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): **July 14, 2022**

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

Delaware	**001-40582**	**81-3638692**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	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 July 14, 2022 with Lee's Pharmaceutical (HK) Limited ("Lee's Pharma") pursuant to which the Company licensed the exclusive right to develop, market and commercialize Renazorb® to Lee's Pharma in Mainland China, Hong Kong and certain other Asia markets. Under the terms of the agreement, Lee's Pharma will be responsible for development, registration filing and approval for Renazorb® in the licensed territories. In addition, Lee's Pharma will have sole responsibility for the importation of the drug product from Unicycive and for the costs of commercialization of Renazorb® in the licensed territories.

The Company will receive an upfront payment of $1 million upon execution of the Agreement and up to $1 million in milestone payments upon product launch in China and will be eligible for tiered royalties upon achievement of prespecified regulatory and commercial achievements. The term of the Agreement shall continue in effect until ten (10) years from the date of the first commercial sale in any country in the territory. Thereafter the Agreement shall be renewed automatically for succeeding terms of one year each unless either party provides six months prior written notice of termination.

The foregoing summary of the Agreement is qualified in its entirety by reference to the Agreement attached as Exhibit 1.1 hereto and is incorporated herein by reference.

Item 8.01 Other Events.

On July 18, 2022, 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.

10.1*	License Agreement effective as of July 14, 2022 by and between Unicycive Therapeutics, Inc. and Lee's Pharmaceutical (HK) Limited
99.1	Press Release of Unicycive Therapeutics, Inc. dated July 18, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

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: July 18, 2022

UNICYCIVE THERAPEUTICS, INC.

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

[*] 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 July 14, 2022 (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 Lee's Pharmaceutical (HK) Limited, a Hong Kong corporation having offices at 1/F, Building 20E, Phase 3, Hong Kong Science Park, Shatin, N.T., Hong Kong ("LP").

RECITALS

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

WHEREAS, LP desires to obtain certain commercialization rights in the Product, and Unicycive has agreed to grant LP such rights, subject and pursuant to the terms and conditions set forth in this Agreement; and

WHEREAS, upon the terms set forth below, Unicycive has agreed to supply the Product to LP,

NOW, THEREFORE, Unicycive and LP agree as follows:

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 3 below.

1.2 "Field of Use" shall mean the treatment of hyperphosphatemia.

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 LP's applications for any Product approvals throughout the Territory), and any other requirements related in any way to the exercise of LP's license rights related to the Product under this Agreement.

1.4 "Product" means Renazorb (lanthanum dioxycarbonate).

1.5 "Product Destination" means the shipping destination, as indicated by LP in a Product Purchase Order.

1.6 "Product Purchase Order" shall have the meaning specified in Section 3.

1.7 "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.

1.8 "Term" means the period of time specified in Section 8.1.

1.9 "Territory" means People's Republic of China ("PRC"), Hong Kong, Macau, Taiwan, and Southeast Asia (i.e., Vietnam, Laos, Cambodia, Thailand, Burma, Singapore, Philippines, Malaysia and Indonesia). For purposes of Section 5.3(i) and (ii), PRC shall be deemed to include mainland China, Hong Kong, Macau and Taiwan, which will be deemed to count as one country.

1.10 "Third Party" means any person who or which is not a party to this Agreement.

2. License Grant; Supply and Inspection Obligations

2.1 License Grant. Subject to the provisions set forth in this Agreement, Unicycive hereby grants to LP, and LP hereby accepts from Unicycive, a non-transferable, non-sublicensable right to develop, market and commercialize the Product solely in the Territory and solely within the Field of Use. Under no circumstances will LP exercise, or allow Affiliates to exercise, the license rights granted hereunder anywhere outside the Territory, nor shall LP 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.

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 LP with all of LP's requirements for the Product, and LP shall purchase exclusively from Unicycive all of such requirements for the Product. LP shall provide forecasts and place orders for its requirements of the Product, and Unicycive shall ship the ordered Products directly to LP. Except as otherwise agreed upon in writing by the parties, LP shall not order the Product from a supplier other than Unicycive.

2.7 Third Party Manufacturers. The parties acknowledge and agree that Unicycive may, at its sole option and discretion, satisfy its supply obligations to LP 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.

2.8 Regulatory Approvals and Filings. LP 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 LP to sell the Products in the Territory necessary to support LP's drug applications in the Territory and otherwise necessary to allow LP to perform its obligations, and exercise its license rights, under this Agreement. Without limiting the foregoing, LP covenants, represents and warrants that: (i) at LP's own expense and sole responsibility, LP 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) LP shall be solely responsible, at LP's own expense, for the import of the API and drug product for local clinical studies in the Territory; and (iii) LP 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.

