations hereunder in compliance with all Applicable Laws.

### **7.4 Joint Steering Committee.**

**7.4.1. Membership.** Within thirty (30) days after the Effective Date, the Parties will establish a joint steering committee to coordinate activities on which the Parties will collaborate under this Agreement with respect to Product in the Territory (the "Joint Steering Committee" or "JSC"). The JSC shall consist of two (2) representatives from each Party. Each Party will designate one (1) of its representatives as the co-chairperson of the JSC. Each Party may replace its appointed JSC representatives or co-chairperson at any time upon reasonable written notice to the other Party.

**7.4.2. Responsibilities.** The responsibilities of the JSC will be to share information and knowledge on the registration and commercialization of the Product and to discuss regulatory, technical, supply, quality assurance or safety issues in relation to the Product. Once the Product is duly registered within a Territory of Registration in the Territory, the responsibilities of the JSC will also include the review and approval of the Annual Marketing Plan.

**7.4.3. Decision making.** The JSC will use good faith efforts, to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter referred to it by any Subcommittee or any matter that is within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of 20 Business Days, then a Party may refer such matter for resolution to the Chief Executive Officer of Quoin (or an executive officer of Quoin designated by the Chief Executive Officer of Quoin who has the power and authority to resolve such matter) and the Chief Executive Officer of the Licensee (or an executive officer of Partner designated by the Chief Executive Officer of the Licensee who has the power and authority to resolve such matter) (collectively, the "Executive Officers"). The Executive Officers will use good faith efforts to resolve any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

**7.4.4. Final Decision-Making Authority.** If the Executive Officers are unable to reach agreement on any such matter referred to them within 20 days after such matter is so referred (or such longer period as the Executive Officers may agree upon), then

- (a) Quoin as Marketing Authorization Holder. At any time during which Quoin is the Marketing Authorization Holder for the Product in the Territory, Quoin will have final decision-making authority over all decisions related to the Product, unless otherwise agreed to in writing by Albireo.
- (b) Licensee as Marketing Authorization Holder. At any time during which the Licensee is the Marketing Authorization Holder for the Product in the Territory, the Licensee will be decision-making authority except for the Annual Marketing Plan under Section 4.3.2.
- (c) Quoin will have final decision making authority over all decisions related to the Annual Marketing Plan under Section 4.3.

**7.4.5. JSC Meetings.** The JSC will meet at least once per calendar quarter unless the Parties agree to meet more or less frequently. Such meetings may be held in person or by any means of telecommunications or video-conference, as the members deem necessary or appropriate. Meetings of the JSC will be effective only if at least one representative of each Party is present or participating. Each Party will be responsible for all of its own expenses of participating in the JSC meetings should the Parties decide to hold a meeting in person. The Parties will alternate hosting the JSC meeting (whether held in person or by teleconference), and the Party hosting a particular JSC meeting is responsible for preparing and circulating the agenda minimum two (2) weeks in advance of such JSC meeting and circulate the minutes within two (2) weeks upon held meeting.

**SECTION 8. REPRESENTATIONS AND WARRANTIES**

**8.1 Quoin Representation and Warranties.** Quoin represents and warrants to Licensee that:

**8.1.1.** it is duly organized and validly existing under the Applicable Law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

**8.1.2.** it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the Person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

**8.1.3.** this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Applicable Law; and

**8.1.4.** it has not granted, and shall not grant during the Term, any right to any Third Party which would conflict with the rights granted to Licensee hereunder.

**8.1.5.** All of the Product Technology are in full force and effect in the Territory and;

**8.1.6.** To Quoin's Knowledge, WinHealth's use of the Product Technology as contemplated in this Agreement will not breach, violate or contravene any obligation of confidentiality or non-use owed by Quoin or a Third Party.

**8.1.7.** Quoin has not as of the Effective Date granted any right to any Third Party under the Product Technology that would conflict with the rights granted to WinHealth hereunder; and

**8.1.8.** Quoin will not, during the Term, grant any right to any Third Party under the Product Technology that would interfere with the rights granted hereunder.

