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December 12, 2023

By EDGAR Submission

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington D.C. 20549

Attn: Ms. Li Xiao and Ms. Angela Connell

Re: Cyclerion Therapeutics Inc.
Form 10-K for the Fiscal Year Ended December 31, 2022
Filed March 22, 2023
Form 10-Q for the Quarterly Period Ended September 30, 2023
Filed November 13, 2023
File No. 001-38787

Dear Ms. Li and Ms. Connell:

Reference is made to a letter dated November 28, 2023 (the "Comment Letter") to Peter M. Hecht, the former Chief Executive Officer of Cyclerion Therapeutics, Inc. (the "Company" or "Cyclerion"), setting forth comments of the staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") to the Annual Report on Form 10-K for the year ended December 31, 2022 (the "Annual Report") and Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023 (the "Quarterly Report"), filed by the Company. As previously announced Peter M. Hecht resigned as an officer and employee of Cyclerion effective December 1, 2023. Regina Gaul, Ph.D. now serves as President of Cyclerion.

This letter sets forth the Company's response to the Staff's comments. The headings and numbered paragraphs in this letter correspond to the headings and numbered paragraphs in the Comment Letter.

Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Annual Report or the Quarterly Report.

Form 10-Q for the quarterly period ended September 30, 2023

Notes to the Condensed Consolidated Financial Statements

4. Discontinued Operations, page 14

- You disclose that on May 11, 2023 you sold all of the assets comprising your zagociguat and CY3018 programs (Program Assets) to Tisento Therapeutics Inc. and have presented the operations of the Program Assets as discontinued operations for all periods presented. Please explain to us how you determined that the disposal of these programs results in a strategic shift in your operations given that you continue to hold other soluble guanylate cyclase ("sGC") stimulators in your product candidate portfolio.**

Company Response

In evaluating whether the Program Assets should be presented as discontinued operations, the Company considered the criteria in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 205-20-45-1B and determined that it met all the criteria to be presented as discontinued operations for the period ended September 30, 2023.



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Furthermore, the Company noted the following excerpt from ASC 205-20-45-1C:

Examples of a strategic shift that has (or will have) a major effect on an entity's operations and financial results could include a disposal of a major geographical area, a major line of business, a major equity method investment, or other parts of an entity.

The definition of “strategic shift” in ASC 205-20-45-1B does not include any bright line guidance. Accordingly, significant judgment is required in order to determine whether a disposal constitutes a strategic shift. When evaluating whether a disposal represents a strategic shift, the Company considered the manner in which management has organized, analyzed and managed its product portfolio; the nature of its portfolio, their development priorities and objectives; and how management discusses and discloses the nature of its business and operations in its financial statements, press releases, and other supplemental information.

Prior to the sale of the Program Assets, Cyclerion’s portfolio included novel sGC stimulators that modulate a key node in a fundamental signaling network in both the central nervous system (“CNS”) and the periphery.

The following table is a high-level summary of Cyclerion’s portfolio assets prior to the sale:

<u>Program</u>	<u>Indication(s)</u>	<u>Description</u>	<u>Status</u>
Zagociguat (CNS-penetrant)	MELAS, CIAS, ADV	zagociguat is a CNS-penetrant sGC stimulator that has shown rapid improvements across a range of endpoints reflecting multiple domains of disease activity, including mitochondrial disease-associated biomarkers.	Sold to Tisento as part of the Asset Purchase Agreement.
CY3018 (CNS-penetrant)	Neuropsychiatric	CY3018 is a CNS-penetrant sGC stimulator in preclinical development that has potential for the treatment of neuropsychiatric diseases and disorders.	Sold to Tisento as part of the Asset Purchase Agreement
Olinciguat (peripheral)	Cardiovascular	olinciguat is a vascular sGC stimulator that the Company intends to out-license for cardiovascular diseases.	Management plans to outlicense olinciguat
Praliguat (peripheral)	Focal Segmental Glomerulosclerosis (FSGS)	praliguat is a systemic sGC stimulator that is licensed to Akebia and being advanced in rare kidney disease.	Outlicensed to Akebia