3. Product Purchase Orders; Forecasts

3.1 All purchases and sales between LP and Unicycive hereunder will be initiated by LP's issuance of written purchase orders sent via overnight courier (such as Fed Ex), air mail or by facsimile or email to Unicycive(a "Product Purchase Order"). Each Product Purchase Order will state unit quantities, the Product Destination, and a delivery date of not less than one hundred and eighty (180) days after the date of the Product Purchase Order (the "Delivery Date"). 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 12 months of the execution of this agreement.

4. Product Delivery

4.1 Product Delivery. Unicycive shall arrange for the delivery of each Product shipment, via a carrier reasonably acceptable to LP, 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.

4.2 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.

4.3 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.

5. Payment Terms

5.1 Upfront Payment. Upfront cash payment of $1,000,000 to be paid within 30 days of the signing of this Agreement.

5.2 Royalties; Minimum Royalties. Throughout the Term, LP shall pay to Unicycive royalties ("Royalties") at the following progressive percentage rates for the following annual Net Sales in the Territory: (i) US$*-US$* – *%; (ii) US$*-US$* – *%; (iii) US$*-US$* – *%; and (iv) above US$* – *%. The Royalties shall be subject to minimum annual royalty payments starting from year * of the Product launch using a base amount equal to * percent (*%) of the annual forecast Total Sales amount as set forth in the annual forecast table in Exhibit A of this Agreement. The minimum annual royalty payments shall be computed using the progressive rate structure set forth above for the Royalties; provided, however, that the minimum annual royalty payments starting from year six and onward shall be capped at the same amount as year five. Failure to pay such minimum payments within thirty (30) days from the end of the preceding calendar year shall constitute a material breach of this Agreement and shall entitle Unicycive to terminate this Agreement and the license granted hereunder. Notwithstanding anything to the contrary in this Agreement, as from * (*) years from the first commercial sale of the Product pursuant to this Agreement in any country in the Territory, LP shall have the right, subject to * (*) months prior written notice to Unicycive, to terminate this Agreement for convenience and to surrender the license granted to it back to Unicycive.

5.3 Milestone Payments. LP shall make the following one-time, non-refundable and non-cancelable payments to Unicycive: (i) $500,000 within thirty (30) days after *; (ii) $500,000 within thirty (30) days after *; and (iii) $* within thirty (30) days after *.

5.4 Taxes. The upfront payment, royalties, minimum royalties, milestone payments and other amounts payable by LP to Unicycive pursuant to this Agreement shall be net amounts without any deductions or set-off but subject to applicable tax withholdings (and LP is entitled to deduct such tax prior to remittance). LP shall pay tax to be withheld to the proper taxing authority in the Territory by the due date and send to Unicycive proof of such tax payment issued by the proper tax authority within sixty (60) days after tax payment.

6. Representations and Warranties

6.1 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.

(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.

6.2 LP. LP 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.

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

6.3 Warranty Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH ABOVE IN THIS SECTION 6, UNICYCIVE AND LP 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 LP SPECIFICALLY DISCLAIM ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

7. Indemnity

7.1 Indemnification by Unicycive. Provided that the procedure for indemnification contained in Section 7.3 below is followed, Unicycive shall defend, indemnify, and hold harmless LP 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.

7.2 Indemnification by LP. Provided that the procedure for indemnification contained in Section 7.3 below is followed, LP 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 LP of its obligations (including warranties) under this Agreement, or from the gross negligence or willful misconduct of LP.

7.3 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.

7.3 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.

8. Term and Termination

8.1 Term. This Agreement shall become effective and binding upon the parties as of the Effective Date. Unless earlier terminated, as provided in Section 5.2, and Sections 8.2 and 8.3 below, the term of this Agreement shall continue in effect until ten (10) years from the date of first commercial sale of the Product pursuant to this Agreement in any country in the Territory. Thereafter, this Agreement shall be renewed automatically for succeeding terms of one (1) year each unless either party provides six (6) months prior written notice of termination during any renewal period.

8.2 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.

8.3 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.

8.4 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 6, 7, 9 and 11-21, as well as any provisions of this Agreement that by their nature and purpose would customarily be deemed to survive.

9. 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.

10. 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.

11. 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 LP, addressed to:	Lee's Pharmaceutical (HK) Limited 1/F, Building 20E, Phase 3 Hong Kong Science Park, Shatin N.T., Hong Kong Attn.: Leelalertsuphakun Wanee Telephone: 2314 1282

12. Governing Law

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

13. 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 is 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.