**8.2 Licensee Representation and Warranties.** Licensee represents and warrants to Quoin that:

**8.2.1.** it is duly organized and validly existing under the Applicable Law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

**8.2.2.** it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the Person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

**8.2.3.** this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Applicable Law;

**8.2.4.** None of Licensee's employees, consultants or contractors: (a) is debarred under Section 306(a) or 306(b) of the Food Drug and Cosmetics Act or by the analogous applicable Laws of any Governmental Authority; (b) has, to Licensee's knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or pursuant to any analogous applicable Laws, or is proposed for exclusion, or is the subject of exclusion or debarment proceedings by a Governmental Authority; or (c) is excluded, suspended or debarred from participation, or is otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs, or is excluded, suspended or debarred by any Governmental Authority from participation, or is otherwise ineligible to participate, in any procurement or nonprocurement programs. Without limiting the foregoing, Licensee hereby represents and warrants, and covenants, as the case may be, that as of the Effective Date and throughout the Term of the Agreement, neither it nor any of its officers, directors or Affiliates is or shall be prohibited by any law, rule or regulation or by any order, directive or policy from manufacturing or selling (as the case may be) pharmaceutical products within the Territory.

**8.3 No Other Representations and Warranties.** EXCEPT FOR THE REPRESENTATIONS OR WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, ORAL OR WRITTEN.

**SECTION 9. CONFIDENTIALITY**

**9.1** At all times during the Term and for a period of ten (10) years following termination or expiration hereof in its entirety, each Party shall and shall cause its officers, directors, employees and agents and sublicensees to, keep confidential and not publish or otherwise disclose to a third party and not use, directly or indirectly, for any purpose, any Proprietary Information furnished or otherwise made known to it, directly or indirectly, by another Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement.

**9.2** Each Party (the “**Receiving Party**”) may disclose Proprietary Information of either of the other Party (each, a “**Disclosing Party**”) to the extent that such disclosure is:

**9.2.1.** made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the Receiving Party’s legal counsel, such disclosure is otherwise required by law, including by reason of filing with securities regulators; *provided, however*, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Proprietary Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided, further*, that the Proprietary Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

**9.2.2.** made by or on behalf of the Receiving Party to the Governmental Authorities as required in connection with any filing, application or request for approval of the Regulatory Approvals or other Permit related to the Exploitation of the Product; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law; or

**9.2.3.** made by or on behalf of the Receiving Party to potential or actual investors, acquirers, licensees or sublicensees as may be necessary in connection with their evaluation of such potential or actual investment, acquisition, license or sublicense; *provided, however*, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Proprietary Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 9.2; *provided, further*, that if either Party seeks to disclose the terms of this Agreement to potential investors, acquirers, licensees or sublicensees, the Party seeking to disclose this Agreement must obtain the other Party’s prior written consent before disclosing this Agreement (such consent not to be unreasonably withheld, delayed or conditioned).

**9.3** No Party shall issue any general press release or make any public statement with respect to this Agreement without the consent of the other Party, except as may be required by Applicable Law or the rules of any applicable stock exchange.

## **SECTION 10. INDEMNIFICATION**

**10.1 Quoin’s Indemnification.** Quoin shall indemnify Licensee and its directors, officers, employees, and agents, and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs, and expenses (including reasonable attorneys’ fees and expenses) (collectively, “**Losses**”) incurred in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, “**Third Party Claims**”) arising from, relating to, or occurring as a result of: (a) the breach by Quoin of this Agreement; (b) the, gross negligence, or willful misconduct on the part of Quoin or its directors, officers, employees or agents in performing its or their obligations under this Agreement; or (c) any claim of infringement or inducement of infringement of the intellectual property rights of any Third Party resulting from the use of the Product Technology in the Exploitation of the Product in the Territory; except, in each case ((a), (b) and (c)), for those Losses for which Licensee has an obligation to indemnify Quoin pursuant to Section 10.2 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

**10.2 Licensee's Indemnification.** Licensee shall indemnify Quoin and its directors, officers, employees, and agents, and defend and save each of them harmless, from and against any and all Losses incurred in connection with any and all Third Party Claims arising from, relating to, or occurring as a result of: (a) the breach by Licensee of this Agreement; (b) the gross negligence, or willful misconduct on the part of Licensee or its directors, officers, employees or agents in performing its or their obligations under this Agreement;; except, in each case ((a), (b) and (c)), for those Losses for which Quoin has an obligation to indemnify Licensee pursuant to Section 10.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

**10.3 Indemnification Procedures.** With respect to each event, occurrence or matter (an "**Indemnification Matter**") as to which Quoin or Licensee, as the case may be (the "**Indemnatee**") is entitled to indemnification from the other Party (the "**Indemnitor**") under this Section 10:

**10.3.1.** Within ten (10) days after the Indemnatee receives written documents underlying the Indemnification Matter or, if the Indemnification Matter does not involve a third party action, suit, claim or demand, promptly after the Indemnatee first has actual knowledge of the Indemnification Matter, the Indemnatee shall give notice to the Indemnitor of the nature of the Indemnification Matter and the amount demanded or claimed in connection therewith ("**Indemnification Notice**"), together with copies of any such written documents.

