

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 6, 2023**

QUOIN PHARMACEUTICALS LTD.

(Translation of registrant's name into English)

State of Israel (State or other jurisdiction of incorporation)	001-37846 (Commission File Number)	92-2593104 (I.R.S. Employer Identification No.)
42127 Pleasant Forest Court Ashburn, VA (Address of Principal Executive Offices)		20148-7349 (Zip Code)

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

Not applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing sixty thousand (60,000) Ordinary Shares, no par value per share	QNRX	The Nasdaq Stock Market LLC
Ordinary Shares, no par value per share*		N/A
* Not for trading, but only in connection with the registration of the American Depositary Shares pursuant to requirements of the Securities and Exchange Commission.		

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 1.01. Entry into a Material Definitive Agreement.*License and Distribution Agreement*

On September 6, 2023, Quoin Pharmaceuticals Ltd. (the “Company”) entered into an Exclusive License and Distribution Agreement, effective as of September 1, 2023 (the “License Agreement”), with Farma Mondo SA, a company incorporated under the laws of Switzerland (“Farma Mondo”).

Pursuant to the License Agreement, the Company granted to Farma Mondo an exclusive license under its Product Technology (as defined in the License Agreement) to commercialize, upon receipt of applicable regulatory approvals, pharmaceutical product QRX003 (in finished dosage form for human use) in Singapore. The foregoing license will be royalty-bearing, and the Company will retain all rights not otherwise licensed under the License Agreement.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed with this Current Report on Form 8-K

Exhibit Number	Description
10.1	License and Distribution Agreement, by and between the Company and Farma Mondo (certain provisions of this exhibit have been omitted pursuant to Regulation S-K, Item 601(b)(10)(iv)).
104	Cover Page Interactive Data file (embedded within the Inline XBRL document)

SIGNATURES

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, hereunto duly authorized.

Date: September 12, 2023

QUOIN PHARMACEUTICALS LTD.

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

[*] CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(B)(10). SUCH EXCLUDED INFORMATION IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT

(version 28 July 2023)

This License and Distribution Agreement (this “**Agreement**”), dated as of September 1, 2023 (“**Effective Date**”), is by and between by and between Quoin Pharmaceuticals, Ltd., a Delaware corporation located at 42127 Pleasant Forest Court, Ashburn, VA 20148 (“**Quoin**”) and Farma Mondo SA, a company incorporated under the laws of Switzerland located at Via Indipendenza 3b, 6830 Chiasso, Switzerland (“**Licensee**”). Quoin and Licensee are sometimes referred to herein individually as a “**Party**,” and together as the “**Parties**.”

Recitals

WHEREAS, Quoin claims that it 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.

WHEREAS, Quoin wishes to grant to Licensee, and Licensee desires to accept, an exclusive license under the Product Technology for Licensee to perform Named Patient Supply after the Effective Date, until such time as Regulatory Approvals are obtained allowing for the Commercialization of the Product, 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 except to Licensee’s Affiliates and their subdistributors. Any other third party involved in the Commercialization of the Product will be notified in writing by Licensee to Quoin, and will be subject to Quoin’s prior written consent, which consent will not be unreasonably withheld or delayed.

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.

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 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 and for a period of twelve (12) months after expiration or termination of the Term for any reason, 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 material 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 material breach, the non-breaching Party may have the right (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 take the necessary steps to obtain all required Regulatory Approvals for the Product for the Initial Indication as soon as reasonably possible following the Effective Date.

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. Subject to the foregoing, upon request from Licensee, Quoin will provide to Licensee reasonable assistance and information, at no charge, that is in the possession of Quoin as necessary for Licensee to obtain such Regulatory Approvals. Licensee will deliver to Quoin any data or information related to the Product generated for purposes of submission of the Regulatory Approvals, and a copy of the applications for Regulatory Approvals upon submission.

3.3 Licensee shall take the necessary steps to file for the Regulatory Approvals for the Product for the Initial Indication in the Territory within six (6) months following the date of Quoin receiving regulatory approval for such Initial Indication in either the FDA in the United States or the EMA in respect to the centralized license procedure for the European Union. 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 six-month period, Licensee shall within a reasonable period of time notify in writing 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 six (6) months following the date of Quoin receiving regulatory approval in either the FDA in the United States or the EMA in respect of the European Union, or such later date as agreed upon by Quoin, Quoin may terminate this Agreement in accordance with Section 11.2.2 hereof, subject to the provisions related to termination. 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 twenty four (24) months after the date of filing such Regulatory Approvals or such later date as agreed upon by Quoin, Quoin may terminate this Agreement in accordance with Section 11.2.2 hereof.

