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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 July 2022 (No. 1)

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

### *Agreement with Altium Growth Fund, LP*

On July 14, 2022, Quoin Pharmaceuticals Ltd. (the “Company”) and its wholly owned subsidiary, Quoin Pharmaceuticals, Inc. (“Quoin”), entered into an Agreement (the “Altium Agreement”) with Altium Growth Fund, LP (“Altium”). Under the Altium Agreement, the parties agreed to, among other things, (i) amend certain terms of the Series A Warrant and Exchange Warrants issued to Altium to, among other things, reduce the Exercise Price to \$0.00 per American Depositary Shares (“ADS”), (ii) cancel the Series C Warrant and a portion of the Series A Warrant issued to Altium, and (iii) terminate Securities Purchase Agreements, pursuant to which the warrants were issued to Altium. Capitalized terms used but not otherwise defined herein have the meaning set forth in the Altium Agreement.

The foregoing description of the Altium Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of such Altium Agreement, attached hereto as [Exhibit 10.1](#), and incorporated by reference herein.

### *ADS Ratio*

On July 12, 2022, the Company’s Board of Directors approved the change in the ratio of ADS evidencing ordinary shares, no par value (“Ordinary Shares”), of the Company from 1 ADS representing four hundred (400) Ordinary Shares to 1 ADS representing five thousand (5,000) Ordinary Shares, which will result in a one for 12.5 split of the issued and outstanding ADSs (the “Ratio Change”). The foregoing Ratio Change will be effective August 1, 2022, subject to the Company’s compliance with all applicable approvals or notification requirements.

### *License and Distribution Agreement, and Supply Agreement*

On July 14, 2022, Quoin entered into (i) a License and Distribution Agreement (the “License Agreement”) with Endo Ventures Limited (“Endo”), and (ii) a Supply Agreement (the “Supply Agreement”) with Endo. Under the terms of the License Agreement, Endo has the exclusive rights to commercialize, upon the receipt of applicable regulatory approvals, pharmaceutical product QRX003 (in finished dosage form for human use) in Canada. Under the terms of the Supply Agreement, Quoin agreed to manufacture and supply (or have manufactured and supplied) to Endo the foregoing pharmaceutical product QRX003 for sale in Canada.

The foregoing descriptions of the License Agreement and Supply Agreement do not purport to be complete and are qualified in their entirety by reference to the complete text of such License Agreement and Supply Agreement, attached hereto as [Exhibit 10.2](#) and [Exhibit 10.3](#), respectively, 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="#">Agreement, dated July 14, 2022, by and among Quoin Pharmaceuticals, Inc., Quoin Pharmaceuticals Ltd. and Altium Growth Fund, LP</a>
<a href="#">10.2</a>	<a href="#">License and Distribution Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F)</a>
<a href="#">10.3</a>	<a href="#">Supply Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F)</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: July 15, 2022

**QUOIN PHARMACEUTICALS LTD.**

By: /s/ Gordon Dunn

Name: Gordon Dunn

Title: Chief Financial Officer

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## AGREEMENT

**THIS AGREEMENT** (this “**Agreement**”), dated as of July 14, 2022 (the “**Effective Date**”), is entered into by and among Quoin Pharmaceuticals, Inc., a Delaware corporation, with headquarters located at 42127 Pleasant Forest Ct, Ashburn, VA 20148 (“**Quoin**”), Quoin Pharmaceuticals Ltd. (formerly known as Collect Biotechnology Ltd.), an Israeli company, with headquarters located at Azrieli Center, Round Tower, 30th Floor, 132 Menachem Begin Blvd, Tel Aviv, 6701101 (the “**Company**”), and the investor listed on the signature page attached hereto (the “**Holder**”). Quoin, the Company and the Holder are referred to collectively herein as the “**parties**” and each as a “**party**.” Capitalized terms used herein and not otherwise defined shall have the definitions ascribed to such terms in the Series A Warrant and/or Exchange Warrants, as applicable.

**WHEREAS:**

A. Pursuant to the Securities Purchase Agreement (as amended, the “**Primary Financing SPA**”) by and among Quoin, the Company and the Holder, dated as of March 24, 2021, Quoin issued to the Holder a Series A warrant (as amended, “**Series A Warrant**”), Series B warrant (as amended, “**Series B Warrant**”) and Series C warrant (as amended, “**Series C Warrant**”) and together with Series A Warrant and Series B Warrant, the “**Primary Financing Warrants**”), which are exercisable to purchase American Depositary Shares (“**ADSs**”) of the Company.

B. Pursuant to the Securities Purchase Agreement (as amended, the “**Bridge SPA**”) by and between Quoin and the Holder, dated as of March 24, 2021, Quoin issued to the Holder three series of warrants to purchase shares of Quoin's common stock, which were exchanged for warrants to purchase ADSs of the Company on October 28, 2021 upon the consummation of the transactions contemplated pursuant to that certain Agreement and Plan of Merger, dated as of March 24, 2021, by and among Quoin, the Company and CellMSC, Inc., a Delaware corporation and wholly owned subsidiary of the Company (as amended, collectively, the “**Exchange Warrants**”).

C. Quoin, the Company and the Holder entered into that certain Registration Rights Agreement, dated as of March 24, 2021 (as amended, the “**RRA**”).

D. Quoin, the Company and the Holder entered into that certain Waiver Agreement, dated as of June 6, 2022 (the “**Waiver**”) and together with the Primary Financing SPA, the Bridge SPA, the RRA, the Primary Financing Warrants and the Exchange Warrants, “**Transaction Documents**”).

E. Series B Warrant was exercised in full, and Quoin, the Company and the Holder wish to further amend the Series A Warrant and the Exchange Warrants, all as set forth herein.

F. Upon receipt by each party to this Agreement of this Agreement duly executed and delivered by such other parties to this Agreement, the amendments, transactions and other provisions of this Agreement shall be effective as of the Effective Date.

**NOW THEREFORE**, in consideration of the foregoing mutual premises and the covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

1. Amendments.

- (a) As of the Effective Date, Section 1(b) of each of the Exchange Warrants and the Series A Warrant is hereby amended and restated to read as follows:

“Exercise Price. For purposes of this Warrant, “**Exercise Price**” means \$0.00 per ADS.”

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(b) As of the Effective Date, Section 2(k) of each of the Exchange Warrants and Section 2(d) of the Series A Warrant is hereby amended and restated to read as follows:

“Change in ADS Ratio. If after the Issuance Date the ratio of ADSs to Ordinary Shares is increased or reduced, then the number of Warrant Shares to be delivered upon exercise of this Warrant will be proportionately adjusted.”

(c) Section 4(a), *Purchase Rights*, of each of the Exchange Warrants and Series A Warrant is hereby deleted.