As referenced in the Company’s October 6, 2022 press release, the Company’s primary focus was on developing treatments for CNS diseases with CNS penetrant sGC stimulators. While acknowledging all assets within Cyclerion’s portfolio include sGC stimulators, the Program Assets (zagociguat and CY3018) sold to Tisento are uniquely different from the assets retained by Cyclerion (olinciguat and praliguat). The Program Assets have high exposure to the CNS (i.e., CNS-penetrant sGC stimulators). In contrast, the retained assets are peripheral sGC

stimulators. The retained assets are therefore not interchangeable with the Program Assets and do not provide the same benefit in CNS and correspondingly the Program Assets do not provide the same benefit for systemic/vascular diseases. Additionally, as part of the Asset Purchase Agreement (“APA”), Cyclerion is contractually prohibited from competing for five (5) years from the closing date from developing CNS-penetrant sGC stimulators or working with any Affiliate or Third Party on CNS-penetrant sGC stimulators (Section 6.13(a) of APA). In addition, Cyclerion does not intend to research CNS-penetrant sGC stimulators in the future. Thus, Cyclerion has strategically shifted out of research and development of CNS-penetrant sGC assets.

After the sale of the Program Assets, the Cyclerion programs being retained are olinciguat and praliguat which are not CNS focused and are either currently out-licensed (praliguat) or management plans to out-license (olinciguat). The Company’s prior strategy to conduct research and development on sGC stimulators for CNS has been discontinued subsequent to the sale of the Program Assets. Cyclerion does not intend to internally pursue research and development or commercialization with any type of sGC assets at this time but intends to utilize royalties and milestones by out-licensing olinciguat and praliguat to pursue opportunities with new assets. The Company has shifted its strategy to identify, **non-sGC** stimulator assets within the CNS therapeutic area to build a new portfolio. Once the Company identifies new assets outside of the sGC stimulator space, the research and development organization will be built in a fit-for-purpose way to the appropriate size with the appropriate skillsets. This new approach was evidenced by the Company’s “go forward strategy” as referenced in the Company’s May 11, 2023 press release.

The Company’s sale of its Program Assets indicated a strategic shift and based on the aforementioned discussion and analysis the Company concluded that the sale of these disposed assets and prohibitions against competition under the Asset Purchase Agreement represent a strategic shift in Cyclerion’s operations.

2. You disclose that you acquired a 10% equity interest in Tisento Therapeutics Holdings Inc. (Tisento Parent) with a fair value of \$5.3 million and that your investment does not provide you with significant influence over Tisento Parent. Please address the following:

- *Provide your analysis under ASC 810-10 in determining whether Tisento Parent is a variable interest entity (VIE), including whether the entity has sufficient equity at risk to finance its activities without additional subordinated financial support.*
- *To the extent that Tisento Parent is determined to be a VIE, provide your analysis under ASC 810-10 supporting your determination that you do not have a controlling financial interest in the VIE. Address the following as part of your response:*
 - *Identify the activities of Tisento Parent that most significantly impact its economic performance and explain how you determined that you do not have the power to direct such activities and therefore do not hold a controlling financial interest.*
 - *To the extent that the power is shared among the variable interest holders, clarify whether there is a tie-breaking mechanism in place with respect to key decision making.*
 - *With respect to investments held by your CEO and any other related parties, provide an analysis under ASC 810-10-25-42 through 25-44B.*
 - *Provide us with a copy of the Asset Purchase Agreement to assist us with our review.*
- *Confirm that you will revise your future filings to provide the VIE-specific disclosures required by ASC 810-10-50, to the extent applicable.*

Company Response

- *Provide your analysis under ASC 810-10 in determining whether Tisento Parent is a variable interest entity (VIE), including whether the entity has sufficient equity at risk to finance its activities without additional subordinated financial support.*

Cyclerion assessed the accounting for its investment in accordance with ASC 810-10, Consolidation—Overall. After determining that no scope exception applies under the guidance of ASC 810-10-15-12 and ASC 810-10-15-17, Cyclerion concluded that it has a variable interest in Tisento Parent through its investment in Tisento Parent common stock. Tisento Parent does not have sufficient equity to finance its activities without additional

subordinated financial support as Tisento Parent is a startup entity in its early stages of raising funds and will require significant capital to advance its programs to commercial stage. Therefore, Cyclerion concluded that its investment in Tisento Parent is a variable interest entity ("VIE") in accordance with ASC 810-10-15-14(a) and is subject to potential consolidation under the VIE model.