In the event that Quoin obtains regulatory approval for any Additional Indication for the Product in the FDA in the United States or the EMA for the European Union, the Parties will meet to discuss if the Licensee wishes to continue in Commercialization of the Additional Indication. If the Parties agree in writing to continue such Commercialization, then Licensee will take the necessary steps to obtain, as soon as reasonably practicable (but in any event within the agreed period of time following such approval in the FDA in the United State or the EMA in the European Union), any Regulatory Approvals required to permit the Commercialization of the Product in the applicable country in the Territory for such Additional Indication.

SECTION 4. COMMERCIALIZATION

4.1 Launch. So long as the Launch Quantities are delivered in accordance with the terms of the Supply Agreement, starting from the Commencement Date, Licensee shall Launch the Product in the Territory within six (6) months following receipt of approval of the Regulatory Approvals, including the Pricing Approval, for the Initial Indication from the Governmental Authorities 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. Prior to the Launch, the Licensee is entitled to provide access to the Product via Named Patient routes in the Territory. Named patient Sales will be made under the same price conditions for commercial sales mentioned in this agreement. In the event that Quoin requests Licensee to provide product to the market on a compassionate use basis, Quoin and Licensee will discuss and agree on the service fee that Quoin will pay Licensee for the compassionate use supply services.

4.2 Commercialization. Licensee shall market, promote, sell, and otherwise commercialize the Product in the Territory during the Term. Licensee shall perform its activities in accordance with the annual Business Plan 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. If, within three years following Launch of the Product in the applicable country of the Territory, Quoin determines that Licensee is not complying with the agreed annual Business Plan to achieve the agreed Net Sales performance targets in the Territory), the Parties will meet promptly following written notice thereof from Quoin to discuss and approve a new Business Plan for Licensee to meet the adjusted performance sales targets. If Licensee thereafter does not achieve the agreed performance targets, then Quoin may terminate this Agreement upon written notice to Licensee, subject to the termination provisions in the Agreement.

The following adjustments will apply when calculating the achievement of the agreed sales targets and the amount of Net Sales, with the Net Sales amounts reduced in accordance with the following provisions:

- (i) A failure of Quoin and its Affiliates to supply the Licensee and its Affiliates or sub-distributors with the requested quantity of Product, including due to a breach by Quoin of this Agreement,
- (ii) A governmental or regulatory change in the pricing or reimbursement requirements which can have an impact on the Product market,

- (iii) Product supply shortage caused by Quoin or its Affiliates (or its representative) or due to a regulatory or safety issue,
- (iv) Quoin or an Affiliate or a third party sells or supplies, directly or indirectly, the Product in the Territory, including taking into account the number of Product units supplied “free of charge” or as “samples” or used for clinical studies or trials in the Territory,
- (v) An intellectual property claim or misappropriation action that impacts the achievement of the applicable sales targets, or
- (vi) A force majeure event.

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 Business 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 Business Plan. Quoin shall not unreasonably withhold its approval of the commercialization Business 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**”), and the Supply Agreement will be incorporated into this Agreement by this reference. Licensee and its Affiliates shall purchase all of their requirements for the Product from Quoin. If the Parties have not entered into a Supply Agreement in form satisfactory to the Parties by [_____], either Party may terminate this Agreement upon sixty (60) days prior written notice to the other Party. Quoin will deliver to Licensee Product with a residual shelf life of at least 18 months.

SECTION 5. FINANCIAL PROVISIONS

5.1 Royalty.

5.1.1. [REDACTED].

5.1.2. Payment of Royalty; Audits; Records. Within thirty (30) 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, on an indication by indication basis, 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 applicable books and records of Licensee directly related to the calculation of the Royalty. If the inspection reveals that the Royalty has been incorrectly calculated, 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 reasonable out-of-pocket costs of the inspection, subject to the provision of acceptable supporting documentation of such costs.

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 undisputed 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.

5.4 In the event of a change in the Pricing Approval, related to the Pricing Approval amount applicable on the date of the invoice after accepted by Quoin, but thereafter the Pricing Approval amount change happened after the Product was shipped to Licensee, then the amount owed by the Licensee shall be adjusted based on the difference in the amount to be paid before such change and the amount otherwise owed after the applicable change became effective. In case that a higher amount was paid by Licensee, then Quoin will reimburse the Licensee for the difference within thirty (30) days after receipt of the invoice from Licensee.

SECTION 6. INTELLECTUAL PROPERTY

6.1 Ownership. Licensee acknowledges Quoin's claim that 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 QRX003 are hereby assigned to Quoin. Licensee shall execute all documents, at the expense of Quoin, necessary or reasonably requested to effect the assignment of the entire right, title and interest to such Inventions to Quoin. The intellectual property rights of Licensee and its Affiliates will continue to be owned by the Licensee and its Affiliates or their third party suppliers.

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 material 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 thereof. 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 material 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 reasonable 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.

