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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): **June 3, 2021**

CYCLERION THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Massachusetts	001-38787	83-1895370
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

245 First Street
18th Floor
Cambridge, Massachusetts 02142

(Address of principal executive offices, including Zip Code)
Registrant's telephone number, including area code: **(857) 327-8778**

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	CYCN	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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

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

Item 1.01. Entry into a Material Definitive Agreement

On June 3, 2021, Cyclerion Therapeutics, Inc. ("Cyclerion") and Akebia Therapeutics, Inc. ("Akebia") entered into a License Agreement (the "Agreement") relating to the exclusive worldwide license by Cyclerion to Akebia of Cyclerion's rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing the pharmaceutical compound known as praliciguat and other related products and forms thereof enumerated in the Agreement (collectively, the "Products").

Pursuant to the Agreement, Akebia will be responsible for all future research, development, regulatory, and commercialization activities for the Products. Cyclerion is eligible to receive up to $15 million in the first 18 months of the term. Further milestone cash payments by Akebia are scheduled in the Agreement based on the initiation of phase 3 clinical trials in the U.S. for Products for first and second indication, for FDA approvals, for approvals in certain other major markets, and for certain sales milestones. In addition to these cash milestone payments, Akebia will pay Cyclerion tiered royalty payments on net sales in certain major markets at percentages ranging from the mid-single digits to the high-teens, subject to certain reductions and offsets.

The Agreement commences effective immediately and will continue, on a Product-by-Product and country-by-country basis, in full force and effect until the expiration of the royalty term applicable to such Product and such country as set forth in the Agreement; provided that the Agreement may be terminated by either party in the event a material breach by the other party, by Cyclerion in event of certain patent disputes or the failure by Akebia to initiate phase 2 clinical trials within a set period of time, and by Akebia, subject to a notice period, at any time after one year from the effective date.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, which Cyclerion intends to file as an exhibit to its Quarterly Report on Form 10-Q for the fiscal quarter ending June 30, 2021. A copy of the press release announcing the Agreement is attached to this Current Report as Exhibit 99.1 and is incorporated herein by reference.

Item 3.02. Unregistered Sales of Equity Securities

On June 3, 2021, Cyclerion entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with seven investors (collectively, the "Investors") for the private placement (the "PIPE Transaction") of 5,735,988 shares (the "Shares") of Cyclerion's common stock, at a purchase price of $3.12 per share, or $3.28 per share with respect to Peter Hecht, Ph.D., Chief Executive Officer of Cyclerion, in compliance with Nasdaq listing rule 5635(c). Cyclerion did not utilize the services of a placement agent or broker in connection with the PIPE Transaction and accordingly incurred no material related transaction fees or commissions. Pursuant to the Purchase Agreement, Cyclerion is required to file a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"), covering the resale of the Shares and to obtain and maintain effectiveness thereof for up to three years, subject to certain exceptions and penalties.

In the PIPE Transaction, the Shares will be issued and sold to "qualified institutional buyers" within the meaning of Rule 144A under the Securities Act or "accredited investors" as defined in Rule 501 under the Securities Act in reliance upon exemptions from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder and corresponding provisions of state securities laws. Cyclerion intends to file a Form D in accordance with the requirements of Regulation D in connection with the PIPE Transaction.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the Purchase Agreement, which Cyclerion intends to file as an exhibit to its Quarterly Report on Form 10-Q for the fiscal quarter ending June 30, 2021. A copy of the press release announcing the PIPE Transaction is attached to this Current Report as Exhibit 99.2 and is incorporated herein by reference.

Forward Looking Statement

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include, among other things, whether the Agreement will result in the creation of any therapies for the treatment of patients with diabetic kidney disease or reno-protective effects in preclinical models of kidney disease; the uncertain utility, development, promise, and commercialization of praliciguat; and whether any of the referenced near-term or development, regulatory and commercialization milestones or royalty payments provided for in the Agreement with Akebia will be achieved. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the ability of any party to raise the funding needed to pursue business and product development plans; the inherent uncertainties associated with developing new products or technologies; the ability to develop, complete clinical trials for, obtain approvals for and commercialize any product candidates, including the ability to recruit and enroll patients in appropriate studies; the ability to address the requests of the U.S. Food and Drug Administration and similar regulators in other jurisdictions; and market conditions. These forward-looking statements are based on current beliefs and expectations of Cyclerion's management team that involve risks, potential changes in circumstances, assumptions, and uncertainties and may be identified, in some cases, by terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks listed under the heading "Risk Factors" and elsewhere in Cyclerion's 2020 Form 10-K filed on February 25, 2021, and Cyclerion's subsequent SEC filings, including the Form 10-Q filed on April 30, 2021. Investors are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Cyclerion undertakes no obligation to update these forward-looking statements, except as required by law.

Item 9.01 Financial Statements and Exhibits

(d)

Exhibit No.	Description
99.1	Press release dated June 4, 2021 announcing the Agreement.
99.2	Press release dated June 4, 2021 announcing the PIPE Transaction.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cyclerion Therapeutics, Inc.

Dated: June 4, 2021

By: /s/ Anjeza Gjino
Name: Anjeza Gjino
Title: Chief Financial Officer

Cyclerion Therapeutics Announces Global Licensing Agreement with Akebia Therapeutics for Praliciguat

Cyclerion eligible to receive up to $585 million in potential future development and commercial milestone payments, and tiered sales-based royalties

Praliciguat out-licensing further enables Cyclerion's strategic focus on CNS, including first-in-class CNS-penetrant sGC stimulators CY6463 and CY3018

CAMBRIDGE, Mass., June 4, 2021 -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN) today announced that it has entered into an exclusive, global license agreement with Akebia Therapeutics, Inc., a leading biopharmaceutical company focused on kidney disease, for the development and commercialization of praliciguat, an oral sGC stimulator.