**10.3.2.** If a third party action, suit, claim or demand is involved, then, upon receipt of the Indemnification Notice, the Indemnitor shall, at its expense and through counsel of its choice, promptly assume and have sole control over the litigation, defense or settlement (the "**Defense**") of the Indemnification Matter, except that (i) the Indemnatee may, at its option and expense and through counsel of its choice, participate in (but not control) the Defense; (ii) if the Indemnatee reasonably believes that the handling of the Defense by the Indemnitor may have a material adverse effect on the Indemnatee, its business or financial condition, or its relationship with any customer, prospect, supplier, employee, salesman, consultant, agent or representative, then the Indemnatee may, at its option and expense and through counsel of its choice, assume control of the Defense, provided that the Indemnitor shall be entitled to participate in the Defense at its expense and through counsel of its choice; (iii) the Indemnitor shall not consent to any Judgment, or agree to any settlement, without the Indemnatee's prior written consent; and (iv) if the Indemnitor does not promptly assume control over the Defense or, after doing so, does not continue to prosecute the Defense in good faith, the Indemnatee may, at its option and through counsel of its choice, but at the Indemnitor's expense, assume control over the Defense. In any event, the Indemnitor and the Indemnatee shall fully cooperate with each other in connection with the Defense including by furnishing all available documentary or other evidence as is reasonably requested by the other.



**10.3.3.** All amounts owed by the Indemnitor to the Indemnitee (if any) shall be paid in full within fifteen (15) business days after a final Judgment (without further right of appeal) determining the amount owed is rendered, or after a final settlement or agreement as to the amount owed is executed.

**10.4 Disclaimer of Certain Losses.** EXCEPT (i) IN THE EVENT OF THE FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTION 9, (ii) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS SECTION 10, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY INDIRECT, INCIDENTAL, PUNITIVE, REMOTE OR SPECULATIVE DAMAGES OR OTHER DAMAGES (INCLUDING LOST PROFITS) THAT ARE NOT PROBABLE AND REASONABLY FORESEEABLE.

**10.6 Insurance.** Licensee shall have and maintain such types and amounts of insurance covering its Exploitation of the Product in the Territory as is (i) normal and customary in the pharmaceutical industry generally for parties similarly situated and (ii) otherwise required by applicable Law. Upon request by Quoin, Licensee shall provide to Quoin evidence of its insurance coverage.

#### **SECTION 11. TERM AND TERMINATION**

**11.1 Term.** This Agreement shall commence on the Effective Date and shall continue in effect for fifteen years from the expiration of the Effective Date, unless earlier terminated in accordance with this Section 11.

**11.2 Early Termination.**

**11.2.1.** The Parties can terminate this Agreement upon mutual written agreement of the Parties.

- to Licensee.
- 11.2.2.** Quoin can terminate this Agreement pursuant to Section 3.4, Section 3.5, Section 4.1, or 4.3 hereof upon written notice
- 11.2.3.** The Licensee can terminate this Agreement by giving one (1) month prior written notice if:
- (a) The performance, and/or the dossier, and/or result of any clinical trial is unable to support the Regulatory Approval for the Product;
  - (b) If Quoin discontinue, reduce or suspend the supply of the Product for a period of more than six (6) consecutive months;
  - (c) If the Product Technology becomes invalid in the Territory leading to the result that the Licensee cannot perform the obligation under this Agreement.

**11.2.4.** Each Party shall have the right to terminate this Agreement upon written notice to the other Party if the other Party has materially breached this Agreement and, after receiving written notification from the terminating Party identifying such material breach in reasonable detail, the breaching Party fails to cure such material breach within thirty (30) calendar days from the date of such notice.

**11.2.5.** Each Party shall have the right to terminate this Agreement upon the filing or institution of any bankruptcy, reorganization, liquidation or receivership proceedings by another Party, or upon the failure by such other Party for more than ninety (90) days to discharge or obtain the dismissal of any such actions filed against it. Such termination shall be effective upon receipt of notice from the Party not involved in such event.