6.4 If Quoin decides in its discretion not to file, prosecute or otherwise enforce and defend and take actions to protect Quoin's applicable intellectual property rights, then Quoin will defend, hold harmless and indemnify the Licensee and its Affiliates from losses arising under this Agreement, including with respect to the damages or Losses resulting from the delay or prevention of the Commercialization by Licensee and its Affiliates of the Product in the Territory.

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 prior to Launch of the Product in the Territory, and will be incorporated into this Agreement by this reference.

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

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.

8.2 **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 AND WITH RESPECT TO STRICT PRODUCT LIABILITY LAWS, 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 five (5) 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 written consent of the other Party, which consent shall not be unreasonably withheld or delayed, 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, its Affiliates 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, including those of Third Parties (collectively, "**Claims**") arising from, relating to, or occurring as a result of: (a) the material breach by Quoin of this Agreement; (b) the negligence, gross negligence, or willful misconduct on the part of Quoin, its Affiliates or their 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 Patent or Product Trademark 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. Except as set forth in Section 10.3, Licensee shall indemnify Quoin, its Affiliates and their 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 Claims arising from, relating to, or occurring as a result of: (a) the material breach by Licensee of this Agreement, including with respect to the Exploitation of the Product by Licensee in the Territory; or (b) the negligence, gross negligence, or willful misconduct on the part of Licensee or its directors, officers, employees or agents in performing its or their material obligations under this Agreement; except, in each case ((a) and (b)), 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 Limitation of Liability. Except with respect to a material breach resulting in Losses deriving from wilful misconduct or gross negligence, the entire liability of Licensee, its Affiliates and their respective officers, directors, agents and employees under this Agreement for all acts or omissions and Losses arising out of or in connection with this Agreement, shall be limited each calendar year to a maximum aggregate amount equal to the last three (3) calendar months of the total payments received by Quoin from Licensee for the calendar year in which the Losses or alleged Losses have occurred.

Nothing in this Agreement shall exclude or limit either Party's liability to the extent that it may not be so excluded under Applicable Laws, including any such liability for death or personal injury caused by negligence under Applicable Laws.

10.4 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 "**Indemnitee**") is entitled to indemnification from the other Party (the "**Indemnitor**") under this Section 10:

10.4.1. Within fifteen (15) days after the Indemnitee 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 Indemnitee first has actual knowledge of the Indemnification Matter, the Indemnitee shall give written 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.

10.4.2. 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 Indemnitee may, at its option and expense and through counsel of its choice, participate in (but not control) the Defense; (ii) if the Indemnitee reasonably believes that the handling of the Defense by the Indemnitor may have a material adverse effect on the Indemnitee, its business or financial condition, or its relationship with any customer, prospect, supplier, employee, salesman, consultant, agent or representative, then the Indemnitee 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 Indemnitee'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 Indemnitee 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 Indemnitee 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.

10.4.3. All amounts owed by the Indemnitee to the Indemnitor (if any) shall be paid in full within thirty (30) 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.

10.5 Disclaimer of Certain Losses.

10.6 EXCEPT (i) IN THE EVENT OF THE FRAUD OF A PARTY OR OF A PARTY'S MATERIAL 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.

10.7 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 5 years from the Commencement Date, unless earlier terminated in accordance with this Section 10, subject to the provisions related to dispute resolution in Section 12.10 and Section 12.11.

11.2 Early Termination.

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

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 to Licensee,

11.2.3. 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.

11.2.4. 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, at the expense of Quoin, 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 subject to the continuation of the payment obligations of Quoin.

11.4 Surviving Obligations. Sections 2.3, 5, 6, 9, 10, and 11.3 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

SECTION 12. OTHER PROVISIONS

12.1 Fees and Expenses. Except as otherwise provided in this Agreement and 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, sent by overnight or international courier or mailed by registered or certified mail, return receipt requested or by email, to the following addresses, and shall be deemed to have been received on the day of personal delivery or delivery by email, one business day after deposit with an overnight domestic courier or three business days after deposit in the mail:

If to Licensee:
Attention:

With a copy to:

If to Quoin:

Attention:

With a copy to:

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 Force Majeure. If the performance of this Agreement is prevented or restricted by government action, war, fire, explosion, flood, strike, lockout, embargo, endemic, pandemic, act of God, or any other similar cause beyond the control of the defaulting Party, the Party so affected shall be released for the duration of the force majeure, or such other period agreed between the Parties as being reasonable in all circumstances, from its contractual obligations directly affected by the force majeure, provided that the Party concerned shall

- i. give prompt notice in writing to the other Party of the cause of force majeure;
- ii. use commercially reasonable efforts to avoid or remove such cause of non-performance; and
- iii. continue the full performance of this Agreement as soon as such cause is removed.

The Parties shall take all reasonable steps to minimise the effects of force majeure on the performance of this Agreement and shall, if necessary, agree on appropriate measures to be taken.

