

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 8-K

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

Date of Report (Date of earliest event reported): **February 1, 2023**

Unicycive Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-40582
(Commission File Number)

81-3638692
IRS Employer
Identification No.)

**4300 El Camino Real, Suite 210
Los Alto, CA 94022**
(Address of principal executive offices)

Registrant's telephone number, including area code: **(650) 351-4495**

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

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

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	UNCY	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

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

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

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement

Unicycive Therapeutics, Inc. (the "Company") entered into a License Agreement (the "Agreement") effective as of February 1, 2023 with Lotus International Pte Ltd. ("Lotus") pursuant to which the Company licensed the exclusive right to develop, market and commercialize Renazorb® to Lotus in the Republic of Korea. Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval for Renazorb® in the licensed territory. In addition, Lotus will have sole responsibility for the importation of the drug product from Unicycive and for the costs of commercialization of Renazorb® in the licensed territory.

The Company will receive an upfront payment of \$750,000 upon execution of the Agreement and up to \$3.7 million in milestone payments and will be eligible for tiered royalties upon achievement of prespecified commercial achievements. The term of the Agreement shall continue in effect until ten (10) years from the date of the first product purchase order. Thereafter the Agreement shall be renewed automatically for succeeding terms of two years each unless either party provides ninety (90) days prior written notice of termination.

The foregoing summary of the Agreement is qualified in its entirety by reference to the Agreement attached as Exhibit 10.1 hereto and is incorporated herein by reference.

Item 8.01 Other Events.

On February 2, 2023, the Company issued a press release announcing that the Company entered into the Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

* Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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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 hereunto duly authorized.

Dated: February 2, 2023

UNICYCIVE THERAPEUTICS, INC.

By: /s/ Shalabh Gupta
Shalabh Gupta
Chief Executive Officer

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[*] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LICENSE AGREEMENT

This License Agreement (this “Agreement”), effective as of February 1, 2023 (the “Effective Date”), is entered into by and between Unicycive Therapeutics Inc., a Delaware corporation having offices at 4300 El Camino Real, Suite #210, Los Altos, California (“Unicycive”) and Lotus International Pte. Ltd, a Singapore corporation having offices at 80 Robinson Road #02-00 Singapore 068898 (“Lotus”).

RECITALS

WHEREAS, Unicycive owns or otherwise controls all rights in and to the Product (as defined below); and

WHEREAS, Lotus desires to obtain certain license rights in the Product, and Unicycive has agreed to grant Lotus such rights, and to provide certain related services concerning development, manufacture and supply, subject and pursuant to the terms and conditions set forth in this Agreement,

NOW, THEREFORE, Unicycive and Lotus agree as follows:

Both Unicycive and Lotus are hereinafter sometimes collectively referred to as the “parties” and each may be referred to in singular as a “party”

1. Definitions

When used in this Agreement the capitalized terms listed in this Section 1 shall have the following meanings:

1.1 “Delivery Date” shall have the meaning specified in Section 5 below.

1.2 “Intellectual Property Rights” means all trade secrets, patents and patent applications, trade marks (whether registered or unregistered and including any goodwill acquired in such trade marks), service marks, trade names, business names, internet domain names, e-mail address names, copyrights (including rights in computer software), moral rights, database rights, design rights, rights in know-how, rights in confidential information, rights in inventions (whether patentable or not) and all other intellectual property and proprietary rights (whether registered or unregistered, and any application for the foregoing), and all other equivalent or similar rights which may subsist anywhere in the world.

1.3 “Legal Requirements” means any present and future national, state or local laws (whether under statute, rule, regulation or otherwise), requirements under permits, orders, decrees, judgments or directives, requirements of any Regulatory Authority (including without limitation all regulatory filings necessary to support applications for any Product approvals throughout the Territory), and any other requirements related in any way to the exercise of Lotus’ license rights related to the Product under this Agreement.

1.4 “Licensed IP” means any Intellectual Property Rights controlled by Unicycive relating to the Licensed Product including Unicycive owned trademarks (including but not limited to Renazorb), patent or patent applications now or in future covering the Licensed Product, registration dossier and any other information or know how and documents that may be relevant for registration and marketing of the Licensed Product in the Territory.