### **11.3 Effects of Expiration or Termination.**

**11.3.1.** Upon expiration or termination of this Agreement, all rights granted by Quoin to Licensee shall revert to Quoin.

**11.3.2.** Expiration or termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.

**11.3.3.** Upon expiration or termination of this Agreement for any reason:

(a) Licensee shall, as soon as possible following such termination or expiration, take all actions required and execute all documents required (including any actions or documents requested by Quoin) to transfer the Regulatory Approvals for the Product in the Territory to Quoin or Quoin's designee free and clear of any liens or encumbrances at the earliest possible time following such termination or expiration. Licensee shall promptly deliver to Quoin copies of all Regulatory Documentation related to the Product; and

(b) At Quoin's request and direction, Licensee will continue to perform under the terms of this Agreement until the transfer of the Regulatory Approvals for the Product has been approved by the applicable Governmental Authorities.

**11.4 Surviving Obligations.** Sections 5, 9, 10, 12.10, and 12.11 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

## SECTION 12. OTHER PROVISIONS

**12.1 Fees and Expenses.** Subject to the parties indemnification rights, Licensee shall pay all of the fees and expenses incurred by it and Quoin shall pay all of the fees and expenses incurred by Quoin, in negotiating and preparing this Agreement and in consummating the transactions contemplated hereby.

**12.2 Notices.** Any notices, requests, demands or other communications required or permitted to be sent hereunder shall be delivered personally or by facsimile, sent by overnight or international courier or mailed by registered or certified mail, return receipt requested, to the following addresses, and shall be deemed to have been received on the day of personal delivery or delivery by facsimile, one business day after deposit with an overnight domestic courier or three business days after deposit in the mail:

If to Licensee:

Attention: Oliver Hao  
Oliver.hao@winhealth.hk

With a copy to:

If to Quoin:

Attention: Michael Myers, Ph.D.  
Mmyers@quoinpharma.com

With a copy to: Peter I Tsoflias, Esq  
Peter.tsoflias@blankrome.com

**12.3 Entire Understanding.** This Agreement, together with the Exhibits and Schedules hereto, state the entire understanding among the parties with respect to the subject matter hereof, and supersede all prior oral and written communications and agreements, and all contemporaneous oral communications and agreements, with respect to the subject matter hereof including all confidentiality letter agreements and letters of intent previously entered into among some or all of the parties hereto. No amendment or modification of this Agreement shall be effective unless in writing and signed by the party against whom enforcement is sought.

**12.4 Assignment.** This Agreement shall bind, benefit, and be enforceable by and against Licensee, Quoin, and each of their respective successors and consented-to assigns. No party shall in any manner assign any of such party's rights or obligations under this Agreement without the express prior written consent of the other parties unless to an affiliate.

**12.5 Waivers.** Except as otherwise expressly provided herein, no waiver with respect to this Agreement shall be enforceable unless in writing and signed by the party against whom enforcement is sought. Except as otherwise expressly provided herein, no failure to exercise, delay in exercising, or single or partial exercise of any right, power or remedy by any party, and no course of dealing between or among any of the parties, shall constitute a waiver of, or shall preclude any other or further exercise of, any right, power or remedy.

**12.6 Severability.** If any provision of this Agreement is construed to be invalid, illegal or unenforceable, then the remaining provisions hereof shall not be affected thereby and shall be enforceable without regard thereto.

**12.7 Counterparts.** This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be an original hereof, and it shall not be necessary in making proof of this Agreement to produce or account for more than one counterpart hereof.

**12.8 Section Headings.** Section and subsection headings in this Agreement are for convenience of reference only, do not constitute a part of this Agreement, and shall not affect its interpretation.

**12.9 References.** All words used in this Agreement shall be construed to be of such number and gender as the context requires or permits.

