# 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): **February 24, 2022**

# 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 2.02 Results of Operations and Financial Condition**.

On February 24, 2022, Cyclerion Therapeutics, Inc. (the "Company") issued a press release announcing its financial and operating results for the year end 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K, which, in its entirety, is incorporated herein by reference.

The information set forth in this Item 2.02 is being furnished pursuant to Item 2.02 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or under the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d)

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Cyclerion Therapeutics, Inc. dated February 24, 2022 |
| 104 | Cover Page Interactive Data File |

**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: February 24, 2022

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

**Exhibit 99.1**

# Cyclerion Announces CY6463 Clinical Pipeline and Corporate Updates

*Phase 2a study in Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like episodes (MELAS) enrollment closed; topline data expected in Q2 2022*

*Phase 1b study in Cognitive Impairment Associated with Schizophrenia (CIAS) enrollment ongoing; topline data expected in H2 2022*

*Phase 2a study in Alzheimer's Disease with vascular pathology (ADv) enrollment ongoing*

**CAMBRIDGE, Mass., Feb 24, 2022** — Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), a clinical-stage biopharmaceutical company on a mission to develop treatments that restore cognitive function, announced today clinical development updates for CY6463, its lead program, and additional corporate progress.

"We are developing CY6463 as a potentially transformative medicine for cognitive impairment associated with certain CNS diseases that are lacking effective therapies today. The development strategy for this lead program is guided by a robust neuroinnovation engine, designed to identify the patient populations mostly likely to benefit from our treatments," said Peter Hecht, Ph.D., Chief Executive Officer of Cyclerion Therapeutics.

Dr. Hecht continued: "We continue to execute on our strategic priority to evaluate the clinical promise of CY6463 in multiple ongoing exploratory studies in patient populations that we believe may be well-suited for the drug candidate's mechanism of action. We have recently closed enrollment on the MELAS study, and we look forward to sharing clinical results in Q2 2022. We also continue to progress our other ongoing CY6463 exploratory studies, including in CIAS, and our recently initiated ADv study. Patient recruitment rates in the CIAS study have been encouraging and we expect topline data in H2 2022. While we drive these studies to data readouts, we plan to advance our earlier stage CNS efforts, and also explore additional external opportunities for value creation."

**Clinical Pipeline Updates**

Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like episodes (MELAS)

The Phase 2a MELAS trial (NCT04475549) is an open-label, single-arm study of oral, once-daily CY6463 in adults aged 18 or older with MELAS. The study includes measures of safety, tolerability, pharmacokinetics, and exploratory pharmacodynamic effects, including MRI and various disease-relevant biomarkers. Study enrollment has closed and topline data are expected in Q2 2022.

Cognitive Impairment Associated with Schizophrenia (CIAS)

The Phase 1 CIAS trial (NCT04972227) is a randomized, placebo-controlled, multiple-ascending-dose study of oral, once-daily CY6463 in adults aged 18-50 diagnosed with schizophrenia. The study includes measures of safety, tolerability, pharmacokinetics, and pharmacodynamics, including a broad battery of EEG-based assessments and a computerized battery of cognitive performance tests. Clinical sites are actively enrolling study participants and topline data are expected in H2 2022.

Alzheimer's disease with vascular pathology (ADv)

The Phase 2a ADv trial (NCT04798989) is a randomized, placebo-controlled study of oral, once-daily CY6463 over a twelve-week dosing period. Study participants must have confirmed Alzheimer's disease pathology as assessed by PET or CSF biomarkers, cardiovascular risk factors, as well as mild-to-moderate subcortical small-vessel disease as assessed by MRI. The study will evaluate safety, tolerability, and pharmacokinetics as well as explore the impact of CY6463 on various disease-relevant pharmacodynamic biomarkers (e.g., EEG, MRI, neuroinflammatory biomarkers) and cognitive performance. The ADv study has initiated, and enrollment is ongoing.

**Collaborations**

- Cyclerion and Ariana Pharma announced an artificial intelligence-driven, precision medicine collaboration *to identify patient-selection biomarkers in neurological and neuropsychiatric diseases associated with cognitive impairment. The collaboration aims to* guide and accelerate the clinical development of Cyclerion's investigational therapeutics.

**Leadership Additions**

- Bruce Kinon, MD has joined Cyclerion as Vice President, Clinical Development and is leading the ongoing CY6463 clinical efforts. Dr. Kinon has been a clinical leader in both academic research and the pharmaceutical industry, at Eli Lilly and Company and Lundbeck Pharmaceuticals LLC, for the development of innovative drug treatments for neuropsychiatric disorders and their effective delivery into clinical practice. He received his M.D. and psychiatry training at the New York University-Bellevue Hospital Medical Center in New York City.

**Financial Position**

- Cash, cash equivalents, and restricted cash balance on December 31, 2021 was approximately $54 million, as compared to approximately $63 million on September 30, 2021.
- Research and development expenses were approximately $37.6 million for the full year 2021, as compared to approximately $56.4 million for the full year 2020. The decrease of approximately $18.8 million was driven by decreases of approximately $16.1 million in salaries and other employee-related expenses and approximately $9.2 million of facilities and operating costs, partially offset by increases of approximately $4.2 million related to a non-cash write-off of leasehold improvements and approximately $2.3 million in CY3018 external research costs.
- General and administrative expenses were approximately $20.6 million for the full year 2021, as compared to approximately $28.8 million for the full year 2020. The decrease of approximately $8.2 million was driven by decreases of approximately 5.4 million in salaries and other employee-related expenses, approximately $2.0 million in facilities and operating costs, and approximately $2.9 million in outside professional and corporate expenses,

partially offset by an increase of approximately $2.1 million related to a non-cash write-off of leasehold improvements.

- Net Loss: Net loss was approximately $51.6 million for the full year 2021, as compared to $77.8 million for the full year 2020.

**About CY6463**

CY6463 is the first CNS-penetrant sGC stimulator to be developed as a symptomatic and potentially disease-modifying therapy for serious CNS diseases. The nitric oxide (NO)-soluble guanylate cyclase (sGC)-cyclic guanosine monophosphate (cGMP) signaling pathway is a fundamental mechanism that precisely controls key aspects of physiology throughout the body. In the CNS, the NO-sGC-cGMP pathway regulates diverse and critical biological functions including neuronal function, neuroinflammation, cellular bioenergetics, and vascular dynamics. Although it has been successfully targeted with several drugs in the periphery, this mechanism has yet to be fully leveraged therapeutically in the CNS, where impaired NO-sGC-cGMP signaling is believed to play an important role in the pathogenesis of many neurodegenerative and neuropsychiatric diseases and other disorders associated with cognitive impairment. As an sGC stimulator, CY6463 acts as a positive allosteric modulator to sensitize the sGC enzyme to NO, increase the production of cGMP, and thereby amplify endogenous NO signaling. By compensating for deficient NO-sGC-cGMP signaling, CY6463 and other sGC stimulators may have broad therapeutic potential as a treatment to improve cognition and function in people with serious CNS diseases.

**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. 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, including statements about the anticipated timing of release of topline results of our clinical trials; the progression of our clinical programs; and the business and operations of the Company. 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 2021 Form 10-K filed on February 24, 2022, and our subsequent SEC filings. 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.

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