1.5 “Net Sales” means, with respect to the Territory and each Product pack, the aggregate gross sales amount invoiced by Lotus and/or its affiliates to Third Parties (such as to wholesalers, buying groups, health insurance companies, governmental agencies and other institutions) for sales of the relevant Licensed Product pack in the Territory on arm’s length basis reduced by: (i) credits or allowances granted on account of rejections, returns, write-offs and invoicing errors; (ii) any tax imposed on the sale or use of the Licensed Product, including without limitation, sales, use, excise or value added taxes (VAT), tariffs, customs duties and surcharges and other governmental charges incurred in connection with the sale, exportation or importation of the Licensed Product; (iii) commissions to wholesaler, discounts, refunds, rebates, chargebacks, and retroactive price adjustments; (iv) inventory management (IMA) fees, wholesaler fees, and speciality charges, (v) freight, postage, shipping & insurance charges; and (v) regulatory costs.

1.6 “Product” and “Licensed Product” mean Renazorb (lanthanum dioxycarbonate nanoparticles) (Phosphate Binder) available as 500 mg, 750 mg, and 1000 mg tablets, including any future improvements, including but not limited to additional formulation, strengths and/or indications, thereof.

1.7 “Product Destination” means the shipping destination, as indicated by Lotus in a Product Purchase Order.

1.8 “Product Purchase Order” shall have the meaning specified in Section 5.

1.9 “Regulatory Authority” means the authority(ies) in each country in the Territory with responsibility for granting regulatory approval for the sale of the Product in such country, and any successor(s) thereto.

1.10 “Sales Quarter” means each period of three (3) consecutive calendar months commencing on the first day of January, April, July and October in any Sales Year.

1.11 “Sales Year” means with respect to the Product, each calendar year during the term of this Agreement after the Delivery Date. For purposes of this definition, the time between the Delivery Date and the end of the calendar year following the calendar year in which the Delivery Date occurred shall be included in the first Sales Year.

1.12 “Term” means the period of time specified in Section 10.1.

1.13 “Territory” means Republic of Korea.

1.14 “Third Party” means any person who or which is not a party to this Agreement.

1.15 “Dossier” shall mean a set of documents (modules 2 to module 5 of CTD format), in accordance with the requirements of the regulatory authority/bodies in the United States (US), as it may be updated from time to time. The Dossier shall be written in the English language and will be delivered to Lotus in electronic form (CD), in the Common Technical Document (CTD) format.

1.16 "Variation" shall mean any changes in the Dossier of Marketing Authorization in the Territory.

2. License Grant; Supply and Inspection Obligations

2.1 License Grant. Subject to the provisions set forth in this Agreement, Unicycive hereby grants to Lotus, and Lotus hereby accepts from Unicycive, an exclusive, non-transferable, sublicensable license rights in and to the Licensed IP for the purpose of enabling Lotus to develop, have developed, use, register, import, store, promote, sell, and offer for sale the Product solely in and for the Territory. Under no circumstances will Lotus exercise, or allow affiliates to exercise, the license rights granted hereunder anywhere outside the Territory, nor shall Lotus sell Products to any person or entity if there is any basis to suspect that such person or entity intends to ship or use the Product outside of the Territory. Lotus is allowed to register the Trademark of Unicycive in the Territory and Unicycive shall cooperate to provide consent to that effect when requested by Lotus.

2.2 Exclusive Supplier of Requirements. Both parties agree to enter into a Manufacturing and Supply Agreement and a Quality Agreement within twelve (12) months of the execution of this Agreement. Unicycive shall use commercially reasonable efforts to supply LOTUS with all of LOTUS's requirements for the Product, and LOTUS shall purchase exclusively from Unicycive all of such requirements for the Product. LOTUS shall provide forecasts (non binding forecast is mentioned in Annexure A) and place orders for its requirements of the Product, and Unicycive shall ship the ordered Products directly to LOTUS. Except as otherwise agreed upon in writing by the parties, LOTUS shall not order the Product from a supplier other than Unicycive.

