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): December 17, 2024 (December 13, 2024)

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 AGREEMENT

On December 13, 2024, Cyclerion Therapeutics, Inc. (the "Company" or "Cyclerion"") and Akebia Therapeutics, Inc. ("Akebia") entered into Amendment #1 to License Agreement (the "Amendment") to the original License Agreement between the parties dated June 3, 2021 (the "2021 License Agreement").

Under the terms of the Amendment, Akebia has agreed to pay to the Company (i) $1,250,000 before December 31, 2024, and (ii) $500,000 on or before September 30, 2025. In addition, Akebia has agreed to assume control of the preparation, filing, prosecution and maintenance of certain Cyclerion patents, and the expenses associated therewith, at an earlier date than as originally agreed between the parties. The parties have agreed to the reduction of certain development milestones and the increase of certain royalty rates on net sales and sublicense income. Pursuant to the terms of the 2021 License Agreement, as amended, Akebia will pay Cyclerion tiered royalties ranging from mid-single digit to twenty percent of net sales. Cyclerion's obligations to deliver certain drug products have also ceased.

The above description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment #1 to License Agreement, which is filed as Exhibit 10.1 to this Form 8-K. Pursuant to the provisions of Item 1.01 of Form 8-K, certain information in the Amendment has been redacted which is of a confidential nature and which is not material.

ITEM 7.01 REGULATION FD DISCLOSURE.

On December 17, 2024, the Company issued a press release entitled "Cyclerion's sGC Stimulator Portfolio Generates Revenues to Enable Company Growth." The full text of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1. The press release was also simultaneously filed on the Company's website. The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

EXHIBIT INDEX

Exhibit Number	Exhibit Title
10.1†	Amendment #1 to License Agreement by and between the Company and Akebia Therapeutics, Inc. dated December 13, 2024
99.1	Press release dated December 17, 2024, titled "Cyclerion's sGC Stimulator Portfolio Generates Revenues to Enable Company Growth."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Registrant has omitted portions of Exhibit 10.1 as permitted under Item 601(b)(10) of Regulation S-K.

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: December 17, 2024

By: /s/ Regina Graul, Ph.D.
Name: Regina Graul, Ph.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 10.1

Certain information has been excluded from this agreement (indicated by "[***]") because such information is both not material and the type that the registrant treats as private or confidential.

AMENDMENT #1 TO LICENSE AGREEMENT

This Amendment #1 (the "**Amendment**") to the License Agreement (the "**License Agreement**") dated June 3, 2021 by and between **Akebia Therapeutics, Inc.,** a Delaware corporation ("**Akebia**"), and Cyclerion Therapeutics, Inc., a Massachusetts corporation ("**Cyclerion**") is effective as of December 13, 2024 (the "**Amendment Effective Date**"). Akebia and Cyclerion are each referenced individually herein as a "**Party**" and together as the "**Parties**". Any capitalized terms used but not herein defined shall have the meaning set forth for such term in the License Agreement.

WHEREAS, Akebia and Cyclerion are parties to the License Agreement pursuant to which Cyclerion granted Akebia an exclusive license under certain intellectual property rights to Exploit Licensed Compounds and Products in the Territory (each as defined in the License Agreement), in each case, in accordance with the terms and conditions set forth in the License Agreement;

WHEREAS, pursuant to the License Agreement, the Parties entered into that certain Supply Agreement dated as of August 3, 2021; and

WHEREAS, the Parties now desire to amend certain provisions of the License Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. **Amendment Payments**. In consideration for the rights granted by Cyclerion to Akebia under this Amendment:
   a. No later than December 31, 2024, Akebia shall pay Cyclerion an upfront amount equal to One Million Two Hundred and Fifty Thousand Dollars ($1,250,000). Such payment shall be nonrefundable and noncreditable against any other payments due hereunder.
   b. No later than September 30, 2025, Akebia shall pay Cyclerion an amount equal to Five Hundred Thousand Dollars ($500,000). Such payment shall be nonrefundable and noncreditable against any other payments due hereunder.
2. **Section 1.62** of the License Agreement is hereby deleted in its entirety and replaced with the following:

   "1.62 [**Reserved]**."
3. **Section 1.94** of the License Agreement is hereby deleted in its entirety and replaced with the following:

   "1.62 "**Patent Transfer Date**" means the earlier of (a) [***] and (b) such date that the Parties may agree, following request by Akebia or Cyclerion.