To the extent that Tisento Parent is determined to be a VIE, provide your analysis under ASC 810-10 supporting your determination that you do not have a controlling financial interest in the VIE. Address the following as part of your response:

- a. **Identify the activities of Tisento Parent that most significantly impact its economic performance and explain how you determined that you do not have the power to direct such activities and therefore do not hold a controlling financial interest.**
- b. **To the extent that the power is shared among the variable interest holders, clarify whether there is a tie-breaking mechanism in place with respect to key decision making.**
- c. **With respect to investments held by your CEO and any other related parties, provide an analysis under ASC 810-10-25-42 through 25-44B.**
- d. **Provide us with a copy of the Asset Purchase Agreement to assist us with our review.**

Company Response

- a. *Identify the activities of Tisento Parent that most significantly impact its economic performance and explain how you determined that you do not have the power to direct such activities and therefore do not hold a controlling financial interest.*

To evaluate potential consolidation under the variable interest model, Cyclerion (1) evaluated the purpose and design of the VIE and the risks the VIE was designed to create and pass along to its variable interest holders; (2) identified the activities related to the risks identified in step 1 that most significantly affect the economic performance of the VIE; and (3) identified the party that makes the significant decisions or controls the activity or activities that most significantly affect the VIE's economic performance, including whether any other parties have involvement in those decisions (shared power).

Tisento Parent and its subsidiary were initially designed to research and develop novel medicines for diseases with significant unmet medical needs. The primary risks the VIE was designed to create and pass along to its variable interest holders are the operational and financial risks related to a new business in a developing area of science. More specifically, Tisento Parent and its subsidiary's economic performance is dependent on the execution of the research and development activities and future commercialization of its technology. Accordingly, the activities related to these risks that most significantly impact Tisento Parent and its subsidiary's economic performance are the decisions relating to the funding, oversight, and execution of research and development activities, which are encapsulated in the operating plan and budget and the personnel of Tisento Parent and its subsidiary.

Cyclerion determined the following activities most significantly impact Tisento Parent and its subsidiary's economic performance: (1) approval of an operating plan and budget, determining which research and development programs to pursue and how to research and develop the corresponding intellectual property, (2) hiring and firing of management and key research personnel and (3) determination of management's compensation.

To assess which party has the power to direct these activities, Cyclerion considered Tisento Parent and its subsidiary's key governance documents, including the articles of incorporation, by-laws, investor rights agreement and voting agreement. Decisions related to the significant activities that most impact the economic performance of Tisento Parent and its subsidiary noted above are made by the Tisento Parent board of directors on behalf of the equity holders. Although there is an executive team led by a CEO running the day-to-day operations, the Tisento board has responsibility for the overall direction, supervision and management of Tisento Parent and its subsidiary.

Tisento Parent's board is comprised of five directors. Two directors are nominated by the preferred stockholders which are diverse group of preferred shareholders, and no single preferred shareholder has a majority ownership; one CEO director was elected by the common stockholders, which is Peter M. Hecht¹; and the remaining two independent directors were designated by agreement of a majority of the other then serving directors. Cyclerion does not have the right to nominate any director.

As noted above, all activities that most significantly impact Tisento Parent and its subsidiary's economic performance are directed by the Tisento Parent board and the board approves decisions by a simple majority. Based on the board composition, Cyclerion determined that no one party has control over the Tisento Parent board and power is not shared because the activities that most significantly affect Tisento Parent and its subsidiary's economic performance do not require the consent of all of the parties. Rather, all decisions are made by a simple majority vote of the Tisento Parent board. Therefore, because Cyclerion controls no director of Tisento Parent, Cyclerion cannot unilaterally direct any of the activities that most significantly impact Tisento Parent and its subsidiary's economic performance. Accordingly, Cyclerion does not hold a controlling financial interest in Tisento Parent.

b. To the extent that the power is shared among the variable interest holders, clarify whether there is a tie-breaking mechanism in place with respect to key decision making.

As stated above, Tisento Parent and its subsidiary's business is directed, managed, and controlled by the Tisento Parent board. Further, the board is composed of five directors, and the decisions that most significantly impact the economic performance require only simple majority approval of the board. Therefore, not all parties with board representation are required to approve all the activities that most significantly affect Tisento Parent and its subsidiary's economic performance. Hence, the power is not shared among variable interest holders and there is no tie-breaking mechanism in place with respect to key decisions.

c. With respect to investments held by your CEO and any other related parties, provide an analysis under ASC 810-10-25-42 through 25-44B.

The following discussion sets forth Cyclerion's analysis under ASC 810-10-25-42 through 25-44B.