**12.10 Controlling Law. THIS AGREEMENT IS MADE UNDER, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, SINGAPORE, APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED SOLELY THEREIN, WITHOUT GIVING EFFECT TO PRINCIPLES OF CONFLICTS OF LAW.**

**12.11 Arbitration.** If a matter cannot be resolved by the Parties, any said dispute shall be submitted to binding arbitration for final decision, and only through binding arbitration. Any such arbitration shall be held in Singapore, in the English language in accordance with the then-existing Rules of Singapore International Arbitration Center (the "**SIAC Rules**"), except where those rules conflict with this Section 12.11, in which case this Section 12.11 controls. Unless otherwise agreed by the Parties, the tribunal shall be comprised of three (3) arbitrators; each Party shall nominate one arbitrator and the two Party-nominated arbitrators shall nominate the third arbitrator. The arbitrators shall decide the merits of any dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. Judgment upon the award rendered by the arbitrators may be entered or enforced in any court having jurisdiction thereof. The decision of the arbitrators shall be final and binding on the Parties and shall be accompanied by a written opinion of the arbitrators explaining the arbitrators' rationale for their decision. Unless otherwise agreed by the Parties in writing, the Party losing the arbitration shall pay all fees and costs of the arbitrators and the SIAC, but each Party shall bear its own attorney and expert fees. The Parties agree that, notwithstanding any provision of Applicable Law, they will not request, and the arbitrators shall have no authority to award, punitive or exemplary damages against either Party. Pending the selection of the arbitrators or pending the arbitrators' determination of the merits of any dispute, either Party may seek appropriate interim or provisional relief from any court of competent jurisdiction as necessary to protect the rights or property of that Party. The intent of the Parties is that except for seeking appropriate interim or provisional relief or the entering of an arbitration order in a court of competent jurisdiction, disputes shall be resolved finally in arbitration as provided above, without appeal, and without recourse to litigation in the courts. The Parties acknowledge that the 1958 United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the "**New York Convention**") applies to this Agreement and to any arbitral award or order resulting from any arbitration concluded hereunder. The award may be made a judgment of a court of competent jurisdiction.

**12.12 No Third-Party Beneficiaries.** No provision of this Agreement is intended to or shall be construed to grant or confer any right to enforce this Agreement, or any remedy for breach of this Agreement, to or upon any Person other than the parties hereto including any customer, prospect, supplier, employee, contractor, salesman, agent or representative of the Quoin.

**12.13 Neutral Construction.** In view of the fact that each of the parties hereto have been represented by their own counsel and this Agreement has been fully negotiated by all parties, the legal principle that ambiguities in a document are construed against the draftsperson of that document shall not apply to this Agreement.

**12.14 Costs in Event of Breach.** In the event that either party hereto breaches this Agreement, the non-breaching party shall be entitled to reimbursement of all costs and expenses associated with enforcing such non-breaching parties rights and remedies under this Agreement, including but not limited to legal fees and costs of litigation.

**[Signature page follows]**

IN WITNESS WHEREOF, the parties have executed or caused to be executed this Agreement effective as of the day and year first above written.

Quoin Pharmaceuticals Inc.

/s/ Dr. Michael Myers

\_\_\_\_\_  
Name: Dr. Michael Myers

Title: CEO

WINHEALTH INVESTMENT (HK) LIMITED

/s/ Oliver Hao

\_\_\_\_\_  
Name: Oliver Hao

[Signature page to License and Distribution Agreement]

## EXHIBIT 1

### DEFINED TERMS

“**Additional Indication**” means any indication other than the Initial Indication.

“**Applicable Law**” means all applicable Laws, rules, and regulations of any Governmental Authority pertaining to the development, manufacture, packaging, labeling, storage, import, export, distribution, marketing, sale and/or intended use of the Product in the Territory and the activities of either Party in performing any covenants under this Agreement.

“**Commercially Reasonable Efforts**” means the carrying out of such obligations or tasks with a level of effort and resources consistent with commercially reasonable practices normally devoted by a pharmaceutical company based on conditions then prevailing including issues of safety and efficacy, product profile, competitiveness of alternative products in the market place, pricing and reimbursement for the Product, the likely timing of the Product’s entry into the market and other relevant technical and commercial factors.

“**Commercialize**” or “**Commercialization**” means the marketing, promotion, sale (and offer for sale or contract to sell), distribution, manufacturing or having manufactured, importation or other commercial exploitation of the Product.

“**Competing Product**” means any product that is approved as a drug for the treatment of the same indication for which the Product is approved and is directly competitive with the Product.

“**Control**” means, with respect to any particular Intangible, possession by the Party granting the applicable right, license, access or release to the other Party as provided herein of the power and authority, whether arising by ownership, license, or other authorization, to disclose and deliver the particular Intangible to the other Party, and to grant and authorize under such Intangible the right, license, access or release, as applicable, of the scope granted to such other Party in this Agreement without giving rise to any violation of the terms of any written agreement with any Third Party existing at the time such disclosure is first made or such right, license, access or release first comes into effect hereunder. “**Controlled**” and “**Controlling**” have their correlative meanings.