2. Exercise of Warrants. Subject to the provisions of Section 1(f) of the Series A Warrant and Exchange Warrants (the “**Blocker Provisions**”), the Holder shall, within thirteen (13) Trading Days after the Effective Date or as soon as practicable thereafter to enable the Holder to exercise without violating the Blocker Provisions, exercise: (i) the Exchange Warrants for, and the Company shall issue and deliver to the Holder, 1,238,429 ADSs (as adjusted for any stock dividend, stock split, stock combination reclassification or similar transaction relating to the ADSs or the Ordinary Shares underlying the ADSs occurring after the Effective Date); and (ii) the Series A Warrant for, and the Company shall issue and deliver to the Holder, 3,761,571 ADSs (as adjusted for any stock dividend, stock split, stock combination reclassification or similar transaction relating to the ADSs or the Ordinary Shares underlying the ADSs occurring after the Effective Date) (ADSs in (i) and (ii), collectively, the “**Final ADSs**”). The Company shall credit the Final ADSs, which shall not bear any restrictive legend, to the Holder's or its designee's balance account with The Depository Trust Company (“**DTC**”) through its Deposit/Withdrawal At Custodian system on or prior to the applicable Share Delivery Date.
3. Termination of Transaction Documents. The Holder acknowledges and agrees that effective upon the Effective Date:
- (a) the remaining outstanding Series A Warrant to purchase 514,681 ADSs is cancelled;
  - (b) Series C Warrant to purchase 2,389,670 ADSs is cancelled;
  - (c) the Company has no obligation to, and the Company will not, issue an additional Series A Warrant and an additional Series B Warrant, each to purchase 2,389,670 ADSs (as adjusted for any stock dividend, stock split, stock combination reclassification or similar transaction relating to the ADSs or the Ordinary Shares underlying the ADSs occurring after the Effective Date); and
  - (d) any and all of the Company's and/or Quoin's other obligations, agreements, and covenants, as applicable, under the Transaction Documents are terminated, and such Transaction Documents are null and void and are of no further force or effect, provided, however, that the RRA shall remain in full force and effect with respect to the registration for resale by the Holder of Ordinary Shares underlying the Final ADSs as Registrable Securities thereunder in accordance with the terms thereof until such time as the Holder has sold such Ordinary Shares; provided, further, that the Series A Warrant and Exchange Warrants, each as amended by the terms of this Agreement, shall remain in full force and effect with respect to the Ordinary Shares underlying the Final ADSs until such time as the Holder has exercised such warrants in accordance with Section 2.
4. Registration Statement. The Company hereby agrees that it shall not file any registration statement with the Securities and Exchange Commission (other than on Form F-4 or Form S-8 (each as promulgated under the Securities Act of 1933, as amended) or their then equivalents relating to equity securities to be issued solely in connection with any acquisition of any entity or business or equity securities issuable in connection with the Company's stock option or other employee benefit plans) until the earlier of (i) thirteen (13) Trading Days after the Effective Date (such actual date of filing, the “**Filing Date**”), and (ii) the date when the aggregate trading volume of ADSs on or after the Effective Date is equal to or exceeds 25 million ADSs (as adjusted for any stock dividend, stock split, stock combination reclassification or similar transaction relating to the ADSs or the Ordinary Shares underlying the ADSs occurring after the Effective Date) (the date described in this clause (ii), the “**Suspension Date**”).
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5. **Lock Up.** The Company may, at any time after the earlier of (i) the date that is ten (10) Trading Days after the Filing Date, and (ii) the Suspension Date, and on no more than one (1) occasion, deliver a written notice (the “**Lock-Up Notice**” and the date the Holder receives the Lock-Up Notice, the “**Lock-Up Notice Date**”) to the Holder instructing the Holder of the Lock-Up Period (as defined below). Such Lock-Up Notice may only be provided after 4:00 p.m. New York City time on the Lock-Up Notice Date. The Holder hereby agrees not to sell, dispose or otherwise transfer, directly or indirectly (including, without limitation, any sales, short sales, swaps or any derivative transactions that would be equivalent to any sales or short positions), ADSs or Ordinary Shares with respect to which the Holder has beneficial ownership within the rules and regulations of the Securities and Exchange Commission during the Lock-Up Period. For the avoidance of doubt, the Holder will not be prohibited as set forth herein in connection with the settlement of any sale of ADSs or Ordinary Shares for which the Holder has entered into a contract for sale prior to the Holder's receipt of the Lock-Up Notice and for which the Holder has not yet settled. As used herein, “**Lock-Up Period**” means the period beginning on 5:00 p.m., New York City time, on the Lock-Up Notice Date and ending by no later than 5:00 p.m., New York City time on the date that is twenty (20) Trading Days following the Lock-Up Notice Date.
  6. **Standstill.** The Holder hereby agrees that neither the Holder nor any of its affiliates have any right to participate in any future public or private offering of securities of the Company.
  7. **Representations and Warranties.** The Holder represents and warrants to the Company and Quoin that the Holder, and each of the Company and Quoin represents and warrants to the Holder that each of the Company and Quoin, as of the Effective Date: (i) is an entity duly organized and validly existing under the laws of the jurisdiction of its formation, has the requisite power and authority to execute and deliver this Agreement and to carry out and perform all of its obligations under the terms of this Agreement; (ii) has duly executed and delivered on behalf of the applicable party this Agreement. The Holder and each of the Company and Quoin represents and warrants, as of the Effective Date, that: (a) this Agreement, once executed and delivered by the parties, constitutes the valid and legally binding obligation of the Holder and each of the Company and Quoin, as applicable, enforceable against such person in accordance with its terms, except as such enforceability may be limited by general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation and other similar laws relating to, or affecting generally, the enforcement of applicable creditors' rights and remedies; and (b) the execution, delivery and performance by the applicable party of this Agreement and the consummation by such person of the transactions contemplated hereby will not (i) result in a violation of the organizational documents of such person, (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which such person is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws) applicable to such person, except in the case of clause (ii) and (iii) above, for such conflicts, defaults, rights or violations which would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the ability of such person to perform its obligations hereunder.
  8. **Cleansing.** The Company hereby agrees to file with the Securities and Exchange Commission on or before 8:30 a.m., New York City time, on the first Trading Day following the Effective Date, a Report of Foreign Private Issuer on Form 6-K (and attaching the form of this Agreement as an exhibit to such filing (including all schedules and attachments), the “**6-K Filing**”), publically disclosing the transactions as contemplated by this Agreement in accordance with applicable laws, rules and regulations. Immediately following the filing of the 6-K Filing, the Holder shall not be in possession of any material, nonpublic information received from the Company, Quoin, any of their respective Subsidiaries or any of their respective officers, directors, affiliates, employees or agents, that is not disclosed in the 6-K Filing. In addition, effective upon the filing of the 6-K Filing, each of Quoin and the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between Quoin and/or the Company, any of their respective Subsidiaries or any of their respective officers, directors, affiliates, employees or agents, on the one hand, and the Holder or any of its affiliates, on the other hand, shall terminate and be of no further force or effect. The Company understands and confirms that the Holder and its affiliates will rely on the foregoing representations in effecting transactions in securities of the Company.
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9. Miscellaneous.

- (a) The Company shall reimburse the Holder for its reasonable legal fees and expenses actually incurred in connection with the preparation and negotiation of this Agreement and transactions contemplated hereby, by paying any such amount to Schulte Roth & Zabel LLP (the “**Holder Counsel Expense**”) within two (2) Business Days of receiving the invoice of Schulte Roth & Zabel LLP by wire transfer of immediately available funds in accordance with the written instructions of Schulte Roth & Zabel LLP. The Holder Counsel Expense incurred in connection with the preparation and negotiation of this Agreement shall be paid by the Company whether or not the transactions contemplated by this Agreement are consummated. Except as otherwise set forth above, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement.
- (b) Provisions of this Agreement may be amended and the observance thereof may be waived, only with the written consent of all parties to this Agreement. Failure of any party to exercise any right or remedy under this Agreement or otherwise, or delay by a party in exercising such right or remedy, shall not operate as a waiver thereof.
- (c) Any notices, consents, waivers or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt, when delivered personally; (ii) upon delivery, when sent by electronic mail (provided that the sending party does not receive an automated rejection notice); or (iii) two days after deposit with an overnight courier service, in each case properly addressed to the party to receive the same. The addresses and e-mail addresses for such communications shall be as follows:

If to the Company or Quoin:  
Quoin Pharmaceuticals Ltd.  
Azrieli Center, Round Tower, 30<sup>th</sup> Floor  
132 Menachem Begin Blvd  
Tel Aviv, 6701101  
Attention: Michael Myers, Ph.D.  
E-mail: [mmyers@quoinpharma.com](mailto:mmyers@quoinpharma.com)

With a copy (for informational purposes only) to:

Blank Rome LLP  
One Logan Square  
130 North 18th Street  
Philadelphia, PA  
Attention: Yelena Barychev, Esq.  
Email: [yelena.barychev@blankrome.com](mailto:yelena.barychev@blankrome.com)

If to the Holder:

c/o Altium Capital Management, LP  
152 West 57th Street, 20th Floor  
New York, NY 10019  
Attention: Joshua Thomas  
Telephone: 212-259-8404  
E-mail: [jthomas@altiumcap.com](mailto:jthomas@altiumcap.com)

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With a copy (for informational purposes only) to:

Schulte Roth & Zabel LLP  
919 Third Avenue  
New York, New York 10022  
Telephone: (212) 756-2000  
Facsimile: (212) 593-5955  
Attention: Eleazer Klein, Esq.  
Email: eleazer.klein@srz.com

or to such other address, facsimile number and/or email address to the attention of such other person as the recipient party has specified by written notice given to each other party five (5) days prior to the effectiveness of such change. Written confirmation of receipt (A) given by the recipient of such notice, consent, waiver or other communication, (B) electronically generated by e-mail transmission containing the time, date, e-mail address or (C) provided by a courier or overnight courier service shall be rebuttable evidence of personal service or receipt from a nationally recognized overnight delivery service in accordance with clause (i), (ii) or (iii) above, respectively.

- (d) All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in The City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**
- (e) If any provision of this Agreement is prohibited by law or otherwise determined to be invalid or unenforceable by a court of competent jurisdiction, the provision that would otherwise be prohibited, invalid or unenforceable shall be deemed amended to apply to the broadest extent that it would be valid and enforceable, and the invalidity or unenforceability of such provision shall not affect the validity of the remaining provisions of this Agreement so long as this Agreement as so modified continues to express, without material change, the original intentions of the parties as to the subject matter hereof and the prohibited nature, invalidity or unenforceability of the provision(s) in question does not substantially impair the respective expectations or reciprocal obligations of the parties or the practical realization of the benefits that would otherwise be conferred upon the parties. The parties will endeavor in good faith negotiations to replace the prohibited, invalid or unenforceable provision(s) with a valid provision(s), the effect of which comes as close as possible to that of the prohibited, invalid or unenforceable provision(s).
- (f) This Agreement constitutes the entire agreement among the parties hereto with respect to the subject matter hereof and supersedes in their entirety all prior negotiations, understandings and agreements between the Company, any of its subsidiaries or any of their respective shareholders, members, partners, officers, directors, managers, affiliates, employees or agents (collectively "**Representatives**"), on the one hand, and the Holder or any of its Representatives, on the other hand, whether written or oral. There are no restrictions, promises, warranties or undertakings with respect to the subject matter hereof, other than those set forth or referred to herein.
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- (g) This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other person.
- (h) The headings in this Agreement are for convenience of reference only and shall not limit or otherwise affect the meaning hereof.
- (i) This Agreement may be executed in identical counterparts, each of which shall be deemed an original but all of which shall constitute one and the same agreement. This Agreement, once executed by a party, may be delivered via electronic mail (including pdf or any electronic signature complying with the U.S. federal E-SIGN Act of 2000, e.g., [www.docusign.com](http://www.docusign.com)) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.
- (j) Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as any other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.
- (k) The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent and no rules of strict construction will be applied against any party.

**[Signature Page Follows]**

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IN WITNESS WHEREOF, the parties have caused their respective signature pages to this Agreement to be duly executed as of the Effective Date.

**COMPANY:**

**QUOIN PHARMACEUTICALS LTD.**

By: /s/ Dr. Michael Myers

Name: Dr. Michael Myers

Title: Chief Executive Officer

**QUOIN:**

**QUOIN PHARMACEUTICALS INC.**

By: /s/ Dr. Michael Myers

Name: Dr. Michael Myers

Title: Chief Executive Officer

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IN WITNESS WHEREOF, the parties have caused their respective signature pages to this Agreement to be duly executed as of the Effective Date.