14. Entire Agreement

This Agreement constitutes the entire agreement between the parties hereto pertaining to the subject matter hereof and supersede 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.

15. 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.

16. 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 16 SHALL NOT APPLY TO LP'S OBLIGATIONS UNDER SECTION 7.

17. Independent Contractors

The relationship of Unicycive and LP 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.

18. 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.

19. 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.

20. 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.

21. 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: _____

Print Name: Shalabh Gupta, MD

Title: Chairman & CEO

Lee's Pharmaceutical (HK) Limited

By: _____

Print Name: Leelalertsuphakun Wanee

Title: Managing Director

EXHIBIT A

ANNUAL SALES FORECAST

*

* Proposed selling price is *

Press Release

Unicycive Announces Exclusive License and Development Agreement with Lee's Pharmaceutical Holdings Limited for Renazorb in China and Certain Other Asian Markets

Expands and accelerates Renazorb opportunity in important markets for patients with hyperphosphatemia through local partner with deep domain expertise

Agreement includes upfront payment, royalties and milestone payments

LOS ALTOS, Calif., July 18, 2022 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced that the Company has entered into an agreement granting exclusive rights to develop, market and commercialize Renazorb® (lanthanum dioxycarbonate) to Lee's Pharmaceutical (HK) Limited, a wholly-owned subsidiary of Lee's Pharmaceutical Holdings Limited ("Lee's Pharm")(SEHK: 950), in Mainland China, Hong Kong, and certain other Asian markets. Renazorb is Unicycive's novel phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease (CKD) patients.

"We are delighted to partner with Lee's Pharm for the development and marketing of Renazorb in China, one of the world's largest markets for end-stage renal disease (ESRD), where we believe our novel phosphate binding agent will bring significant benefit to patients with hyperphosphatemia," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Lee's Pharm has the clinical, regulatory and commercial expertise in these Asian markets and we are confident this relationship will maximize the market opportunity for our proprietary nanotechnology-based asset in these territories while bringing meaningful benefit to patients. Unicycive owns global rights for Renazorb and by partnering Renazorb in select Asian countries, we begin to unlock its value for patients, physicians and for our shareholders."

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

Unicycive will receive an upfront payment of $1.0 million upon signature and up to $1.0 million in milestone payments upon product launch in China and will be eligible for tiered royalties upon achievement of prespecified regulatory and commercial achievements.

"The global renal disease market in Asia is growing due to the rise in chronic kidney disease, and in turn, results in increased incidence of hyperphosphatemia. The need for an effective phosphate binder with reduced pill burden would be a welcome addition to the treatment armamentarium as patient compliance is an important factor to achieving target serum phosphorous levels. Uncontrolled hyperphosphatemia is a persistent challenge that results in increased hospitalizations and in a greater risk of mortality," said Ms. Leelalertsuphakun Wanee, Managing Director of Lee's Pharm. "Renazorb also provides Lee's Pharm's commercial team with another product in our portfolio to sell in Asian markets."

The incidence and prevalence of ESRD in China was projected to increase by 1.19 and 1.95 % annually and was expected to reach 250.5 per million people (pmp) (95 % CI, 247.7-253.3) and 1505 pmp (95 % CI, 1450-1560) by 2025.[i] In patients with ESRD, the prevalence of hyperphosphatemia varies from 50% to 74%.[ii]

i BMC Nephrol. 2016 Jun 13;17(1):60. doi: 10.1186/s12882-016-0269-8.

ii Leaf DE, Wolf M. A physiologic-based approach to the evaluation of a patient with hyperphosphatemia. Am J Kidney Dis. 2013 Feb;61(2):330-6. [PMC free article] [PubMed]

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 Lee's Pharm

Lee's Pharm is a research-driven and market-oriented biopharmaceutical company with more than 25 years of operation in the pharmaceutical industry in China. Lee's Pharm is fully integrated with solid infrastructures in drug development, clinical development, regulatory, manufacturing, sales and marketing based in Mainland China with global perspectives. Lee's Pharm has established extensive partnerships with over 20 international companies and currently markets more than 25 proprietary, generic and licensed-in pharmaceutical products in Mainland China, Hong Kong, Macau and Taiwan. The Company focuses on several key disease areas such as cardio-renal, woman health, pediatrics, rare diseases, oncology, dermatology and obstetrics, and has more than 40 products under different development stages stemming from both internal research and development as well as from the licensing of development, commercialization, and manufacturing rights from various United States, European and Japanese companies. More information is available at www.leespharm.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.

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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