Under the terms of the agreement, Akebia has obtained an exclusive license to research, develop and commercialize praliciguat globally and will be solely responsible for these activities going forward. Cyclerion is eligible to receive up to $225M in pre-commercial milestones, including up to $15M in the first 18 months. Total potential future development, regulatory, and commercialization milestone payments could result in up to $585M. Cyclerion is also eligible to receive tiered, sales-based royalties ranging from single-digit to high-teen percentages.

"We are very pleased to license praliciguat to Akebia, whose demonstrated leadership in kidney disease and extensive R&D and commercialization capabilities make it an ideal partner for the future development of praliciguat. This transaction provides Cyclerion with meaningful participation in any potential near and longer-term value creation and enables us to focus on our mission to develop treatments for cognitive impairment, including our foundational assets CY6463 and CY3018, where we see enormous clinical promise," said Peter Hecht, Ph.D., Chief Executive Officer of Cyclerion.

"We are pleased to expand our clinical development pipeline with the in-licensing of praliciguat, which is highly complementary of our strategy to identify and efficiently develop novel therapeutics for people impacted by kidney disease," said John P. Butler, Chief Executive Officer of Akebia Therapeutics, Inc. "We look forward to leveraging our capabilities to explore development and commercialization of praliciguat."

About Cyclerion Therapeutics

Cyclerion Therapeutics is a clinical-stage biopharmaceutical company on a mission to develop treatments that restore cognitive function. Cyclerion is advancing novel, first-in-class, CNS-penetrant, sGC stimulators that modulate a key node in a fundamental CNS signaling pathway. The multidimensional pharmacology elicited by the stimulation of sGC has the potential to impact a broad range of CNS diseases. The most advanced compound, CY6463, has shown rapid improvement in biomarkers associated with cognitive function and is currently in clinical development for Alzheimer's Disease with Vascular pathology (ADv), Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes (MELAS), and Cognitive Impairment Associated with Schizophrenia (CIAS). Cyclerion is also advancing CY3018, a next-generation sGC stimulator.

For more information about Cyclerion, please visit https://www.cyclerion.com/ and follow us on Twitter (@Cyclerion) and LinkedIn (www.linkedin.com/company/cyclerion).

Forward Looking Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the uncertain utility, development, promise, and commercialization of praliciguat; and whether any of the referenced or other development, regulatory, and commercialization milestones or royalty payments provided for in the license agreement with Akebia will be achieved. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the ability of any party to raise the funding needed to pursue business and product development plans; the inherent uncertainties associated with developing new products or technologies; the ability to develop, complete clinical trials for, obtain approvals for and commercialize any product candidates, including the ability to recruit and enroll patients in appropriate studies; the ability to address the requests of the U.S. Food and Drug Administration and similar regulators in other jurisdictions; and market conditions. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties. We may, in some cases use terms such as “predicts,” “believes,” “potential,” “continue,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “likely,” “will,” “should” or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks listed under the heading “Risk Factors” and elsewhere in our 2020 Form 10-K filed on February 25, 2021, and our subsequent SEC filings including the Form 10-Q filed on April 30, 2021. Investors are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Cyclerion undertakes no obligation to update these forward-looking statements, except as required by law.

Investors
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ctanzi@kendallir.com

Media
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Verge Scientific Communications
asellers@vergescientific.com

Exhibit 99.2

Cyclerion Therapeutics Announces $18 Million Private Placement

Proceeds to fund ongoing clinical development of CY6463 and advancement of next generation CY3018 program

CAMBRIDGE, Mass., June 4, 2021 -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), a clinical-stage biopharmaceutical company on a mission to develop treatments that restore cognitive function, today announced a direct private sale of approximately $18 million of Cyclerion shares of common stock to EcoR1 Capital, LLC, Slate Path Capital, LP, MFN Partners, LP, Invus, Peter Hecht, Ph.D., Lincoln Park Capital Fund, LLC and Polaris Partners.

“We are pleased with the ongoing support of this highly respected group of investors. This capital, coupled with the praliciguat out-license announced today, reinforces our strategic focus in CNS and will accelerate the advancement of clinical studies for CY6463 and the further development of our next generation molecule, CY3018. CY6463 is currently in clinical development in multiple neurological diseases associated with cognitive impairment, an area of tremendous unmet need where we believe CY6463 has the potential to offer meaningful clinical benefit,” said Peter Hecht, Ph.D. Chief Executive Officer of Cyclerion.

In the private placement, signed on June 3, 2021, the Company agreed to sell 5,735,988 shares of common stock at a price of $3.12 per share, or $3.28 per share with respect to Peter Hecht, Ph.D. in compliance with Nasdaq listing rules. The securities to be sold in the private placement have not been registered under the Securities Act of 1933, as amended (the “Securities Act”), or any state or other applicable jurisdiction’s securities laws, and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state or other jurisdictions’ securities laws. The Company has agreed to file a registration statement with the U.S. Securities and Exchange Commission registering the resale of the shares of common stock issued in the private placement within 10 business days after the date of the securities purchase agreement for the private placement.

About Cyclerion Therapeutics

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