**HOLDER:**

**ALTIUM GROWTH FUND, LP**

By: /s/ Mark Gottlieb

Name: Mark Gottlieb

Title: COO

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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 July 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**”) Endo Ventures Limited, a company duly incorporated under the laws of Ireland, with its principal place of business at First Floor, Minerva House, Simonscourt Road, Ballsbridge, Dublin 4, Ireland (“**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 distribution right and 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 and an exclusive right of distribution (even as to Quoin and its Affiliate), in each case so as to Exploit the Product in the Territory, which license and right shall not be sublicensable except as set forth in Section 2.2 below.

**2.2 Sublicense.** The licenses herein granted are not to be sublicensed by Licensee without Quoin’s prior written consent not to be unreasonably withheld. Quoin hereby consents to a sublicense granted by Licensee to its Affiliate Paladin Labs Inc. For the avoidance of doubt, it shall not be deemed to be a sublicense for which consent is required to authorize a sub-distributor to whom Licensee or its Affiliates sells the Product solely to resell such Product to the next level of the trade (eg. a wholesaler such as McKesson).

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**2.3 Performance by Affiliates and Subcontractors.** Licensee shall have the right to perform some or all of its obligations under this Agreement through Affiliates and/or Third Party subcontractors in the Territory; provided, however, that Licensee shall remain responsible for such performance by its Affiliates and subcontractors and cause its Affiliates and subcontractors to comply with the terms and conditions of this Agreement in connection with such performance.

**2.4 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.

**2.5 Non-Competition.**

**2.5.1.** 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 or otherwise Exploit the Product 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.

**2.5.2.** During the Term and thereafter until the earlier of (i) the transfer of the Regulatory Approval for the Product in the Territory to Quoin or its designee as set forth in Section 11.3.3 below or (ii) for a period of sixty (60) days 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.

**2.5.3.** The Parties hereto agree that any breach by either Party of the covenants and agreements contained in this Section 2.5 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.

**2.5.4.** If any portion of the covenants and agreements contained in this Section 2.5, 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 within the timelines contemplated in Section 3.4 below.

**3.2 Ownership of Regulatory Approvals.** All Regulatory Approvals for the Product in the Territory shall be held by Licensee in its name.

**3.3** 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 and which development work Licensee agrees, in its discretion, to undertake, including any supplemental clinical trials. Subject to the foregoing, upon request from Licensee, Quoin will provide to Licensee reasonable assistance and information 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.

**3.4** Quoin shall promptly advise Licensee upon its receipt of regulatory approval for the Initial Indication in the United States or the European Union (whichever occurs first). Quoin shall promptly provide Licensee with the full Data Package submitted in connection with such filings. Licensee shall use Commercially Reasonable Efforts to file for the Regulatory Approvals for the Product for the Initial Indication in the Territory within nine (9) months following the later of (i) the date of Quoin receiving regulatory approval for such Indication or (ii) providing to Licensee the full Data Package in respect of its United States or European Union regulatory approval as aforesaid. 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 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.

**3.5** 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 nine (9) months following the later of (i) the date of Quoin receiving regulatory approval in either the United States or the European Union or (ii) providing the Data Package as aforesaid, or such later date as agreed upon by Quoin, Quoin may, terminate this Agreement in accordance with Section 11.2.2 hereof. 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 24 months after the date of filing such Regulatory Approvals or such later date as agreed upon by the Parties, Quoin may terminate this Agreement in accordance with Section 11.2.2 hereof.

**3.6** In the event that Quoin obtains regulatory approval for any Additional Indication for the Product in the United States or the European Union, Quoin shall promptly advise the Licensee and provide to the Licensee the full Data Package used in connection with that approval. Licensee will use Commercially Reasonable Efforts to obtain, as promptly as practicable (but in any event within nine (9) months following the later of (i) the date that Quoin receives regulatory approval for such Additional Indication and (ii) delivery of such Data Package), any Regulatory Approvals required to permit the Exploitation of the Product in the Territory for such Additional Indication. If the Regulatory Approvals for such Additional Indication have not been submitted to the applicable Governmental Authorities in the Territory on or before such date which is 24 months after the date of filing such Regulatory Approvals or such later date as agreed upon by the Parties, Quoin may terminate this Agreement in accordance with Section 11.2.2 hereof.

**3.7 Regulatory Assistance.** Quoin shall make its representatives reasonably available to Licensee to answer questions relating to such Quoin Know-How until all Regulatory Approvals required in respect of the Product and the Data Package for all relevant indications have been obtained.

**3.8 Licensee's Rights.** Quoin hereby grants to Licensee (and its Affiliates) rights to reference, access and use, in association with exercising Licensee's rights and performing its obligations under this Agreement, Quoin's Data Package and regulatory approvals outside the Territory that are necessary or required for Regulatory Approval in the Territory. Quoin shall provide to Licensee, to the extent accessible to and Controlled by Quoin, all necessary and appropriate letters of authorization to applicable regulatory authorities advising such applicable regulatory authorities of such rights of reference and use.

#### **SECTION 4. COMMERCIALIZATION**

**4.1 Launch.** So long as the Launch quantities are delivered in accordance with the terms of the Supply Agreement, and no Interfering Event has occurred, Licensee shall Launch the Product in the Territory within twenty-four (24) months following receipt of approval of the Regulatory Approvals 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.

**4.2 Commercialization.** Licensee shall use Commercially Reasonable Efforts to 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.** If, within three years following Launch of the Product in the Territory, Quoin determines in its reasonable discretion that Licensee is not using Commercially Reasonable Efforts to maximize Net Sales in the Territory (with respect to any criteria in Quoin's reasonable discretion, including, without limitation, maintaining Regulatory Approvals, placement of the Product in any formulary, Product treatment with respect to reimbursements and distribution infrastructure), the Parties will meet promptly following notice thereof from Quoin to discuss and approve a commercially reasonable 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 in form satisfactory to Quoin and Licensee failed to achieve at least [\*\*\*\*] of the purchases that it set out in its Forecast (as set forth in the Supply Agreement) for at least two consecutive years within the said three (3) year period, then Quoin may terminate this Agreement upon written notice to Licensee.

**4.3.2.** If, within three years following Launch of the Product in the Territory, Licensee determines in its reasonable discretion that it is not in Licensee's commercial interests to Exploit the Product in the Territory (with respect to any criteria in Licensee's reasonable discretion), the Parties will meet promptly following notice thereof from Licensee to discuss and approve a commercially reasonable plan for Licensee to Exploit the Product in the Territory. If the Parties are unable to reach an agreement with respect to the aforementioned plan in form satisfactory to them, then Licensee may terminate this Agreement upon written notice to Quoin.

**4.3.3.** If Licensee applies for Regulatory Approval for the Product for an indication other than for the Initial Indication or an Additional Indication as set forth in Section 3.6, which indication is not for the treatment of a rare disease or condition (an "**Other Indication**"), 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. In the event that Quoin does not approve such commercialization plan, the Licensee shall not proceed to Exploit such Other Indication.

**4.4 Supply.** Contemporaneously herewith, the Parties have entered into a supply agreement 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 Supply Price.

**5.1.1.** In consideration of the supply of the Product by Quoin, Licensee shall pay a Supply Price equal to the aggregate of (i) the Initial Transfer Price as determined under the Supply Agreement and (ii) the Additional Transfer Price determined under this Agreement.

**5.1.2. Additional Transfer Price.** Commencing on the Launch of the Product in the Territory, Licensee shall pay to Quoin an additional transfer price equal to of Net Sales (the “**Additional Transfer Price**”). 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.

**5.1.3. Payment of Additional Transfer Price; 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 Additional Transfer Price for the Product on such sales. Licensee shall pay any Additional Transfer Price due to Quoin with an additional forty-five (45) days following the delivery to Quoin of the statement showing such calculation. In order to verify quarterly reports, Quoin or its authorized representative shall be entitled, annually, 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 Additional Transfer Price. If the inspection reveals that the Additional Transfer Price 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 out-of-pocket costs of the inspection.

**5.1.4. 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.

**5.1.5. 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 (as announced by the Bank of Canada from time to time) plus two (2) percentage points or the maximum rate allowable by Applicable Laws, whichever is less.

**5.2 Withholding Tax.** Licensee will make all payments to Quoin under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment. Any tax required to be withheld on amounts payable by Licensee under this Agreement will be timely paid by Licensee on behalf of Quoin to the appropriate Governmental Authority, and Licensee will furnish Quoin with the corresponding proof of payment of such tax, as may be required in order to enable Quoin to request reimbursement or deduction of the withheld amount, or to otherwise comply with its duties. Licensee and Quoin agree to cooperate to legally minimize and reduce such withholding taxes and provide any information or documentation required by any taxing authority.

**5.3 Currency Conversion.** The Additional Transfer Price will be generated in \$CAD and paid in \$USD. The exchange rate will be the average of the rates over the course of the relevant calendar quarter, as appropriate, as reported by the Bank of Canada during such calendar quarter as appropriate, provided that in the event that a reporting period is less than a full calendar quarter, the exchange rate will be based on the average for the relevant time.

## 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 pursuant to this Agreement and related to the Product Technology are hereby assigned to Quoin. 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 and obligation 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. Quoin's legal counsel shall keep Licensee's legal counsel (retained at Licensee's option and sole expense) reasonably informed with respect to material events in the progress and settlement of any enforcement actions to the extent practicable and permissible under any applicable protective order. Licensee's counsel may provide input relating to the management and settlement of such enforcement actions, and Quoin shall consider the suggestions of Licensee's counsel in good faith.