“**Data Package**” means the documentation containing information regarding the Product and the processes, techniques, studies, and data in connection with the Product and documentation for the Product, as prepared for Quoin to obtain approval of the marketing authorization for the Product in the United States and Europe.

“**Entity**” means any corporation (including any non-profit corporation), general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity.

**“Exploit”** means to develop, have developed, import, warehouse, release, distribute, sell, offer for sale, commercialize, register, manufacture, have manufactured, hold or keep (whether for disposal or otherwise), use, have used, import, export, transport, distribute, or otherwise dispose of. “Exploitation” means the act of Exploiting a product.

**“Governmental Authority”** means any: (a) nation, principality, republic, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature, and any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or Entity and any court or other tribunal); (d) multi-national organization or body; or (e) individual, Entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

**“Including”** means including but not limited to.

**“Initial Indication”** means the treatment of Netherton Syndrome in humans in the Territory.

**“Intangible”** means any and all of the following and any and all rights and interests in, arising out of, or associated therewith, throughout the world: (a) all Inventions (whether patentable or not), (b) all Know-How (c) all Product Patents; (d) the Product Trademark; (e) Proprietary Information, (f) all logos, symbols, trade dress, and slogans, and all goodwill associated therewith and/or symbolized thereby; (g) all databases and data collections and all rights therein; (h) all moral, integrity, paternity, and economic rights of authors and inventors, however denominated; and (i) any similar or equivalent rights to any of the foregoing, including any intangible asset of any nature, whether or not in use, under development or design, or inactive.

**“Inventions”** means any inventions and/or discoveries, including information, processes, methods, assays, designs, protocols, and formulas, and improvements or modifications thereof, patentable or otherwise, that are generated, developed, conceived or reduced to practice by or on behalf of a Party or their respective sublicensees pursuant to activities conducted under this Agreement or otherwise with respect to the Product, in each case including all rights, title and interest in and to the intellectual property rights therein and thereto.

**“Judgment”** means any order, writ, injunction, citation, award, decree or other judgment of any nature of any Governmental Authority.

**“Know-How”** means with respect to the Product all of the following: manufacturing protocols and methods, product specifications, analytical methods and assays, processes, formulations, product designs, plans, trade secrets, ideas, concepts, manufacturing information, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical data, pharmacological data, pharmacokinetic data, toxicological data, pharmaceutical data, physical and analytical data, safety data, quality assurance data, quality control and clinical data, technical information, other data, and research records.



**“Launch”** means the date of the first arms-length sale for monetary value of the Product for use or consumption by the end user following receipt of the Regulatory Approvals.

**“Law”** means any provision of any foreign, federal, state or local law, statute, ordinance, charter, constitution, treaty, code, rule, regulation or guideline, including common law.

**“Net Sales”** means the gross amounts invoiced for sales of the Product by or on behalf of Licensee and its affiliates or permitted transferees, licensees and sublicensees (each a **“Selling Party”**) to Third Parties in the Territory, less the following deductions (the **“Sales Deductions”**), to the extent accrued or actually taken in accordance with GAAP (as generally and consistently applied by Selling Party):

- (a) normal and customary trade, quantity and prompt pay discounts accrued or actually allowed and taken with respect to sales of the Product such discounts;
- (b) refunds, credits, allowances and other similar adjustments given or made for rejection or return of previously sold Product or for retroactive price reductions and billing errors;
- (c) rebates, coupons, and chargeback payments actually granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and reimbursers, or to trade customers;
- (d) costs of freight, insurance, and other transportation charges directly related to the distribution of such Product; and
- (e) Taxes, duties or other governmental charges (including any Tax such as a value added or similar Tax, but excluding any Taxes based on income) levied on or measured by the billing amount for the Product, as adjusted for rebates and refunds.

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of Product between Licensee and its affiliates or any other Selling Party for resale are excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party is included within the computation of Net Sales. For purposes of determining Net Sales, the Product shall be deemed sold when invoiced and a “sale” shall not include transfers or dispositions of such Product for pre-clinical or non-commercial clinical purposes, as samples or under named patient use, compassionate use, patient assistance, or test marketing programs or other similar programs or studies.