4. **Section 5.1** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.1 **Initial Supply of Products**. Notwithstanding the terms of the Supply Agreement dated August 3, 2021 between the Parties (the "**Supply Agreement**") pursuant to which Cyclerion agreed to deliver Drug Product (as defined in the Supply Agreement) and placebo to Akebia for clinical use (the "**Initial Supply**"), the Parties acknowledge and agree that Cyclerion did not deliver the Initial Supply to Akebia, and as of the Amendment Effective Date, Akebia will have sole control over and decision-making authority with respect to the Manufacture of all Drug Product in accordance with Section 5.6. Akebia hereby further agrees that it is not entitled to any damages of any kind that could be awarded as a result of Cyclerion's failure to deliver the Initial Supply.

5. **Section 5.2** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.2 [Reserved]."

6. **Section 5.3** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.3 [Reserved]."

7. **Section 5.5** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.5 Additional Development Materials. The Parties acknowledge that as of the Effective Date, Cyclerion was in physical possession of that inventory of [***](the "Additional Development Materials"), in each case as set forth on Schedule 11.1(u). Following the Amendment Effective Date, Cyclerion shall provide Akebia with a written update regarding the quantity and type of Additional Development Materials in Cyclerion's physical possession as of the Amendment Effective Date. Cyclerion shall perform testing on [***] at its sole cost and expense, and shall deliver a written summary of the type of tests conducted and the results of such testing to Akebia in the form of a Certificate of Analysis or Results Summary issued by the contract manufacturing organization performing such testing (the "**Test Results**").

For a period of [***] following Cyclerion's delivery of the Test Results to Akebia (the "Purchase Period"), Akebia may elect, in its sole discretion, to purchase and take delivery of any or all of such inventory of Additional Development Materials, in units that are readily available and, notwithstanding any provision to the contrary in Schedule 11.1(u), at a purchase price for the Additional Development Materials to be negotiated in good faith by the Parties prior to Akebia's election to purchase the Additional Development Materials. If Akebia elects to purchase the Additional Development Materials, Akebia shall also reimburse Cyclerion for the cost of such testing as part of such negotiated transfer price. If Akebia elects to purchase the Additional Development Materials in this manner, it shall do so by providing written notice to Cyclerion that Akebia elects to purchase and have delivered the Additional Development Materials, and Cyclerion shall deliver such inventory to Akebia or its designee at Akebia's direction, at Akebia's sole cost and expense, which for the sake of clarity, shall include any tariffs. Title to such Additional Development Materials shall transfer to Akebia at the time of delivery. Cyclerion shall use reasonable efforts to manage any storage and handling of Additional Development Materials in its physical possession as of the Amendment Effective Date in accordance with standard industry practice. Akebia shall reimburse Cyclerion all reasonable costs incurred by Cyclerion or its Affiliates in connection with the storage of such Additional Development Materials during such period until delivery thereof to Akebia, within [***] after receipt of an invoice therefor. Notwithstanding the foregoing, prior to Akebia's delivery of an election to purchase notice to Cyclerion, on a material-by-material basis Akebia may waive its option to purchase some or all of such Additional Development Materials by providing written notice of such waiver, and from the date of delivery of such notice Akebia shall no longer reimburse Cyclerion for the costs incurred by Cyclerion or its Affiliates in connection with the storage of such material.

In the event Akebia does not elect to purchase the Additional Development Materials during the Purchase Period, Akebia shall have no obligation with respect to such Additional Development Materials and Cyclerion shall remain responsible for the costs of such testing.