**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 in the Quality Agreement and Regulatory Approval. 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 is intended to 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 and obligation to take 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 Days 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 are outside the scope of customary interactions with Governmental Authorities or may materially and adversely 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 within one hundred eighty (180) days prior to the Launch of the Product.

**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.

## **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;

**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.** Quoin has informed Licensee about all material information in its possession or control concerning the safety and efficacy of the Products, and any side effects, injury, toxicity or sensitivity reactions and incidents associated with all uses, studies, investigations or tests involving the Products (animal or human) throughout the world;

**8.1.6.** As of the Effective Date, Quoin is not aware of any facts that would reasonably lead it to conclude that the Products will be unable to receive Regulatory Approval other than those which has already been disclosed to Licensee;

**8.1.7.** Products shall be manufactured in accordance with the Specifications therefore and shall be manufactured, packaged, stored and shipped by Quoin in accordance with all laws and regulations applicable to the Territory and to the country in which the Products are manufactured, including GMP;

**8.1.8.** Quoin has, and will continue during the Term to have the full and unfettered right to grant to Licensee all of the rights granted to it hereunder and to satisfy the purpose of this Agreement;

**8.1.9.** Quoin has and will continue during the Term to have all of the rights necessary to enter into this Agreement and to grant the exclusive and non-exclusive licenses hereunder and for avoidance of doubt no party other than the Quoin has or will have any right, title or interest in or to the Products in the Territory;

**8.1.10.** The Product Technology licensed hereunder is valid and enforceable and are owned or validly licensed by Quoin; and

**8.1.11.** Quoin has not received any notice that the manufacture, sale, or use of the Products in the Territory infringes upon any intellectual property rights of any Third Parties in the Territory.

**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 or to its knowledge, those of its consultants or contractors who are engaged in the Exploitation of the Product: (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 three (3) 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, to the extent practicable, 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.

**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 negligence, 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; (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 Trademark in the Exploitation of the Product in the Territory; or (d) any claim for personal injury, death or property damage arising from the use of the Product by any person except, in each case ((a), (b) (c) or (d)), 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 negligence, 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; or (c) the Exploitation of the Product by Licensee in the Territory; 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 “**Indemnitee**”) is entitled to indemnification from the other Party (the “**Indemnitor**”) under this Section 10:

**10.3.1.** Within ten (10) 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 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 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.

**10.3.3.** 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. Licensee may also determine to self-insure (including self-insurance through one or more Affiliates). 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 (15) years from Launch, unless earlier terminated in accordance with this Section 10. This Agreement shall automatically renew for successive, consecutive additional terms of two (2) years each, unless a Party sends a notice of non-renewal to the other at least six (6) months prior to the expiry of the then current Term.

### **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 Sections 3.5, 3.6 or 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 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;

(b) At Quoin's request, Licensee will take reasonable steps to facilitate the on-going supply of Product to patients using the Product until the transfer of the Regulatory Approvals for the Product has been approved by the applicable Governmental Authorities.

**11.3.4. Disposition of Inventory.** Upon expiry or termination of this Agreement by Licensee due to a breach by Quoin, Licensee and its Affiliates will be entitled, during the period ending on the last day of the twelfth (12th) month, following the effective date of such termination or until the Regulatory Approval has been transferred to Quoin or their designee whichever is earlier, to sell any inventory of Product affected by such termination or expiry that remains on hand as of the effective date of the termination or expiry or is delivered afterwards, so long as Licensee pays the Additional Transfer Price applicable to said subsequent sales, with respect to sales in the Territory, as applicable, in accordance with the terms and conditions set forth in this Agreement and otherwise complies with the terms set forth in this Agreement Upon termination of this Agreement by Quoin due to breach by Licensee, Quoin shall have the right (but not the obligation) to purchase any remaining inventory at Licensee's landed cost.

**11.4 Surviving Obligations.** Sections 2.4, 2.5.2, 2.5.3, 2.5.4, 5.1.3, 5.1.4, 5.1.5, 5.2, 5.3, 8.1.7, 9, 10, 11 and 12 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: Endo Ventures Limited  
First Floor, Minerva House  
Simmons Court Road, Ballsbridge  
Dublin 4, Ireland  
Attention: Legal Department  
Email: [bolger.marietherese@endo.com](mailto:bolger.marietherese@endo.com)

With a copy to: Paladin Labs Inc.  
100 Alexis Nihon Boulevard, Suite 600  
Saint-Laurent, QC H4M 2P2  
Canada  
Attention: Isabelle Trempe  
Email: [Trempe.Isabelle@endo.com](mailto:Trempe.Isabelle@endo.com)

With a copy to: Davies Ward Phillips & Vineberg  
1501 McGill College Avenue, 26th Floor  
Montreal  
Quebec, H3A 3N9  
Canada  
Attention: Hillel W. Rosen  
Email: [hrosen@dwpv.com](mailto:hrosen@dwpv.com)

If to Quoin: Quoin Pharmaceuticals Inc.  
42127 Pleasant Forest Court  
Ashburn, VA 20148  
Attention: Michael Myers Ph.D.  
Email: [Mmyers@quoinpharma.com](mailto:Mmyers@quoinpharma.com)

With a copy to: Blank Rome LLP  
One Logan Square, 130 N 18th St.  
Philadelphia, PA 19103-6998  
Attention: Peter I Tsouflas, Esq.  
Email: [PTsouflas@blankrome.com](mailto:PTsouflas@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 not to be unreasonably withheld or delayed.

**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, THE LAWS OF THE STATE OF New York, UNITED STATES OF AMERICA, 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 New York, New York, in the English language in accordance with the then-existing Rules of Arbitration of the International Chamber of Commerce (the “**ICC 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 ICC, 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 draftsman 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 reasonable 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.**

by /s/ Dr. Michael Myers

Name: Dr. Michael Myers

Title: CEO

**ENDO VENTURES LIMITED**

by /s/ Marie-Therese Bolger

Name: Marie-Therese Bolger

Title: Director

[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 Licensee’s Affiliate in the Territory and 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.

**“Competing Product”** means any product that is approved as a drug for the treatment of the same indication for which the Product is approved in the Territory of 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 by Quoin to obtain approval of the marketing authorization for the Product (including approval in respect to the Initial Indication and any Additional Indication) 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.

**“Improvements”** means any new indications, dosage strengths, reformulations, line extensions or other advances in, modifications or improvements to the Product.

**“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.

**“Interfering Event”** means any of the following events: (i) any Applicable Law that prohibits the commercialization of the Product in the Territory; (ii) pending litigation concerning the Regulatory Approval or the Product in the Territory; or (iii) any litigation threatened in writing by a Third Party that the development or manufacture of the Product infringes any intellectual property rights of any Third Party.

**“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 provided that sales for purposes of establishing pricing Approval shall not constitute a Launch.

“**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;
- (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;
- (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; and
- (f) credits or allowances given to customers for recalls or, on account of retroactive price reductions affecting the Product.



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.

“**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 and all Improvements thereto.

“**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 any trademark and/or trademarks under which the product will be marketed by the Licensee in the Territory, as it shall be determined and indicated in due time by Quoin to Licensee and which shall be the sole and exclusive property of Quoin.

“**Product Technology**” means all Intangibles owned or Controlled by Quoin and necessary or useful 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, permits, registrations, clearances, consents, authorizations, and approvals required by the applicable Governmental Authority to have import, store, transport, market, promote, sell, place on the market, and distribute the Product (including, without limitation 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 Regulatory Approvals 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 Canada.

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

**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**

**SUPPLY AGREEMENT**

This Supply Agreement (this “Agreement”), dated as of July 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 Endo Ventures Limited, a company duly incorporated under the laws of Ireland, with its principal place of business at First Floor, Minerva House, Simonscourt Road, Ballsbridge, Dublin 4, Ireland (“Licensee”). Quoin and Licensee are sometimes referred to herein individually as a “Party,” and together as the “Parties.”

**WITNESSETH:**

**WHEREAS**, Quoin and Licensee are parties to that certain License and Distribution Agreement, dated \_\_\_\_ (“License Agreement”), pursuant to which Quoin granted to Licensee an exclusive license under the Product Technology for Licensee to obtain the Regulatory Approvals and Exploit the Product in the Territory, subject to the terms of the License Agreement;

**WHEREAS**, Section 4.4 of the License Agreement provides that the Parties shall enter into a commercial supply agreement pursuant to which Quoin will manufacture and supply, or have manufactured and supplied, to Licensee the Product for sale in the Territory; and

**WHEREAS**, the Parties now desire to enter into this Supply Agreement to establish the terms and conditions under which Quoin will have the Product manufactured and supplied to Licensee for sale in the Territory.

**NOW, THEREFORE**, in consideration of the premises and mutual covenants contained herein and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereto agree as follows:

**ARTICLE I**

**DEFINITIONS**

Section 1.1 Definitions. Capitalized terms used in this Agreement have the meanings specified in Schedule 1 to this Agreement. As used herein the words “including” or “includes” shall be deemed to mean “including, without limitation,” or “includes, without limitation.”

**ARTICLE II**

**MANUFACTURE AND SALE OF PRODUCT**

Section 2.1 Engagement. During the Term and upon the terms and subject to the conditions set forth herein, Quoin agrees that it will manufacture and supply the Product to Licensee, and, in turn, Licensee agrees that it will exclusively purchase one hundred percent (100%) of the Licensee’s requirements of the Product from Quoin for commercialization solely within the Territory.