12.11 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of Switzerland, without reference to its conflict of laws provisions. The Parties agree to exclude the application of any international statutes on the sales of goods, including the UN Convention on the International Sales of Goods (CISG), to this Agreement. The Parties agree that any dispute shall be exclusively submitted to the courts of Zurich, Switzerland.

12.12 Arbitration. Any controversy or claim arising out of or relating to this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce as follows:

- (a) The arbitration tribunal ("Tribunal") shall consist of three (3) arbitrators.

- (b) The place of arbitration shall be in Zurich, Switzerland, and the arbitration proceedings shall be held in English.
- (c) The award of the Tribunal shall be final and judgment upon such an award may be entered in any competent court or application may be made to any competent court for juridical acceptance of such an award and order of enforcement.
- (d) No Party or its Affiliates nor any arbitrator may disclose the existence, content, or results of any arbitration under this Agreement without the prior written consent of the applicable Parties, unless and only to the extent such disclosure is required by law.

Notwithstanding anything contained in this section, either Party or its Affiliate may seek interim or provisional relief or measures in any applicable courts and tribunals that may be necessary to protect the rights of the Party or its Affiliates, pending the establishment of the Tribunal and/or pending the Tribunal's determination of the merits of the controversy.

12.13 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.

12.14 Compliance with Data Protection Laws. The Parties recognise that the performance of this Agreement involves the "processing" of "personal data" (as defined under art. 4.1 of Regulation (EU) 2016/679 – "Regulation" or "GDPR"). In this regard, the Parties agree that complying with the laws on the protection of personal data respectively applicable in the European Union ("EU"), Switzerland, the USA and in the Territory (collectively "**Privacy Laws**") is essential for the performance of this Agreement, and undertake to comply, and to support the other Party comply, with the Privacy Laws respectively applicable

[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.

FarmaMondo SA

By _____
Name:
Title:

Quoin Pharmaceuticals Inc.

By s/ Denise Carter
Name: Denise Carter
Title: Chief Operating Officer

[Signature page to License and Distribution Agreement]

EXHIBIT 1

DEFINED TERMS

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

“Affiliate” means with respect to a particular Party, a person, corporation or other Entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party. For the purposes of this definition, “control” means the direct or indirect ownership by a Party of at least fifty percent (50%) of the outstanding voting securities of the controlled entity; provided, that in any country where the law does not permit foreign equity ownership of at least fifty percent (50%), then with respect to corporations organized under such country’s laws, “control” shall mean the direct or indirect ownership by a Party of outstanding voting securities of such corporation at the maximum amount permitted by the law of such country.

“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.

“Business Plan” means the annual plan to be prepared and delivered by Licensee in accordance with the Agreement, subject to Quoin’s prior written review and approval, which details for the next calendar year the various commercial, medical, regulatory and other activities, as applicable, to be undertaken by Licensee for the Product. The Business plan will include details of any Named Patient Supply and Compassionate Use activities .

“Commencement Date” shall mean, on a country by country basis, the date of first commercial sale of the Product by Licensee to a customer in the applicable country of the Territory after the Launch of the Product.

“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 after all Regulatory Approvals have been obtained in the applicable Territory, including Pricing Approvals.

“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 FDA for the United States and the EMA for the European Union.

“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 (including for Named Patient Supply), 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, 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, and research records.

“Launch” means, on a country by country basis in the Territory, the date of the first arms-length commercial sale for monetary value of the Product for use or consumption by the end user following receipt of the Regulatory Approvals, including Pricing 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.

“Named Patient Supply” means means the supply of an unlicensed product which does not have a Regulatory Approval in the applicable country of the Territory (but does have a Regulatory Approval in another country outside of the Territory) and is supplied to meet the special needs of a specific patient or patients under the order of a medical practitioner or any other person lawfully permitted to prescribe such product to a specific patient or patients in the Territory or relevant part of it. In certain countries of the Territory this supply may include the supply of larger quantities of the product subject to applicable laws, including without limitation local regulation and import permissions.

“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) Any future mandatory trade or quantity discounts with respect to sales of the Product;
- (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 addition, to the above-referenced Sales Deductions, Licensee will also notify in writing Quoin of governmental mandated rebates, governmental “claw-backs” and “entry fees” or other similar cost containment measures paid or to be paid by Licensee or its Affiliates (including on behalf of Quoin) related to the sale of the Product, which amount will also be calculated together with the Sales Deductions amount for the computation of the amount of Net Sales.

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 Supply 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 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 the trademark identified in Exhibit XXX .

“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 but excludes the intellectual property rights of Licensee and its Affiliates and their suppliers.

“Regulatory Approvals” shall mean the licenses, registrations, clearances, consents, authorizations, and approvals required to have 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 Singapore and any country agreed in writing to be included in the Agreement.

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