8. **Section 5.6** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.6 **Manufacture of Licensed Compounds and Products**. As between the Parties, Akebia shall have sole control over and decision-making authority with respect to, at its expense, (a) Manufacturing (or having Manufactured) the Licensed Compounds and Products and (b) Manufacturing (or having Manufactured) [***], and all other intermediates and other precursors of the Licensed Compounds and the Products, solely for the purpose of Manufacturing the Licensed Compounds and the Products for Development and Commercialization in the Field in the Territory by Akebia and its Affiliates and Sublicensees."

9. **Section 7.2** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"7.2 **Development and Regulatory Milestone Payments.** In partial consideration of the rights granted by Cyclerion to Akebia hereunder and subject to the terms and conditions set forth in this Agreement, including Section 7.2, Akebia shall pay to Cyclerion the applicable milestone payment set forth in Table 7.2 within [***] after the first achievement of each of the following milestones by Akebia or its Affiliates for the first Product:

Table 7.2 – Development and Regulatory Milestones

U.S.	***Development and Regulatory Milestone Payment***
Initiation of a Phase 2 Clinical Trial in the U.S. for a Product for the first Indication	[***]
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the first Indication	[***]
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the second Indication	[***]
Receipt of Regulatory Approval by the FDA for a Product for the first Indication	[***]
Receipt of Regulatory Approval by the FDA for a Product for the second Indication	[***]
[***]	[***]

[***]	***Development and Regulatory Milestone Payment***
Receipt of [***] Regulatory Approval for a Product for the first Indication	[***]
Receipt of [***] Regulatory Approval for a Product for the second Indication	[***]
[***]	[***]

[***]	***Development and Regulatory Milestone Payment***
Receipt of Regulatory Approval by the PMDA for a Product for the first Indication	[***]
Receipt of Regulatory Approval by the PMDA for a Product for the second Indication	[***]
[***]	[***]

Each milestone payment in this Section 7.2 shall be payable one time only upon the first achievement of such milestone by the first Product.

If Akebia or its Affiliates achieves any milestone set forth in this Section 7.2 for a particular Product in a particular Indication before an earlier listed milestone for the same Product in the same Indication, then the earlier listed milestone shall become payable at the same time as the achieved milestone for the same Product in such Indication. No milestone payments in this Section 7.2 shall be due based on the achievement of any of the foregoing milestone events by any Significant Sublicensee."

10. **Section 7.3** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"7.3. [Reserved]."

11. **Section 7.5(a)** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"(a) **Akebia Royalty Rate – [***].** As further consideration for the rights granted to Akebia hereunder, subject to the terms and conditions of this Agreement, including the other terms of this Section 7.5, [***], during the Royalty Term for a Product [***], Akebia shall pay to Cyclerion tiered royalties based on Net Sales recorded by Akebia or its Affiliates of all Products [***] in a Calendar Year at the applicable royalty rates set forth below:

Table 7.5 – Akebia Royalties [***]

[***]	[***]
[***]	[***]
[***]	[***]
[***]	Twenty Percent (20%)

12. **Section 7.6** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"7.6 **Sublicense Income.**

(a) Akebia shall pay to Cyclerion an amount equal to [***].

(b) Akebia shall pay to Cyclerion an amount equal to [***].

(c) For purposes of calculating [***].

(d) Akebia shall pay Cyclerion its portion of [***]."

13. **Miscellaneous**.

a. All capitalized terms used but not defined herein shall have meanings set forth in the License Agreement.

b. Except as otherwise provided herein, all provisions of the License Agreement, as amended hereby, shall remain in full force and effect.

c. This Amendment, the Supply Agreement and the License Agreement (including any schedules or other attachments hereto or thereto) constitute the entire agreement between the Parties with respect to the subject matter hereof and thereof, and no oral or written statement may be used to interpret or vary the meaning of the terms and conditions hereof or thereof. This Amendment supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

d. This Amendment may only be assigned in connection with any permitted assignment of the License Agreement, and shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Cyclerion or Akebia, as the case may be.

e. In the event of any conflict between the provisions of this Amendment and the License Agreement, the provisions of this Amendment shall control as to the subject matter set forth herein.

f. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

g. This Amendment may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Amendment. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Amendment.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Amendment effective as of the Amendment Effective Date written above.