ASC 810-10-25-42

Cyclerion concluded that the assessment in ASC 810-10-25-42 is not applicable because there is no single reporting entity (including with consideration of its related parties) having the power to direct the activities of Tisento Parent that most significantly affect Tisento's economic performance. Therefore, there is no "single decision maker." The Tisento business is controlled by Tisento's board and the decisions that most significantly impact the economic performance of Tisento require only simple majority approval of its board. Because, as noted above, no one party has the power to designate a majority of the directors to the Tisento board, no one party has the power to act as a single decision maker with respect to Tisento.

ASC 810-10-25-43

Cyclerion considered the composition of Tisento's board of directors in its primary beneficiary analysis. Cyclerion's former CEO serves on Tisento's board of directors. Cyclerion considered the definition of related parties for purposes of applying the ASC 810 accounting analysis to include de facto agents pursuant to ASC 810-10-25-43, which states that officers, employees and members of the governing board of the reporting entity are considered

¹ At the time the Asset Purchase Agreement was executed, Peter M. Hecht was Cyclerion's CEO and a member of the Company's Board of Directors. Peter M. Hecht resigned as President and CEO of Cyclerion on November 30, 2023.

de facto agents. The Company noted that no preferred or common stockholder in Tisento is a Reporting Person² of Cyclerion other than Peter M. Hecht. No other de facto agents or related parties of Cyclerion serves as a member of Tisento's board of directors other than Peter M. Hecht. Accordingly, Cyclerion's former CEO and current member of Cyclerion's board of directors is deemed a de facto agent of Cyclerion. Additionally, the other Board of Directors of Tisento are not considered related parties or de facto agents of Cyclerion. As a result, none of the five Tisento board seats are controlled by Cyclerion and only one board seat is a de facto agent which is considered to be a related party under the ASC 810 accounting analysis.

ASC 810-10-25-44

The guidance of ASC 810-10-25-44 states in part (**emphasis added**):

The guidance in this paragraph shall be applicable for situations in which ***the conditions in paragraph 810-10-25-44A have been met or when power is shared for a VIE***. In situations in which a reporting entity concludes that neither it nor one of its related parties has the characteristics in paragraph 810-10-25-38A but, as a group, the reporting entity and its related parties (including the de facto agents described in paragraph 810-10-25-43) have those characteristics, then the party within the related party group that is most closely associated with the VIE is the primary beneficiary.

The guidance in ASC 810-10-25-44 is not applicable due to the criteria of ASC 810-10-25-44A having not been met and shared power not being present, as explained in this paragraph and below with respect to the analysis of ASC 810-10-25-44A. ASC 810-10-25-38D states that power "is shared if two or more unrelated parties together have the power to direct the activities of a VIE that most significantly impact the VIE's economic performance and if decisions about those activities require the consent of each of the parties sharing power." As discussed above, all key decisions that most significantly affect Tisento's economic performance are made by a majority vote of its board at a meeting, or for administrative convenience, may be made by unanimous written consent of the Tisento board if a vote is not held. Therefore, not all parties in the related party group are required to approve the activities that most significantly affect Tisento's economic performance. Hence, the power is not shared and the guidance in this paragraph is not applicable.

In reaching the conclusion that power is not shared, Cyclerion considered interpretative guidance on the determination of shared power, all of which indicated that for shared power to exist, the unanimous consent of all parties is required for effective decisions. The following example from Section 7.4.2.2 of Deloitte & Touche LLP's Consolidation Roadmap illustrates a similar scenario (**emphasis added**):

*Three related parties (A, B, and C) not under common control form Entity X (a VIE) and hold 25 percent, 35 percent, and 40 percent, respectively, of the entity's voting interests. Decisions about the activities that most significantly affect the VIE's economic performance require a simple majority vote of the voting interests. Consequently, two of the three parties must agree on all of the decisions that most significantly affect the VIE's economic performance. In this example, even though the related-party group holds 100 percent of the voting rights and economics, **because X's corporate governance does not require the consent of all the parties, power is not considered shared.** Therefore, performance of the related-party tiebreaker test is not required, and no party will consolidate X.*

Ernst & Young LLP's *Financial Reporting Developments, Consolidations* describes shared power in section 9.3 as follows (**emphasis added**):

*In certain instances, power can be shared by a group of entities that are related parties. **We believe this will happen when the consent of each of the related parties is required to make the decisions about the significant activities.***....