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Section 2.2 Subcontractors. Quoin shall have the right to subcontract its obligations under this Agreement to a third party that shall meet the requirements and obligations set forth herein and in the Quality Agreement (it being agreed that, wherever Quoin makes a commitment under this Agreement or the Quality Agreement with respect its obligations, such obligation shall be deemed satisfied if performed by such subcontractor in accordance with the terms of this Agreement and the Quality Agreement). Notwithstanding the foregoing, Quoin shall allow Licensee up to one year to update its Establishment License in the Territory and shall not subcontract from or with any subcontractor prior to Licensee receiving the updated Establishment License. Further, notwithstanding that Quoin is permitted to use subcontractors in the performance of its obligations under this Agreement, Quoin shall remain fully liable and responsible for all actions or omissions of any such subcontractor as though such actions or omissions were those of Quoin.

Section 2.3 Packaging and Labeling. The Licensee will be responsible for ensuring the accuracy of all information contained in the labels or labeling for Product for the Territory and the compliance of all such labels and labeling with applicable Law and the Regulatory Approvals for the Territory. Licensee will approve all artwork and labeling information necessary for the packaging and labeling of the Product for the Territory. Quoin will, or will cause its contractors to, supply all packaging and labels for Product under this Agreement. Such packaging and labels will be in accordance with the Specifications and the cost of same is included in the Initial Transfer Price. Quoin will make any changes to labeling and packaging Specifications required in writing by the Licensee after the launch of the Product in the Territory, at Licensee's sole cost and expense (including the cost of any obsolete labeling inventory), within a reasonable timeframe to be agreed upon in writing by both Parties. The Licensee will be responsible for submitting any such changes to all applicable Governmental Authorities in the Territory for approval.

Section 2.4 Facility Maintenance; Inspection; Reports.

(a) Quoin shall, at all times, maintain and operate, or cause its contractors to maintain and operate, all facilities where Product is manufactured, packaged, tested, stored, warehoused or shipped in compliance with cGMP. Not more than once every twelve (12) months, Quoin shall permit, or cause its contractors to permit, quality assurance representatives of the Licensee or designated third parties (subject to appropriate confidentiality obligations) to inspect such facilities, operations, documents, and records directly related to the handling, manufacture, testing, inspection, packaging, storage, disposal and transportation of the Product by Quoin or the applicable contractor upon reasonable notice (which shall not be less than ten (10) days), during normal business hours and on a confidential basis. Quoin shall also permit, and cause its contractors to permit, representatives of the applicable Governmental Authority to inspect such facilities as requested by the such Governmental Authority.

(b) Quoin shall maintain adequate and accurate records consistent with the applicable Specifications, including records covering quality control testing and release of the Product and all other manufacturing services provided hereunder in material compliance with cGMP.

(c) Quoin shall notify Licensee as soon as reasonably practicable and in any event within five (5) business days following receipt of notice of any Governmental Authority inspection of the manufacturing facility if such inspection pertains to the Product.

Section 2.5 Adverse Events. Prior to the launch of Product the Parties shall each assign a representative to negotiate in good faith and agree on a process and procedure for sharing adverse event information which shall be documented in a safety data exchange (SDEA) agreement which the Parties shall use commercially reasonable efforts to agree upon and execute prior to commercialization of the Product.

## ARTICLE III

### FORECASTS, ORDERS AND SHIPMENT

Section 3.1 Forecasts. In order to assist in the planning of production runs for the Product, the Licensee will, at least one hundred and eighty (180) days prior to the launch of the Product in the Territory, provide Quoin with a non-binding written forecast of estimated quantities of Product that the Licensee anticipates ordering from Quoin during the next twenty-four (24) month period (the "Forecast"). This initial Forecast will be updated at least five (5) business days before the first day of the following calendar quarter after the date hereof and each successive calendar quarter and each such updated Forecast will be promptly delivered to Quoin by the Licensee. The first three (3) months of each such Forecast (the "Firm Order Period") shall be binding on Licensee. The remaining twenty-one (21) months of each such forecast shall be non-binding estimates for planning purposes. No Forecast shall be required for any period of time that extends beyond the Term (as in effect at the time of such Forecast). The Licensee will forecast in amounts comprising full batch and in multiples of batch quantities, as such quantities are set forth on Schedule 6.1. Each Forecast will be made by the Licensee in good faith, taking into account reasonable projections of demand for the Product including, without limitation, allowing for reasonable safety stock of finished Product.

#### Section 3.2 Orders.

(a) The Licensee will place firm purchase orders ("Firm Orders") for Product in writing for delivery at least ninety (90) days after the Purchase Order Date. A Firm Order shall only be deemed binding on Quoin upon acceptance in writing by Quoin provided that Quoin shall accept or reject each Firm Order in writing within seven (7) Business Days after Quoin's receipt of each valid order. Quoin shall not be permitted to reject an order if that such order meets the requirements specified below. For certainty, Quoin shall be deemed to have accepted the order if it complies with such requirements or if Quoin does not respond within such delay. Each Firm Order will specify the quantity and description of each Product ordered, the requested delivery date (which delivery dates will not be on a Saturday, Sunday or holiday), and carrier and any special instructions requested; provided that no Firm Order shall include a quantity of a Product that is greater than 125% of the quantity of such Product set forth in the Firm Order Period of the most recent Forecast delivered to Quoin by the Licensee. The minimum size of any order placed by the Licensee will be a full batch (or multiples of a full batch) in accordance with Schedule 6.1 hereto, except with the prior approval of Quoin and payment of any additional expenses or fees that are required for split batches. The date an order will be deemed placed (the "Purchase Order Date") will be the date that Quoin actually receives the purchase order form. The Licensee will be fully responsible for any changes to a Firm Order. Orders will be deemed accepted by Quoin unless Quoin provides notification of rejection to the Licensee within seven (7) Business Days of receipt of the Firm Order.

(b) Quoin will supply the Product in accordance with each Firm Order placed pursuant to the terms of this Agreement by the Licensee to the extent accepted (or deemed accepted) by Quoin.

(c) Quoin shall deliver the Product to Licensee with at least **75% (seventy five percent)** of remaining shelf life at the shipment date in accordance with Section 3.2(b).

(d) The terms of this Agreement shall prevail over any conflicting, inconsistent or additional terms set forth in any Firm Order, invoice, or acceptance form.

Section 3.3 Delivery.

(a) All Product shipped under this Agreement will be shipped FOB the facility where the Product is manufactured. The Licensee shall make necessary arrangements to pick up the shipment and will pay all freight, insurance charges, taxes, import and export duties, inspection fees and other charges applicable to the sale and transport of Product purchased by the Licensee consistent with FOB principles. Title and risk of loss and damages to Product purchased by the Licensee will pass to the Licensee upon pickup of the Product by the Licensee's carrier at the facility of manufacture consistent with FOB principles. In the event of damage or loss to the Product after delivery, the Licensee will be responsible to file claims with the carrier. Quoin shall notify Licensee of the following information concurrently with each shipment of Product: (i) date of shipment, (ii) quantity and type of Product shipped, and (iii) order number or other identifying information.

(b) Quoin shall perform quality assurance testing with respect to the Product sold hereunder, including stability testing, so that the Product conforms with the Specifications. Quoin shall provide Licensee with a Certificate of Analysis ("COA") and a Certificate of Compliance ("COC") confirming that the Product in such shipment has been tested in accordance with the Regulatory Approval and meets the Specifications via facsimile transmission. Any deviations and investigations related to such Product shall be completed in compliance with applicable Regulatory Approval and the Quality Agreement (as defined in Section 5.5 hereof).

Section 3.4 Supply Shortage.

(a) In the event that at any time Quoin foresees that it will be unable to supply to Licensee (or its nominee) in whole or in part an ordered or forecasted quantity of Product by the delivery date for any reason, including a Force Majeure event, Quoin shall:

(i) notify Licensee of such inability as soon as possible, the reasons therefor and the date such inability is expected to end, the quantities of Product available during such period and the proposed amount of the raw materials and/or resources prioritized to Licensee in the event such inability is caused by a shortage of raw materials and/or resources required for the Manufacture of Product;

(ii) use commercially reasonable efforts to eliminate, cure or overcome such Product shortage and to resume performance of its obligations hereunder as soon as reasonably possible;

(iii) supply Licensee with a fair quantity of Products based on Licensee receiving its pro-rated share of available or to be manufactured Product having regard to then applicable forecasted commercial Product supply requirements amongst Licensee, Quoin and Quoin's other distributors, sublicensees, agents etc.;

(iv) Quoin shall exercise commercially reasonable efforts to transfer/initiate production of the Product to a secondary manufacturer as specified in the quality agreement in order to manufacture and supply the Product for the Territory.

(b) Quoin will use commercially reasonable efforts to ensure the maintenance of sufficient manufacturing time in the Product production schedule and sufficient volumes of raw materials for Product to meet the Firm Orders and binding portion Licensee's Forecasts.

## ARTICLE IV

### REPRESENTATIONS AND WARRANTIES

Section 4.1 Representations and Warranties of Quoin. Quoin hereby represents and warrants to the Licensee as follows:

(a) Product Compliance. All Product delivered pursuant to this Agreement by Quoin (or any sub-contractor thereof) to the Licensee or its designee during the Term will at shipment be in compliance in all material respects with this Agreement, the Specifications and the Quality Agreement. At the time Quoin makes each shipment of Product available for pick-up by Licensee (or Licensee's carrier), the Product shall be free of any lien or other encumbrance.