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler
Print Name: John P. Butler
Title: President & CEO

CYCLERION THERAPEUTICS, INC.

By: /s/ Regina S. Graul
Print Name: Regina S. Graul
Title: President and Chief Executive Officer

Exhibit 99.1

Cyclerion's sGC Stimulator Portfolio Generates Revenues to Enable Company Growth

– Cyclerion Has Renegotiated Praliciguat License Agreement to Obtain Upfront and Near-Term Payments as well as Entered into a License Option Agreement for Olinciguat –

CAMBRIDGE, Mass., December 17, 2024 – Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), today announced an update on its progress in catalyzing the Company's next stage of growth. The Company is leveraging its legacy soluble guanylate cyclase (sGC) stimulator assets to generate near-term revenues which will be used to implement its strategic building plan without near-term dilution.

"These agreements demonstrate Cyclerion's progress in maximizing its legacy asset value while redirecting resources toward acquiring potential new assets," said Regina Graul, Ph.D., President and Chief Executive Officer of Cyclerion. "These newly finalized agreements, combined with our significant reduction of operating expenses, enable the focused use of our capital to support our anticipated pipeline build in the central nervous system (CNS) space. Concurrently, we plan to raise capital, as needed, to fund our product plans to create value for shareholders and patients." Graul continued, "Cyclerion's diligence team, comprised of committed external experts in their respective fields, is currently in advanced stages of conducting promising asset evaluations, which we believe have the potential to be the new foundation for Cyclerion."

Cyclerion and Akebia have re-negotiated a mutually beneficial amendment to their exclusive license agreement for praliciguat, a systemic sGC stimulator. Under the new license amendment with Akebia, Cyclerion will receive $1.75 million in upfront and near-term payments. In addition, Akebia will assume responsibility for all intellectual property expenses associated with praliciguat after Q1 2025. In 2021, Akebia paid a $3.0 million upfront payment to the Company upon signing of the license agreement, and the Company is eligible to receive additional milestone cash payments of up to approximately $560 million in total potential future development, regulatory, and commercialization milestone payments for praliciguat. In exchange for a reduction in certain development milestone payments, Cyclerion is eligible to receive certain higher, tiered, sales-based royalties ranging from mid-single-digits to twenty percent.

Cyclerion has also entered into an exclusive license option agreement for its vascular sGC stimulator, olinciguat, with a separate entity, wholly controlled by CVCO Therapeutics, Inc., a clinical stage company focused on microvascular dysfunction in cardiovascular, inflammatory and metabolic disease states. Under the terms of the agreement, the potential partner has exclusive rights to evaluate olinciguat during the option period. During the option period, the grantee has assumed responsibility for all ongoing intellectual property-related expenses associated with olinciguat.

As part of its strategic initiatives, Cyclerion previously announced a definitive agreement for the sale of its CNS assets zagociguat and CY3018 to Tisento Therapeutics in May 2023 for an $8 million cash payment and a 10% equity stake in Tisento. The amended agreement for praliciguat, and if the option for olinciguat is exercised, would represent the likely final steps in the monetization of Cyclerion's historical portfolio. Cyclerion believes it is well positioned for the next phase in its overall strategy, to bring in new CNS assets to rebuild the pipeline.

Forward Looking Statement

Certain matters discussed in this press release are “forward-looking statements”. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should”, “positive”, or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this press release include, but are not limited to, statements about pursuing collaborations, licenses, mergers, acquisitions and/or other targeted investments aimed at enhancing shareholder value. We cannot assure you that the forward-looking statements in this press release will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including, those under the heading “Risk Factors” in our Annual Report on Form 10-K filed with the SEC on March 5, 2024 as well as other risks and uncertainties which may be described in any subsequent quarterly report on Form 10-Q filed by the Company and the other reports the Company files with the SEC. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Contacts

Investor & Media Relations
Email: IR@cyclerion.com