**“Patents”** means: (i) all national, regional and international patents and patent applications, including provisional patent applications; (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of the foregoing, including divisionals, continuations, continuations-in-part, provisionals, and converted provisionals; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii) and (iii)); and (v) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

**“Permit”** means any license, permit, approval, certification, waiver, order, authorization, right or privilege of any nature, granted, issued, approved or allowed by any Governmental Authority.

**“Person”** means any individual, Entity or Governmental Authority.

**“Pricing Approval”** means any and all pricing and Third Party reimbursement approvals necessary to commercialize the Product in the Territory.

**“Product”** means pharmaceutical product QRX003, QRX004 in finished dosage form for human use.

**“Product Patents”** means any Patent Controlled or owned by Quoin in the Territory that, absent the license in Section 2.1, would be infringed by the importation, sale, or use of the Product in the Territory by a third party.

**“Product Trademark”** means *[to be inserted if Product is to be sold globally under a trademark.]*

**“Product Technology”** means all Intangibles owned or Controlled by Quoin and necessary for the Exploitation of the Product in the Territory, including, without limitation, the Data Package and the Product Trademark.

**“Proprietary Information”** means all financial information, marketing information, sales information, customer information, raw materials, Know-How, drawings, compositions, manufacturing and other specifications, analytical procedures, flow sheets, reports, market studies, preclinical and clinical test results, regulatory submissions, software and other medical, research, technical, and marketing information disclosed, directly or indirectly, by a Party to any other Party, information designated “Confidential,” “Proprietary” or the like, or information that by its nature is information normally intended to be held in confidence. Proprietary will not include information (a) in the public domain at the time of disclosure, (b) published or otherwise part of the public domain after disclosure other than by breach of this Agreement by the receiving party, (c) already known by the receiving party at the time of disclosure and not acquired, directly or indirectly, from the disclosing party or anyone on behalf of the disclosing party, provided that the source of such information was not known by the receiving party or any of its representatives to be bound by a confidentiality agreement with respect to such information, and such prior knowledge is properly demonstrated by the receiving party’s written records, or (d) lawfully provided to the receiving party by a third party who did not require the receiving party to hold the same in confidence and who did not acquire such information, directly or indirectly, from the disclosing party or anyone on behalf of the disclosing party as demonstrated by the receiving party’s written records. For clarity, the Data Package and the Product Technology shall be considered Proprietary Information of Quoin.

**“Regulatory Approvals”** shall mean the licenses, registrations, clearances, consents, authorizations, and approvals required to have market authorization, developed, manufactured, store, import, transport, market, promote, sell, place on the market, and distribute the Product (including, without limitation, Pricing Approvals and labeling approvals) in the Territory, and all amendments thereto or supplements thereof.

**“Regulatory Documentation”** means all (a) regulatory filings and supporting documents, chemistry, manufacturing and controls data and documentation (including, but not limited to, batch records, master batch production records, standard operating procedures relevant to the Product, testing logs, sample logs, laboratory logs, and stability logs), preclinical and clinical studies and tests, (b) records maintained under record keeping or reporting requirements of any Governmental Authority with respect to the Product, the Regulatory Approvals, or any other Permit related to the Exploitation of the Product, (c) the complete complaint, adverse event and medical inquiry filings with respect to the Product, (d) all documentation relating to any Governmental Authority inspections relating to the Product and any communication with any Governmental Authority relating to the Product, the Regulatory Approvals, or any Permit related to the Exploitation of the Product, including correspondence and minutes of telephone calls or meetings.

**“Specifications”** means the standards, instructions, and specifications applicable to the manufacture and supply of the Product as set forth in the marketing authorization for the Product.

**“Tax”** means (a) any foreign, federal, state or local income, earnings, profits, gross receipts, franchise, capital stock, net worth, sales, use, value added, occupancy, general property, real property, personal property, intangible property, transfer, fuel, excise, payroll, withholding, workers compensation, unemployment compensation, social security, retirement, escheat, unclaimed property or other tax of any nature; (b) any foreign, federal, state or local organization fee, qualification fee, annual report fee, filing fee, occupation fee, assessment, sewer rent or other fee or charges of any nature; or (c) any deficiency, interest or penalty imposed with respect to any of the foregoing.

**“Territory”** means Greater China, including Hong Kong, Macau and Taiwan.

**“Third Parties”** means any Person other than Licensee, Quoin, any of their respective affiliates or any of their respective successors or assigns.