2.3 Third Party Manufacturers. The parties acknowledge and agree that Unicycive may, at its sole option and discretion, satisfy its supply obligations to Lotus hereunder through arrangements with Third Parties who are engaged to perform services or supply in connection with the manufacture, testing and/or packaging of the Product, provided that such arrangements shall not relieve Unicycive of its express obligations under this Agreement.

2.4 Regulatory Approvals and Filings. Lotus shall apply for, obtain and maintain all regulatory approvals from Regulatory Authorities in the Territory, and comply with all Legal Requirements with respect to the Product necessary for Lotus to sell the Products in the Territory necessary to support Lotus' drug applications in the Territory and otherwise necessary to allow Lotus to perform its obligations, and exercise its license rights, under this Agreement. Lotus shall use commercial reasonable efforts: (i) at Lotus' own expense and sole responsibility, Lotus shall import API or drug substance and drug product from the contract manufacturer organization(s) and conduct all necessary analytical testing(s) or pre-clinical studies in the Territory for regulatory approvals; (ii) Lotus shall be solely responsible, at Lotus' own expense, for the import of the API and drug product for local clinical studies in the Territory; and (iii) Lotus has and assumes full financial and operational responsibility for the Product development (pre-clinical and clinical), registration and filing, and for obtaining any and all required approvals anywhere in the Territory. Unicycive shall provide documents not included in the US Dossier but available at the site, free of charge, including 3 batches of Process Validation of the Product, API DMF, GMP documents and GCP documents required for registration in the Territory. Lotus will bear the translation cost if those documents are not available in English.

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2.5 Variation filing. Unicycive is responsible for all the regulatory and development study cost if the variation is raised by Unicycive or the CMO; Lotus is responsible for all the regulatory and development study cost if the variation is raised by Lotus. Unicycive shall use commercially reasonable efforts to supply the Licensed Product according to the approved dossier in the Territory.

3. Product Development. The parties agree as follows with respect to the development of the Product:

3.1 Unicycive shall immediately start providing the documents of the Dossier to Lotus based on the list shared by Lotus which are available with Unicycive at Effective Date of this Agreement. Unicycive shall keep Lotus informed and updated on monthly basis on the studies, data, documents and information, as required for obtaining regulatory approval. Unicycive will, at its own expense and sole responsibility, carry out the complete development of the Licensed Product, including but not limited to all studies, data, documents and information, as required for obtaining regulatory approval in the United States (US dossier), and provide such Dossier to LOTUS by June 30, 2023. Any pending studies, data, documents and information, as required for obtaining regulatory approval in the United States (US dossier), in the Dossier shall be shared no later than December 31, 2023. Unicycive shall also provide marketed Certificate of Pharmaceutical Product (CPP) for the Licensed Product to Lotus as soon as reasonably possible.

3.2 Based on the US dossier, Lotus will obtain scientific advice from regulatory authority in order to obtain regulatory approval in the Territory, and will also carry out, at its own expense, any additional studies if required for obtaining regulatory approval in the Territory. Additionally, Lotus will be responsible, at its own expense, for registration of the License Product in the Territory and Unicycive shall provide all reasonably required assistance in this regard.

3.3 Unicycive will provide necessary samples of the Licensed Product free of charge to Lotus if required to fulfil its obligations hereunder. Moreover, Unicycive will use its commercially reasonable efforts to support Lotus (i) in conducting additional studies (including but not limited to pre-clinical and clinical studies) and (ii) during the regulatory procedure to obtain approval in the Territory.

4. Manufacturing and Supply. Unicycive will manufacture and supply the Licensed Product to Lotus in the Territory at the following supply prices: (i) * per tablet containing 500 mg lanthanum dioxycarbonate; (ii) * per tablet containing 750 mg lanthanum dioxycarbonate; and (iii) * per tablet containing 1000 mg lanthanum dioxycarbonate. The above mentioned Supply prices shall be fixed for period of * years from launch of the Product in the Territory and thereafter periodically subject to revision based on mutual agreement between the Parties.