(b) Authorization. This Agreement has been duly executed and delivered by Quoin and, assuming due execution and delivery by the Licensee, constitutes a valid and binding obligation, enforceable against Quoin in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of Quoin and its respective officers and directors.

(c) Absence of Conflicts. The execution, delivery and performance of this Agreement by Quoin does not conflict with or constitute a default under any agreement, instrument or understanding, oral or written to which it is a party or by which it may be bound, does not conflict with any provision of any of its organizational documents and does not conflict with or violate any applicable Law or court order or decree.

(d) Organization and Standing. Quoin is a corporation, duly organized, validly existing and in good standing under the laws of Delaware.

(e) Power and Authority. Quoin has the corporate power and authority to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby.

(f) Compliance With Law. Quoin has and will maintain throughout the Term of this Agreement all permits, licenses, registrations and other forms of governmental authorization and approval as required in order for Quoin to execute and deliver this Agreement and to perform its obligations hereunder.

(g) No Debarment. Quoin is not debarred and has not and will not use in any capacity the services of any person debarred under subsection 306(a) or (b) of the Generic Drug Enforcement Act of 1992. If at any time this representation and warranty is no longer accurate, Quoin shall promptly notify Licensee of such fact.

Section 4.2 Representations and Warranties of the Licensee. The Licensee hereby represents and warrants to Quoin as follows:

(a) Authorization. This Agreement has been duly executed and delivered by the Licensee and, assuming due execution and delivery by Quoin, constitutes a valid and binding obligation, enforceable against the Licensee in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of the Licensee and its respective officers and directors.

(b) Absence of Conflicts. The execution, delivery and performance of this Supply Agreement by the Licensee does not conflict with or constitute a default under any agreement, instrument or understanding, oral or written to which it is a party or by which it may be bound, does not conflict with any provision of any organizational documents of the Licensee and does not conflict with or violate any applicable Law or court order or decree.

(c) Organization and Standing. The Licensee is a corporation, duly organized, validly existing and in good standing under the laws of Ireland.

(d) Power and Authority. The Licensee has the corporate power and authority to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby.

(e) Product Compliance in the Territory. Product delivered by Quoin in accordance with this Agreement is and shall be during the Term consistent in all respects with all Laws applicable to the manufacture, import, sale, use, storage and commercialization of the Product in the Territory.

Section 4.3 Disclaimer. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT ARE THE PARTIES' ONLY WARRANTIES AND NO OTHER WARRANTY, EXPRESS, IMPLIED OR STATUTORY, WILL APPLY. EACH PARTY EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. FOR THE AVOIDANCE OF DOUBT, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF NON-INFRINGEMENT THAT ARE NOT EXPRESSLY SET FORTH IN THIS AGREEMENT.

## ARTICLE V

### QUALITY ASSURANCE

Section 5.1 Quoin's Covenants. Quoin hereby covenants during the Term that it will:

(a) manufacture, fill, package, test, handle, store, warehouse and ship the Product in conformity with this Agreement, Quality Agreement (subject to Section 5.5 of this Agreement) and the Specifications;

(b) promptly (but in any event no later than five (5) Business Days after becoming aware) inform Licensee of any adverse events related to the Product and any inspections, communications, or material issues raised by the FDA or other Governmental Authority in connection with the Manufacturing of the Product, and shall provide Licensee with copies of any correspondence (including emails) relating thereto;

(c) obtain and maintain all permits reasonably necessary to manufacture and supply Product in accordance with this Agreement; and

(d) if Quoin becomes aware of any Product supplied to Licensee hereunder that have not been manufactured in accordance with the Specifications, promptly inform Licensee in writing.



Section 5.2 The Licensee's Covenants. The Licensee hereby covenants during the Term that it will:

- (a) hold, store, handle, ship, deliver, distribute, offer for sale, and/or sell the Product in accordance with applicable Law and the terms of the License Agreement, and in compliance with the Specifications;
- (b) except as set forth herein or in the Quality Agreement between the Parties, upon delivery of the Product to the Licensee, the Licensee will be solely responsible for compliance with all quality control testing and other testing requirements set forth in this Agreement and, further, all applicable Law with respect to the manufacture, import, sale, use, storage and commercialization of the Product in the Territory;
- (c) where appropriate maintain the Regulatory Approvals for the Product in full force and effect throughout the Term.

Section 5.3 Rejection of Delivered Product. Within thirty (30) days of receipt of any shipment of Product and applicable COA and COC by the Licensee at its applicable warehouse in the Territory, the Licensee will undertake a customary inspection of the Product, COA and COC and advise Quoin of any defect actually revealed from such inspection whereby the Product does not conform to the Specifications. Any Product not refused within thirty (30) days will be deemed accepted in respect of any such apparent defect. If the Licensee wishes to refuse acceptance, the Licensee will, within such 30-day period, provide written notice to Quoin of its refusal to accept the defective Product and the reason(s) therefor. In the event a hidden defect (i.e., one which could not have been reasonably identified during the initial 30-day Licensee inspection period by a customary inspection) is discovered at a later date whereby the Product does not conform to the Specifications, the Licensee shall inform Quoin within fifteen (15) days after Licensee becomes aware of the alleged hidden defect. In the event that the Licensee refuses acceptance or rejects the Product due to a hidden defect, Quoin, upon confirmation of the reasons for refusal or rejection of the Product, will replace within ninety (90) days or as soon as reasonably practicable the defective Product at Quoin's sole cost and expense (including the cost of shipping) or refund the Initial Transfer Price and reimburse the shipping expense, at the Licensee's option. If Quoin and the Licensee do not agree on the refusal or rejection of Product, then either Party may refer the matter for final analysis to a specialized laboratory of national reputation acceptable to both Parties for the purpose of determining the results. Any determination by such laboratory will be final and binding upon the Parties. The cost of any such review by a laboratory shall be borne by the Licensee if it is determined that the Product conforms to the Specifications, and by Quoin if determined that it does not. Except as set out in this Section 5.3 and Section 10.1, Quoin shall have no liability to Licensee for any defect for which it has not received notice from the Licensee as specified herein.

Section 5.4 Recall. Licensee, in consultation with Quoin, shall have the exclusive right to institute a recall and shall be responsible for managing the recall and communications with customers and Governmental Authorities. The Parties shall cooperate with each other in connection with any such efforts. In the event that any Product is quarantined or recalled by Licensee, or is subject to stop-sale action, whether voluntary or by governmental action, it is agreed and understood that any reasonable and documented expenses, including any out-of-pocket administrative costs and reasonable and documented fees of any experts or attorneys that may be utilized by either Party, government fines or penalties, related to such recall, quarantine or stop-sale, will be borne by the Licensee unless it is determined that the reason for the quarantine, recall or stop-sale action is the result of the failure by Quoin to manufacture and supply (or have manufactured and supplied) Product that meets the Specifications and other requirements therefor under this Agreement and the Quality Agreement (including release and stability), and in such case such expenses will be the responsibility of Quoin. If the Parties do not mutually agree on which Party is responsible for the recall or other field action (or in what proportions), the responsibility for the recall or field action shall be determined by a mutually acceptable independent qualified third party whose fees shall be shared equally by the Parties.

Section 5.5 Quality Procedures. Quoin and Licensee shall comply with the terms of the quality requirements set forth in a quality agreement to be negotiated in good faith by the Parties and entered into by the Parties as soon as practicable after the date hereof but in any event at least one hundred eighty days (180) before anticipated launch of the Product in the Territory (the “Quality Agreement”) with respect to the manufacture of the drug substance used in the Product and the Product. To the extent that any inconsistencies or conflicts exist between the Quality Agreement and this Agreement with regard to quality requirements and compliance with applicable Law, the provisions in the Quality Agreement shall prevail.

Section 5.6 Manufacturing Changes.

(a) Licensee may unilaterally and in its sole discretion make one or more Required Manufacturing Changes by giving written notice thereof to Quoin, whereupon the Parties shall cooperate in implementing such Required Manufacturing Changes as promptly as reasonably practicable. Licensee may request one or more Discretionary Manufacturing Changes by giving at least ninety (90) days written notice thereof to Quoin, whereupon if Quoin accepts the requested Discretionary Manufacturing Changes (such acceptance not to be unreasonably withheld or delayed), the Parties shall cooperate in implementing such Discretionary Manufacturing Changes as promptly as reasonably practicable. Quoin shall promptly provide to Licensee Quoin’s good faith and detailed estimate of the actual and reasonable costs that will be incurred by Quoin resulting directly from any such Required or Discretionary Manufacturing Changes, including the cost of any obsolete inventory resulting from the changes. All such reasonable and documented costs shall be borne by Licensee.

(b) Quoin shall not in any respect amend, modify or supplement the Specifications or the manufacturing process or any materials or sources of materials used in connection with manufacturing the Product without the prior written consent of Licensee. Quoin may request or recommend one or more Discretionary Manufacturing Changes by giving at least ninety (90) days written notice thereof to Licensee and shall provide Licensee with appropriate documentation relating to any such changes to the Specifications or manufacturing process. If Licensee approves any such Discretionary Manufacturing Change, Quoin may implement such change in accordance with the specifications provided by Quoin to Licensee. All costs arising out of any Discretionary Manufacturing Changes requested by Quoin shall be borne by Quoin including the costs incurred by Licensee (if any) in obtaining Regulatory Approval for such Discretionary Manufacturing Change.

## ARTICLE VI

### PRICE AND PAYMENTS

Section 6.1 Prices. The price payable by the Licensee for Product will be the price set forth on Schedule 6.1 and will be adjusted pursuant to Section 6.3 (the “Initial Transfer Price”). The price for the Product set forth on Schedule 6.1 shall be equal to the Manufacturing Costs of Quoin.