² Reporting Person means an officer, Director, or greater than ten percent stockholder of the Company within the meaning of Rule 16a-2 under the Exchange Act, who is required to file reports pursuant to Rule 16a-3 under the Exchange Act.

KPMG LLP's *Handbook, Consolidations* describes shared power in Question 6.5.10 (emphasis added):

Interpretive response: Power is shared if: [810-10-25-38D]

— two or more unrelated parties together meet the power criterion; and

— **all decisions about the VIE's most significant activities require the consent of each party** (i.e. one party cannot unilaterally make decisions related to the VIE's most significant activities).

PricewaterhouseCoopers LLP's *Consolidation* describes shared power in Section 5.7.1 (emphasis added):

In situations where power over an entity's most significant activities is shared among related parties, a qualitative analysis is required to determine which party within the related party group is most closely associated with the VIE. The party within the related party group that is most closely associated with the VIE is the primary beneficiary and is required to consolidate and disclose the impact of the VIE. Refer to CG 5.8 for further discussion related to the application of the related party tiebreaker test.

*If no single party within the related party group has stated power, and a VIE's significant activities require the consent of two or more related parties, a reporting entity must assess whether power is shared. **As discussed in CG 5.2.4, shared power exists only when the unanimous consent of all parties believed to share power over a VIE's economically significant activities is required.** This concept is illustrated in Example CG 5-13.*

Based on the above analysis, the guidance of ASC 810-10-25-44 is not applicable because shared power does not exist. The unanimous consent of all parties is not required to make decisions about the activities that most significantly affect Tisento's economic performance.

ASC 810-10-25-44A

The guidance of ASC 810-10-25-44A states as follows:

In situations in which a single decision maker concludes, after performing the assessment in paragraph 810-10-25-42, that it does not have the characteristics in paragraph 810-10-25-38A, the single decision maker shall apply the guidance in paragraph 810-10-25-44 only when the single decision maker and one or more of its related parties are under common control and, as a group, the single decision maker and those related parties have the characteristics in paragraph 810-10-25-38A.

This guidance is also not applicable. As discussed above in the discussion of ASC 810-10-25-42, there is no single decision maker, and Cyclerion is not under common control with any of the entities in the related party group.

ASC 810-10-25-44B

The guidance of ASC 810-10-25-44B provides as follows:

*This paragraph applies to a related party group that has the characteristics in paragraph 810-10-25-38A only when **both of the following criteria are met**. This paragraph is not applicable for legal entities that meet the conditions in paragraphs 323-740-15-3 and 323-740-25-1.*

- a. *The conditions in paragraph 810-10-25-44A are not met by a single decision maker and its related parties.*
- b. *Substantially all of the activities of the VIE either involve or are conducted on behalf of a single variable interest holder (excluding the single decision maker) in the single decision maker's related party group.*

The single variable interest holder for which substantially all of the activities either involve or are conducted on its behalf would be the primary beneficiary. The evaluation in (b) above should be based on a qualitative assessment of all relevant facts and circumstances. In some cases, when performing that qualitative assessment, quantitative information may be considered. This assessment is consistent with the assessments in paragraphs 810-10-15-14(c)(2) and 810-10-15-17(d)(2).



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Cyclerion notes that criterion (a) above is not applicable because there is no single decision maker. As described above, the Tisento board has complete discretion and authority over the management and control of Tisento. Criterion (b) does not require evaluation because criterion (a) is not met.

Because both criteria (a) and (b) above have to be met for the application of the guidance in ASC 810-10-25-44B and criteria (a) has not been met, Cyclerion concluded that it should not consolidate Tisento under the VIE model.

d. Provide us with a copy of the Asset Purchase Agreement to assist us with our review.

The Asset Purchase Agreement is available on EDGAR as Exhibit 10.3 to the second quarter 10-Q filed with the SEC on July 28, 2023 as well as the definitive proxy statement filed with the SEC on June 20, 2023.

Confirm that you will revise your future filings to provide the VIE-specific disclosures required by ASC 810-10-50, to the extent applicable.

Company Response

Cyclerion will revise its future filings to provide the VIE specific disclosures required by ASC 810-10-50.

We appreciate the opportunity to respond to the Commission and, if you have any questions, please do not hesitate to contact the undersigned.

Sincerely,

/s/Regina Graul

Name: Regina Graul Ph.D.

Title: President

(Principal Executive Officer)

cc:

Neil Aronson, Partner, Gennari Aronson, LLP