5. Product Purchase Orders; Forecasts. All purchases and sales between Lotus and Unicycive hereunder will be initiated by Lotus' issuance of written purchase orders sent via overnight courier (such as Fed Ex), air mail, facsimile, or by e-mail (a "Product Purchase Order"). Each Product Purchase Order will state unit quantities, the Product Destination, and for the first Purchase Order a delivery date of not less than one hundred and eighty (180) days after the date of the Product Purchase Order (the "Delivery Date"). The subsequent Purchase Orders shall have a delivery date of not less than one hundred and twenty (120) days after the date of the Product Purchase Order. Each Product Purchase Order shall be subject to Unicycive's acceptance which shall be done within ten (10) days from receipt of Product Purchase Order. The Product Purchase Order shall be deemed to be accepted if there is no response from Unicycive within such ten (10) days period. Each Product Purchase Order shall be subject to Unicycive's acceptance. Except as otherwise provided herein, no term or condition contained in a Product Purchase Order may add, delete, supplement or otherwise modify any term or condition contained in this Agreement. In case of any conflict between any term or condition contained in a Product Purchase Order and this Agreement, the terms and conditions of this Agreement shall prevail. All mutual responsibilities for product manufacturing and supply, including the product forecast requirements, shall be detailed in the Product Manufacturing & Supply Agreement, which both parties agree shall be completed within * months of the execution of this Agreement.

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6. Product Delivery

6.1 Product Delivery. Unicycive shall arrange for the delivery of each Product shipment, via a carrier reasonably acceptable to Lotus, on or before the Delivery Date, to the Product Destination. All Product shipments shall be shipped C.I.F. destination. Unicycive shall ensure that the delivery of all Product shipments is accomplished in

accordance with applicable Legal Requirements, including without limitation all applicable customs, import and export requirements.

6.2 Delivery and Timing. Unicycive shall use commercially reasonable efforts to ensure that all deliveries of Product shipments are made on a timely basis to meet the Delivery Date.

6.3 Packaging; Labeling. Unicycive shall use commercially reasonable efforts to ensure that all Product shipments are properly packaged and labeled in accordance with all applicable Legal Requirements.

7. Payment Terms. In full consideration of the license rights granted to Lotus under this Agreement, Lotus shall pay to Unicycive a total of up to US\$4,450,000.00, as well as annual royalties, as follows:

7.1 Upfront Payment. Lotus shall pay to Unicycive an upfront cash payment of US\$750,000.00, to be paid within thirty (30) from the Effective Date of this Agreement.

7.2 Milestone Payments. Lotus shall pay to Unicycive the following amounts within thirty (30) days of achieving the following specified regulatory and commercial sales milestones: (i) * upon obtaining price reimbursement approval in the Territory; (ii) * upon the successful launch of the Licensed Product in the Territory; (iii) * upon the first time annual Net Sales reaching *; (iv) * upon the first time annual Net Sales reaching *; (v) * upon the first time annual Net Sales reaching *; and (vi) * upon the first time annual Net Sales reaching *.

7.3 Royalties; Minimum Royalties. Throughout the Term, Lotus shall pay to Unicycive royalties ("Royalties") on annual Net Sales in the Territory as follows: (i) * – *% of annual Net Sales; (ii) * – *% of annual Net Sales; (iii) * – *% of annual Net Sales; and (iv) above * – *%. By way of example: If the annual Net Sales is *, then the applicable Royalty for such year will be * - i.e., the amount resulting from: * x *% + * x *% + * x *%. For the purpose of reconciliation of the Royalties; Lotus shall provide report to Unicycive of Net Sales of the Product in writing within 45 days after the end of the relevant Sales Quarter (including a detailing of all deductions taken in the calculation of Net Sales). Such Royalty shall be payable by Lotus within 30 days from the Sales Year.

7.4 Lotus shall be entitled to deduct the amount of any withholding taxes required by law to be withheld, from its payments of the Upfront or Milestones and any other service payments payable under this Agreement (except for Product supply price) to Unicycive. Lotus shall promptly furnish Unicycive with copies of any tax certificate or other documentation evidencing such withholding. Lotus and Unicycive agree to reasonably cooperate in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

8. Representations and Warranties

8.1 Unicycive. Unicycive represents and warrants that:

(a) It has full power and authority to execute, deliver and perform this Agreement; it is a corporation duly organized, validly existing and in good standing under the laws governing its incorporation and has full corporate power and authority to execute, deliver and perform this Agreement.