Section 6.2 Other Costs. Any additional costs such as stability costs, scale-up expenses, and additional analytical or testing expenses that may be specifically incurred at the request of Licensee will be charged at actual cost to the Licensee. Quoin will provide prior information to the Licensee before incurring any such costs and/or expenses. A separate invoice will be issued to Licensee for such costs and/or expenses.

Section 6.3 Adjustment. Quoin shall be permitted to increase the Initial Transfer Price of Product on an annual basis commencing no earlier than twelve (12) months following launch of the Product in the Territory and on at least ninety (90) days' notice to the extent of any documented actual increase in the Manufacturing Costs.

Section 6.4 Invoices. Quoin will send all invoices in respect of any Product to a single address specified in writing by the Licensee to Quoin following the date that such Product subject to any Firm Order shall have been made available to the Licensee under Section 3.3(a). Payments for Product sold hereunder will be made by the Licensee to Quoin within sixty (60) days after the date of the invoice by electronic funds transmission in United States dollars as specified in any invoice, without any offset or deduction of any nature whatsoever. All payments will be made to such account as Quoin will have specified in writing to the Licensee with written confirmation of payment sent by email or facsimile to such address as Quoin will have specified in writing to the Licensee. Licensee shall advise Quoin within ten (10) calendar days of any disputed invoice. If the Licensee fails to pay any undisputed invoiced amount when due, a service charge will be imposed by Quoin equal to the lesser of one percent (1%) per month or the highest rate permitted by law of the outstanding amount for each month or portion thereof that such undisputed amount is overdue.

Section 6.5 Withholding Tax. Licensee will make all payments to Quoin under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment. Any tax required to be withheld on amounts payable by Licensee under this Agreement will be timely paid by Licensee on behalf of Quoin to the appropriate Governmental Authority, and Licensee will furnish Quoin with the corresponding proof of payment of such tax, as may be required in order to enable Quoin to request reimbursement or deduction of the withheld amount, or to otherwise comply with its duties. Licensee and Quoin agree to cooperate to legally minimize and reduce such withholding taxes and provide any information or documentation required by any taxing authority.

Section 6.6 Separate Sale. Each shipment of Product to the Licensee will constitute a separate sale, obligating the Licensee to pay therefor, whether said shipment is in whole or only partial fulfillment of any order or confirmation issued in connection therewith.

Section 6.7 Deductions. Except as otherwise required by applicable law, the Licensee agrees not to make any deductions of any kind from any payments becoming due to Quoin unless the Licensee will have received prior written authorization from Quoin authorizing such deduction.

## ARTICLE VII

### TERM AND TERMINATION

Section 7.1 Term. The provisions of this Agreement will commence on the date hereof and will terminate upon and simultaneously with the termination of the License (the "Term").

Section 7.2 Termination. Either Quoin, on the one hand, or the Licensee, on the other hand, as applicable, will have the right to terminate this Agreement with immediate effect (except as otherwise stated below) upon written notice to the other upon the occurrence of the following:

(a) Quoin, on the one hand, or the Licensee, on the other hand, files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or becomes subject to involuntary proceedings under any bankruptcy or insolvency Law;

(b) Quoin, on the one hand, or the Licensee, on the other hand, fails to cure any non-compliance with any of the terms and conditions hereof within the time period specified in any prior written notice (which will be at least thirty (30) days) delivered to the non-compliant Party by another Party;

(c) The termination of the License Agreement.

Section 7.3 Effects of Termination.

If this Agreement is terminated by Quoin pursuant to Section 7.2(a) or (b):

(a) The Licensee acknowledges and agrees that Quoin will be entitled to cancel any Firm Order accepted prior to the date of termination, and will not be obligated to supply any Product ordered by the Licensee pursuant to such Firm Order, with respect to any Product to be delivered after the effective date of the termination. In addition, Quoin may at its election deliver in accordance with the shipping terms of this Agreement all quantities of components, materials, APIs and work-in-progress, and finished product in Quoin's or its Affiliates' possession, and to the extent such components, materials, API, work-in-progress, and finished product have not already been paid for by Licensee and are not reasonably allocable to or usable for other activities being carried out by Quoin or its Affiliates, then the Licensee shall purchase them from Quoin at Quoin's actual cost, which amount shall be payable no later than thirty (30) days after receipt thereof by the Licensee.

(b) Subject to Section 7.3(a) hereof, termination or expiration of this Agreement for any reason will not relieve the Parties of any obligation accruing prior to such termination or expiration (including in respect of any Firm Orders). The rights and obligations of the Parties under Sections **4.1(a)**, **5.1(d)**, **5.3**, **5.4**, **6.4**, **6.5**, **7**, **10** and **11** of this Agreement will survive the expiration or termination of this Agreement.

## ARTICLE VIII

### FORCE MAJEURE

Section 8.1 Force Majeure. Neither Party will be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term or provision of this Agreement (other than the payment of money) when such failure or delay will be caused (directly or indirectly) by a circumstance beyond the reasonable control of the affected Party, including, without limitation, fire; flood; accident; explosion; other Acts of God; terrorism, sabotage; strike, or any labor disturbance (regardless of the reasonableness of the demands of labor); civil commotions; riots; invasions; wars (present or future); acts, restraints, requisitions, regulations, or directions of any Governmental Authority, except where such acts, restraints, requisitions, regulations or directions are the result of a Party's violation of applicable Law (each a "Force Majeure"). Any Party asserting its inability to perform any obligation hereunder for any such contingency shall promptly notify the other Party of the existence of any such contingency and shall use commercially reasonable efforts to mitigate such contingency and re-commence its performance of such obligation as soon as commercially practicable. Neither Party shall suffer penalty or incur any liability for its inability to perform hereunder by reason of Force Majeure. If a Party fails to perform any of its obligations under this Agreement by reason of Force Majeure and such non-performance continues for a period of one hundred and eighty (180) days from the first occurrence of the event of Force Majeure, the other Party may terminate this Agreement by providing written notice to that effect to the non-performing Party. In the event of such termination, the provisions contained in Section 7.3 shall apply.

**ARTICLE IX**  
**CONFIDENTIALITY**  
**ARTICLE X**  
**INDEMNIFICATION**

Section 10.1 By Quoin. From and after the Effective Date, Quoin will indemnify, defend and hold harmless, and pay and reimburse, the Licensee, its Affiliates and their respective officers, directors, employees, agents, advisors, and shareholders from and against any and all liabilities, losses, claims, damages, costs, and expenses (including reasonable attorneys' fees) ("Losses") resulting from or relating to any claim by a Third Party resulting from or arising out of: (i) Quoin's or its contractors' or Affiliate's negligence or willful misconduct, or (ii) any breach by Quoin of any of its representations and warranties, covenants, agreements or obligations contained in this Agreement; except to the extent such Losses arise as a result of the breach of this Agreement, or the negligence, willful misconduct, or breach of this Agreement by Licensee or its contractors or Affiliates.

Section 10.2 By the Licensee. From and after the Effective Date, the Licensee will indemnify, defend and hold harmless, and pay and reimburse, Quoin and its Affiliates and their respective officers, directors, employees, agents, advisors and shareholders from and against any and all Losses resulting from or relating to any claim by a Third Party resulting from or arising out of: (a) the Licensee's negligence or willful misconduct, or (b) breach of any of its representations and warranties, covenants, agreements or obligations contained in this Agreement; provided, however, that the Licensee shall not be liable for any Losses to the extent arising from Quoin's or its contractors' negligence, willful misconduct, or breach of its representations and warranties, covenants, agreements or obligations contained in this Agreement.

Section 10.3 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 Article X:

(a) Within ten (10) 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 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.

(b) 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.

(c) 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.

Section 10.4 Limitations.

(a) In no event shall either Party be liable by reason of any breach of any representation, warranty, condition or other term of this Agreement or any duty of common law, for any consequential, special, indirect or incidental or punitive loss or damage (whether for loss of current or future profits, loss of enterprise value or otherwise) and each Party agrees that it shall not make any such claim; provided, however, that the foregoing does not limit any of the obligations or liability of either Party or its Affiliates under Sections 10.1 and 10.2 with respect to claims of unrelated third parties or liability arising from fraud or willful misconduct of a Party or its Affiliates or contractors.

(b) Notwithstanding any other provision of this Agreement, in the event that the Licensee asserts or claims that Quoin has breached any of its obligations hereunder or that Quoin is liable pursuant to Section 10.1, Quoin's maximum liability under or in connection with any such claim herein shall be limited to the greater of \$2,000,000 and the policy limit amount stipulated in Quoin's commercial liability insurance policy, provided, however, that the foregoing shall not limit any liability arising from fraud or willful misconduct of Quoin or its Affiliates or contractors.