(b) The execution, delivery and performance of this Agreement have been duly authorized by all necessary action of Unicycive. Unicycive is qualified to do business in all jurisdictions where such qualification is required for its performance hereunder. This Agreement constitutes a legal, valid and binding agreement of Unicycive, enforceable against Unicycive in accordance with its terms, except as limited by bankruptcy, insolvency, receivership and similar creditor's rights laws in effect from time to time.

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(c) Unicycive holds all required permits, licenses, approvals or other authorizations, and is in compliance with all necessary filing requirements necessary to perform its obligations hereunder.

8.2 Lotus. Lotus warrants and represents that:

(a) It has full power and authority to execute, deliver and perform this Agreement; it is a corporation duly organized, validly existing and in good standing under the laws governing its incorporation and has full corporate power and authority to execute, deliver and perform this Agreement. Lotus will perform all of its obligations under this Agreement in a professional, diligent and timely manner and in accordance with all Legal Requirements and prevailing international standards.

(b) The execution, delivery and performance of this Agreement have been duly authorized by all necessary action of LOTUS; this Agreement constitutes a legal, valid and binding agreement of LOTUS, enforceable against LOTUS in accordance with its terms, except as limited by bankruptcy, insolvency, receivership and similar creditor's rights laws in effect from time to time.

8.3 Warranty Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH ABOVE IN THIS SECTION 8, UNICYCIVE AND LOTUS GRANT TO EACH OTHER NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND UNICYCIVE AND LOTUS SPECIFICALLY DISCLAIM ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

9. Indemnity

9.1 Indemnification by Unicycive. Provided that the procedure for indemnification contained in Section 9.3 below is followed, Unicycive shall defend, indemnify, and hold harmless LOTUS and its officers, directors, employees, independent contractors, and agents from and against any and all actual or threatened loss, liability, claims, demands, suits, proceedings, expenses, recoveries, and damages, including attorneys' fees, expert witness fees, and court costs, arising out of or related to the gross negligence or willful misconduct of Unicycive.

9.2 Indemnification by Lotus. Provided that the procedure for indemnification contained in Section 9.3 below is followed, Lotus shall defend, indemnify, and hold harmless Unicycive and its officers, directors, employees, independent contractors, and agents from and against any and all actual or threatened loss, liability, claims, demands, suits, proceedings, expenses, recoveries, and damages, including attorneys' fees, expert witness fees, and court costs, arising out of or related to a breach by Lotus of its obligations (including warranties) under this Agreement, or from the gross negligence or willful misconduct of Lotus.

9.3 Procedure for Indemnification. The indemnified party shall promptly notify the indemnifying party of any claim for which the indemnified party seeks indemnification. Upon receiving such notice, the indemnifying party shall, within fifteen (15) days, notify the indemnified party as to whether it shall defend the claim. If the indemnifying party agrees to defend the claim, it shall have the sole right to defend or settle the claim; provided, that: (i) the indemnified party may retain counsel at its own expense to monitor such defense or settlement; (ii) if there is an actual or potential conflict of interest between the parties in such proceedings, the indemnified party may retain counsel at the expense of the indemnifying party and participate in such defense; and (iii) the indemnified party shall have the right to consent to any settlement, such consent not to be unreasonably withheld. If the indemnified party withholds consent from a settlement that includes an unconditional release of the indemnified party, then the indemnifying party's indemnification obligations shall be limited to the amount payable under such proposed settlement, and the indemnifying party shall have no further

obligation to defend such claim. The indemnifying party shall consult with the indemnified party and keep it informed with respect to the proceedings. The indemnified party shall offer its full cooperation in defense of a claim.

9.4 Control of Defense. If the indemnifying party fails to assume or diligently defend any claim, the indemnified party, at its sole and absolute discretion, may assume control over such defense or settlement, with fees and expenses paid by the indemnifying party; provided that the indemnifying party shall have the right to consent to any settlement, such consent not to be unreasonably withheld.

10. Term and Termination

10.1 Term. This Agreement shall become effective and binding upon the parties as of the Effective Date. Unless earlier terminated, as provided in Sections 10.2 and 10.3 below, the term of this Agreement shall continue in effect until ten (10) years from the Delivery Date. Thereafter, this Agreement shall automatically renew for successive periods of two (2) years unless either party provides written notice of termination during the last ninety (90) days of any renewal period.

10.2 Material Breach. In the event of any material breach of this Agreement by any party hereto, the other party shall be entitled to dispatch to the party alleged to be in breach a written demand for correction of such breach within a stipulated period, which period shall not be less than ninety (90) days following the date of dispatch of the written demand, and if the party alleged to be in breach fails to correct the breach within the period so stipulated in the written demand for correction, the other party shall have the unconditional right and option to terminate this Agreement by giving the party hereto in breach written notice to that effect, termination being effective on the effective date of such notice.

10.3 Other Termination Rights. This Agreement also may be terminated:

(a) By mutual assent of the parties;

(b) By either party, upon the other party's filing of a voluntary petition for bankruptcy, reorganization or arrangement under any state statute, or upon assignment for the benefit of creditors, or upon the appointment of a receiver or trustee with respect to such party or its assets, or upon the filing of a petition of the kind referenced above, against a party or its assets by a third party, which filing is made without the agreement of the subject party and is not dismissed within sixty (60) days of the date of such filing.

(c) By Lotus

(i) in case of failure of registration of the Licensed Product (failure to obtain Marketing Authorization) in the Territory;

(ii) in case additional studies conducted by Lotus fail to meet Korean FDA standards, notwithstanding Lotus' use of commercially reasonable efforts.

10.4 Survival. The following sections of this Agreement, in accordance with the terms and conditions of such sections shall survive expiration or termination of this Agreement: Sections 8, 9, 13, 14 as well as any provisions of this Agreement that by their nature and purpose would customarily be deemed to survive.

11. Force Majeure

Either party shall be excused for the period of any suspension in the performance of its obligations hereunder, when such party is prevented from performing by cause or causes which are beyond the reasonable control of such party, its agents, subcontractors or assignees and which could not have been reasonably foreseen or prevented, including without limitation, acts of God, civil commotion, war, invasion, rebellion, hostilities, strikes, or delays in the Regulatory Authority review process or orders of Regulatory Authorities pertaining to the subject matter of this Agreement (excluding, in each case, any such event caused in whole or in part by the party claiming a *force majeure* hereunder). The party making a claim of a *force majeure* event hereunder (an "Affected Party") shall provide prompt written notice to the other party describing the particulars of the occurrence, including an estimate of its expected duration and the probable impact on the performance of the Affected Party's obligations. The Affected Party also shall furnish periodic reports with respect thereto. Notwithstanding the foregoing: (i) the permitted suspension of the Affected Party's performance shall be of no greater scope and of no longer duration than is reasonably required by the *force majeure* event; (ii) no liability of either party which arose prior to the occurrence of the *force majeure* event shall be excused because of such occurrence; and (iii) the Affected Party shall use reasonable efforts to continue to perform its obligations hereunder and to cure or correct the *force majeure* event and to limit or mitigate damages to the other party.

12. Product Supply

Unicycive acknowledges the importance of ensuring a stable and consistent supply of the Product during the term of this Agreement. Therefore, the parties agree to meet and confer during the first twelve (12) months of this Agreement to discuss and establish commercially reasonable mechanism to achieve this mutual aim.

13. Notices

Any notice, communication or consent required or permitted by this Agreement will be in writing and will be sent: (i) by prepaid mail, return receipt requested; or (ii) via telecopy, followed within five (5) days by a copy mailed in the preceding manner, addressed to the other party at the following address or at such other address for which such party gives notice as provided under this Agreement. Such notice will be deemed to have been given when delivered or, if delivery is not accomplished by some fault of the addressee, when tendered:

If to Unicycive, addressed to:

Unicycive Therapeutics Inc.
4300 El Camino Real
Suite# 210, Los Altos, CA 94022
Attn.: Shalabh Gupta, MD
Telephone: 650-351-4495

If to Lotus, addressed to:

Lotus International Pte. Ltd.
80 Robinson Road #02-00
Singapore 068898
Attn.: Petar Vazharov
Telephone: +65 8876 0431

14. Governing Law

This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of New Jersey, excluding the Convention on Contracts for the International Sale of Goods and that body of law known as conflicts of laws.