**ARTICLE XI**

**MISCELLANEOUS**

Section 11.1 Assignment. Neither Party may assign its rights or obligations under this Agreement without the prior written consent of the other Party; provided, however either Party may assign its rights and obligations under this Agreement, without the prior written consent of the other Party, to an Affiliate or to a successor of the assigning Party by reason of merger, sale of all or substantially all of its assets or the portion of its business which relates to a Product, or any similar transaction. Any permitted assignee or successor-in-interest will assume all obligations of its assignor under this Agreement. No assignment will relieve either Party of its responsibility for the performance of any obligation. This Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

Section 11.2 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable by any Law or public policy, the remaining provisions of this Agreement will nevertheless remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom as long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to either Party. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties will negotiate reasonably and in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

Section 11.3 Notices. All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and shall be deemed duly given (a) on the date delivered, if personally delivered, (b) on the date sent by telecopier with automatic confirmation by the transmitting machine showing the proper number of pages were transmitted without error, (c) on the Business Day after being sent by Federal Express or another recognized overnight mail service which utilizes a written form of receipt for next day or next Business Day delivery or (d) two (2) Business Days after mailing, if mailed by United States postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable Party at the address set forth below; provided that a Party may change its address for receiving notice by the proper giving of notice hereunder:

(a) if to the Licensee, to:

Endo Ventures Limited  
First Floor, Minerva House  
Simmons Court Road, Ballsbridge  
Dublin 4, Ireland  
Attention: Legal Department  
Email: bolger.marietherese@endo.com

With a copy (which shall not constitute notice) to:

Paladin Labs Inc.  
100 Alexis Nihon, Suite 600  
Saint-Laurent, Montreal  
Quebec, H4M 2P2  
Canada  
Attention: Isabelle Trempe  
Email address: Trempe.Isabelle@endo.com

With a copy (which shall not constitute notice) to:

Davies Ward Phillips & Vineberg  
1501 McGill College Avenue, 26th Floor  
Montreal  
Quebec, H3A 3N9  
Canada  
Attention: Hillel W. Rosen  
Email address: hrosen@dwpv.com

(b) if to Quoin, to:

Quoin Pharmaceuticals Inc.  
42127 Pleasant Forest Court  
Ashburn, VA 20148  
Attention: Michael Myers  
Email address: Mmyers@quoinpharma.com

with a copy (which shall not constitute notice) to:

Blank Rome LLP  
One Logan Square, 130 N 18th St.  
Philadelphia, PA 19103-6998  
Attention: Peter I Tsouflas, Esq.  
Facsimile: 202.379.9021  
Email: PTsouflas@blankrome.com

It is understood and agreed that this Section 11.3 is not intended to govern the ordinary course business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement, including the placement of orders and the delivery of Forecasts.

Section 11.4 Applicable Law. THIS AGREEMENT IS MADE UNDER, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, UNITED STATES OF AMERICA, APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED SOLELY THEREIN, WITHOUT GIVING EFFECT TO PRINCIPLES OF CONFLICTS OF LAW.

Section 11.5 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 New York, New York, in the English language in accordance with the then-existing Rules of Arbitration of the International Chamber of Commerce (the “ICC Rules”), except where those rules conflict with this Section 11.5, in which case this Section 11.5 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 ICC, 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.



Section 11.6 Entire Agreement. This Agreement and the attached Schedules, which are incorporated herein constitute the entire agreement between the Parties with respect to the subject matter hereof and all prior agreements with respect hereto are superseded. Each Party confirms that no representations, warranties, covenants or understandings of any kind, nature or description whatsoever are being made or relied upon by any Party. No amendment or modifications hereof will be binding upon the Parties unless set forth in a writing specified to be an explicit amendment to this Agreement duly executed by authorized representatives of each of the Parties. The Parties recognize that, during the Term of this Agreement, a purchase order, acknowledgement form or similar routine document (collectively "Forms") may be used to implement or administer provisions of this Agreement. Therefore, the Parties agree that the terms of this Agreement, as it may be amended, will prevail in the event of any conflict between this Agreement and the printed provision of such Forms, or typed provisions of Forms that add to, vary, modify or are in conflict with the provisions of this Agreement with respect to the Product sold during the Term of this Agreement.

Section 11.7 Headings. The headings used in this Agreement are intended for convenience only and will not be considered part of the written understanding among the Parties and will not affect the construction of this Agreement.

Section 11.8 Independent Contractors. The relationship between Quoin, on the one hand, and the Licensee, on the other hand, is solely that of Licensee and seller. It is expressly agreed that Quoin, on the one hand, and the Licensee, on the other hand, will be independent contractors and that neither the relationship among the Parties nor this Agreement will be construed as creating a partnership, joint venture or agency. Neither Quoin, on the one hand, nor the Licensee, on the other hand, will have the authority to make any statements, representations or commitments of any kind, or to take any action or to incur any liability or obligation which will be binding on the other, without the prior consent of the other Party to do so. All persons employed by a Party will be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment will be for the account and expense of such Party.

Section 11.9 Waiver. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other or subsequent breach or failure by said other Party whether of a similar nature or otherwise.

Section 11.10 Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will constitute one and the same instrument.

Section 11.11 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and nothing herein, express or implied, is intended to or will confer upon any person or entity any legal or equitable rights, benefits or remedies, other than to the extent set forth in Sections 10.1 and 10.2.

**[signature page follows]**

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed by their respective representatives thereunto duly authorized, all as of the date first written above.

**QUOIN PHARMACEUTICALS, INC.**

by /s/ Dr. Michael Myers

Name: Dr. Michael Myers

Title: CEO

**ENDO VENTURES LIMITED**

by /s/ Marie-Therese Bolger

Name: Marie-Therese Bolger

Title: Director

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Schedule 1.1  
DEFINITIONS

As used in this Agreement, the following terms will have the meanings ascribed to them below:

- (a) “Active Pharmaceutical Ingredient” or “API” means the active pharmaceutical ingredient for Product.
  - (b) “Affiliate” of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.
  - (c) “cGMPs” means current good manufacturing practice requirements of both the FDA (as promulgated under the Federal Food Drug and Cosmetics Act at 21 C.F.R. (parts 11, 210 and 211), and the European Medicines Agency as set forth in Regulation No. 1252/2014 and Commission Directive 91/356/EEC, as amended by Directive 2003/94/EC) and of Health Canada and applicable Law in the Territory.
  - (d) “COA” has the meaning set forth in Section 3.3(b).
  - (e) “COC” has the meaning set forth in Section 3.3(b).
  - (f) “Discretionary Manufacturing Change” means change to the Specifications or manufacturing processes that is not a Required Manufacturing Change.
  - (h) “FDA” means the United States Food and Drug Administration and any successor agency thereto
  - (i) “Firm Order” has the meaning set forth in Section 3.2.
  - (j) “Firm Order Period” has the meaning set forth in Section 3.1.
  - (k) “Force Majeure” has the meaning set forth in Section 8.1.
  - (l) “Forecast” has the meaning set forth in Section 3.1.
  - (m) “Forms” has the meaning set forth in Section 12.6.
  - (n) “Governmental Authority” means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country, or (ii) a federal, state, province, county, city or other political, administrative or regulatory subdivision thereof; in each case, in the jurisdiction where the Product is manufactured and/or in the Territory.
  - (o) “Inability to Supply” means either a Long Term Inability to Supply or a Short Term Inability to Supply and means both a Long Term Inability to Supply and a Short Term Inability to Supply collectively.
  - (q) “Law” means each federal, state, provincial, municipal, local, or foreign law, statute, ordinance, order, determination, judgment, common law, code, rule, official standard, or regulation, enacted, enforced, entered, promulgated, or issued by any Governmental Authority.
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(s) “Manufacturing” or “Manufactured” means the manufacture and packaging of Product, including, without limitation, mix, fill and finish.

(t) “Manufacturing Costs” means, with respect to a Product, (x) where Quoin is the actual manufacturer of such Product, the actual cost of manufacturing the Product (expressed on a per unit manufactured basis), which consists of (i) actual direct cost of any raw materials, intermediates, packaging materials and labor utilized in such Manufacturing, (ii) an appropriate share of factory overhead costs allocated to Manufacture of the Product, but excluding any costs related to under-utilized capacity, all calculated in accordance with GAAP, and (iii) any transportation, freight expenses actually incurred by Quoin to ship the material along with any costs paid to third parties with respect to any portion of manufacturing or testing the Product, or (y) where Product is manufactured by any subcontractor for any of the foregoing, the aggregate amount paid to such subcontractor and any other third parties with respect to any portion of manufacturing or testing the Product.

(u) “Party” or “Parties” means Quoin and/or the Licensee, as applicable.

(v) “Person” means any individual, corporation, partnership, limited liability company, limited liability partnership, syndicate, person, trust, association, organization or other entity, and including and successor, by merger or otherwise, of any of the foregoing.

(w) “Product” has the meaning set forth in the License Agreement.

(x) “Purchase Order Date” has the meaning set forth in Section 3.2(a).

(y) “Licensee” has the meaning set forth in the preamble.

(z) “Licensee Taxes” has the meaning set forth in Section 6.4.

(aa) “Licensee Trademark” has the meaning set forth in Section 11.1.

(bb) “Quality Agreement” has the meaning set forth in Section 5.6.

(cc) “Regulatory Approval” has the meaning set forth in the License Agreement.

(dd) “Required Manufacturing Change” means a change to the Specifications or manufacturing process that is required by a Governmental Authority or applicable Law.

(ff) “Specifications” means the requirements and standards for the manufacture, packaging, testing, storage and shipment of the drug substance used in the Product and the Product set forth in the Regulatory Approval and in Quality Agreement, as amended or supplemented in accordance with this Agreement.

(gg) “Term” has the meaning set forth in Section 7.1.

(hh) “Territory” means Canada.

(ii) “Third Party” means any Person, other than Licensee and its Affiliates, and other than Quoin and its Affiliates.

(jj) “Initial Transfer Price” means the amount to be paid by the Licensee to Quoin pursuant to Section 6.1 and as may be adjusted from time to time pursuant to Section 6.2.

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SCHEDULE 6.1  
INITIAL TRANSFER PRICE AND BATCH QUANTITIES

INITIAL TRANSFER PRICES AND BATCH QUANTITIES FOR DOSAGES AS OF EFFECTIVE DATE: [\*\*\*]

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