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15. Assignment

The parties agree that their rights and obligations under this Agreement may not be transferred or assigned to a third party without the prior written consent of the other party hereto. Notwithstanding the foregoing, (i) either party may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise, and (ii) in the event Unicycive is acquired or assigns its rights in the Product to any third party, which it may do at its sole option and discretion, all of Unicycive's rights and obligations under this Agreement will be transferred and delegated to the acquiring or assignee entity.

16. Entire Agreement

This Agreement constitutes the entire agreement between the parties hereto pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions of the parties, whether oral or written. There are no warranties, representations or other agreements between the parties in connection with the subject matter hereof, except as specifically set forth herein.

17. Modification and Waiver

No modification to this Agreement, nor any waiver of any rights, shall be effective unless assented to in writing by the party to be charged and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

18. Limitation of Liability

IN NO EVENT WILL A PARTY HERETO BE LIABLE TO THE OTHER PARTY HERETO FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. THIS LIMITATION WILL APPLY EVEN IF SUCH OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. NOTWITHSTANDING THE ABOVE, THE LIMITATIONS OF THIS SECTION 18 SHALL NOT APPLY TO LOTUS'S OBLIGATIONS UNDER SECTION 8.

19. Independent Contractors

The relationship of Unicycive and Lotus established by this Agreement is that of independent contractors, and nothing contained in this Agreement shall be construed to: (i) give either party the power to direct or control the day-to-day activities of the other party; (ii) constitute the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking; or (iii) allow either party to create or assume any obligation on behalf of the other party for any purpose whatsoever.

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20. Counterparts

This Agreement may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

21. Parties Bound

This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors in interest and permitted assigns.

22. Severability

If any provision of this Agreement shall be determined to be void or unenforceable, the remaining provisions of this Agreement shall not be affected thereby, and every other provision of this Agreement shall remain in full force and effect and enforceable to the fullest extent permitted by law.

23. Further Assurances

The parties each agree to execute additional instruments and documents and to do all such further things as the other party may reasonably require in order to carry out the intent of this Agreement. In addition, the parties agree to reasonably cooperate with one another in connection with the execution of the other parties' obligations hereunder.

IN WITNESS WHEREOF, the parties have by duly authorized persons executed this Agreement as of the Effective Date.

Unicycive Therapeutics Inc.

By: /s/ Shalabh Gupta
Print Name: Shalabh Gupta, MD
Title: Chairman & CEO

Date February 1, 2023

Lotus International Pte. Ltd.

By: /s/ Petar Vazharov
Print Name: Petar Vazharov
Title: Director

Date:

Annexure A

*



Unicycive Announces Exclusive License and Development Agreement with Lotus for Renazorb in the Republic of Korea

Develops Renazorb opportunity in new market for patients with hyperphosphatemia

Agreement includes upfront payment, royalties, and milestone payments

LOS ALTOS, Calif., February 2, 2023 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced that it has entered into an exclusive license agreement with Lotus Pharmaceutical ("Lotus", Taiwan TWSE ticker: 1795), a leading global pharmaceutical company, for the development and commercialization of Renazorb® (lanthanum dioxycarbonate) in the Republic of Korea. Renazorb is Unicycive's novel phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease (CKD) patients.

"We are especially pleased to announce our second partnership for Renazorb in Asia and are delighted to be working with Lotus, a renowned global pharmaceutical leader. We believe this collaboration provides the optimal infrastructure for the further development and commercialization of Renazorb in the Korean market," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Hyperphosphatemia continues to be a serious problem for end stage renal patients around the world, particularly as compliance with currently available phosphate binders is challenging. There remains a need for a new treatment with a product profile that has meaningful patient adherence benefits, such as Renazorb."

"At Unicycive, one of our key goals is to bring Renazorb to hyperphosphatemia patients around the world and this latest partnership underscores our commitment to that mission. We continue to advance discussions with potential partners in other key geographies and look forward to building on the foundation of global partnerships we have initiated in Asia," added Dr. Gupta.

"The partnership with Unicycive is a testament to our efforts to bring novel treatment options for patients with chronic diseases. Nephrology is one of the key therapeutic areas for Lotus, and Alvogen Korea, an affiliate of Lotus group has been dominant and has contributed to the nephrology market with its other blockbuster products, such as Epoetin for CKD treatment, which has leading market share (45% based on 3Q 2022 IQVIA data). Renazorb® is expected to provide another high value of clinical benefits to CKD patients in Korea," said Petar Vazharov, Chief Executive Officer of Lotus.

Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval of Renazorb in the Republic of Korea. In addition, Lotus will have sole responsibility for the importation of the drug product from Unicycive and for the costs of commercialization of Renazorb in the Republic of Korea.

Unicycive will receive an upfront payment of \$750,000 and may receive up to \$4.45 million in milestone payments and tiered royalties upon achievement of prespecified regulatory and commercial achievements.

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About Renazorb (lanthanum dioxycarbonate)

Renazorb is a next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD). Its potential best-in-class profile has meaningful patient adherence benefits over currently available treatment options as it requires smaller and fewer number of pills per dose and is swallowed instead of chewed.

About Hyperphosphatemia

Hyperphosphatemia is a serious medical condition that occurs in nearly all patients with End Stage Renal Disease (ESRD). If left untreated, hyperphosphatemia leads to secondary hyperparathyroidism (SHPT), which then results in renal osteodystrophy (a condition similar to osteoporosis and associated with significant bone disease, fractures and bone pain); cardiovascular disease with associated hardening of arteries and atherosclerosis (due to deposition of excess calcium-phosphorus complexes in soft tissue).

Importantly, hyperphosphatemia is independently associated with increased mortality for patients with chronic kidney disease on dialysis. Based on available clinical data to date, over 80% of patients show signs of cardiovascular calcification by the time they become dependent on dialysis.

Dialysis patients are already at an increased risk for cardiovascular disease (because of underlying diseases such as diabetes and hypertension), and hyperphosphatemia further exacerbates this. Treatment of hyperphosphatemia is aimed at lowering serum phosphate levels via two means: (1) restricting dietary phosphorus intake; and (2) using, on a daily basis, and with each meal, oral phosphate binding drugs that facilitate fecal elimination of dietary phosphate rather than its absorption from the gastrointestinal tract into the bloodstream.

About Lotus

Lotus (1795: TT) is an international pharmaceutical company with a global presence that is focused on commercializing novel and generic pharmaceuticals, offering patients better, safer and more accessible medicines. The Company has a recognized best-in-class R&D and manufacturing platform in Asia and has established partnerships in nearly every global market including the U.S., Europe, Japan, China, and Brazil. Lotus runs over 100 strategically selected pharmaceutical projects in development and registrations across Asia and the US, with over 250 commercial products. The Company invests in diversified best portfolio consisting of high-barrier oncology, complex generics as well as 505(b)2 and NCE via internal R&D investment and licensing-in partnership, and also strengthens its portfolio competitiveness by adding biosimilar products with support from strategic partners. Its industry-leading infrastructure certified by most of the advanced regulatory authorities around the world, including US FDA, EU EMA, Japan PMDA, China FDA, and Brazil ANVISA.

More information is available at www.lotuspharm.com

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug, Renazorb, is a novel phosphate binding agent being developed for the treatment of hyperphosphatemia. UNI-494 is a patent-protected new chemical entity in late preclinical development for the treatment of acute kidney injury. For more information, please visit www.unicycive.com.

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Forward-looking statement

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified using words such as “anticipate,” “believe,” “forecast,” “estimated” and “intend” or other similar terms or expressions that concern Unicycive’s expectations, strategy, plans or intentions. These forward-looking statements are based on Unicycive’s current expectations and actual results could differ materially. There are several factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses; dependence on key personnel; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled ‘Risk Factors’ in Unicycive’s Annual Report on Form 10-K for the year ended December 31, 2021, and other periodic reports filed with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Unicycive specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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