

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2023  
or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from            to  
Commission File Number 001-38787

**CYCLERION THERAPEUTICS, INC.**

(Exact Name of Registrant as Specified in its Charter)

Massachusetts  
(State or other jurisdiction of  
incorporation or organization)

83-1895370  
(I.R.S. Employer  
Identification No.)

245 First Street, 18<sup>th</sup> Floor, Cambridge, Massachusetts  
(Address of principal executive offices)

02142  
(Zip Code)

(857) 327-8778

Registrant's Telephone Number, Including Area Code

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 Capital Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of May 1, 2023, the registrant had 43,524,894 shares of common stock, no par value, outstanding.

**CYCLERION PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2022**  
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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties. All statements in this report, other than statements of historical facts, including statements about future events, financing plans, financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations, are forward-looking statements that involve certain risks and uncertainties. Use of the words “may,” “might,” “will,” “would,” “could,” “should,” “believes,” “estimates,” “projects,” “potential,” “expects,” “plans,” “seeks,” “intends,” “evaluates,” “pursues,” “anticipates,” “continues,” “designs,” “impacts,” “affects,” “forecasts,” “target,” “outlook,” “initiative,” “objective,” “designed,” “priorities,” “goal” or the negative of those words or other similar expressions may identify forward-looking statements that represent our current judgment about possible future events, but the absence of these words does not necessarily mean that a statement is not forward-looking.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, our actual results may differ materially from those contemplated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national, or global political, economic, business, competitive, market and regulatory conditions and the following:

- we could be delisted from Nasdaq;
- there is substantial doubt regarding our ability to continue as a going concern;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching and commercializing our product candidates, including zagociguat and CY3018;
- our relationships with third parties, collaborators and our employees;
- our ability to execute our strategic priorities;
- our ability to finance our operations and business initiatives;
- the success of collaboration or license agreements of our product candidates;
- our ability to access capital, capabilities, and transactions necessary to advance the development of our assets;
- our ability to pursue a transaction or that any transaction, if pursued, will be completed on attractive terms, including in particular whether the Asset Purchase Agreement (as defined below in Note 1 to the Condensed Consolidated Financial Statements) will be consummated in accordance with its terms;
- whether the praliciguat out-license will result in the creation of any therapies;
- whether any development, regulatory, and commercialization milestones or royalty payments provided for in the agreement with Akebia (as defined below in Note 1 to the Condensed Consolidated Financial Statements) will be achieved;
- the impact on our business of workforce and expense reduction initiatives;
- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;
- the safety profile and related adverse events of our product candidates;
- the efficacy and perceived therapeutic benefits of our product candidates, their potential indications and their market potential;
- U.S. and non-U.S. regulatory requirements for our product candidates, including any post-approval development and regulatory requirements, and the ability of our product candidates to meet such requirements;

- our ability to attract and retain employees needed to execute our business plans and strategies and our ability to manage the impact of any loss of key employees;
- our ability to obtain and maintain intellectual property protection for our product candidates and the strength thereof;
- our future financial performance, revenues, expense levels, payments, cash flows, profitability, tax obligations, capital raising and liquidity sources, real estate needs and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- the impact of government regulation in the life sciences industry, particularly with respect to healthcare reform;
- the coronavirus ("COVID-19") pandemic may continue to disrupt our business, including our development activities; and
- trends and challenges in the markets for our potential products.

See the "Risk Factors" section in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and elsewhere in this Quarterly Report on Form 10-Q for a further description of these and other factors. We caution you that the risks, uncertainties, and other factors referenced above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot assure you that we will realize the results, benefits, or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. There can be no assurance that (i) we have correctly measured or identified all of the factors affecting our business or the extent of these factors' likely impact, (ii) the available information with respect to these factors on which such analysis is based is complete or accurate, (iii) such analysis is correct or (iv) our strategy, which is based in part on this analysis, will be successful. All forward-looking statements in this report apply only as of the date of this report or as of the date they were made and, except as required by applicable law, we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise.

**Cyclerion Therapeutics, Inc.**  
**Condensed Consolidated Balance Sheets**  
(In thousands except share and per share data)  
(Unaudited)

	March 31, 2023	December 31, 2022
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 7,169	\$ 13,382
Accounts receivable	96	96
Prepaid expenses	567	805
Other current assets	503	537
Total current assets	8,335	14,820
Operating lease right-of-use asset	1,171	1,218
Other assets	1,950	2,041
Total assets	\$ 11,456	\$ 18,079
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,925	\$ 2,970
Accrued research and development costs	1,605	2,275
Accrued expenses and other current liabilities	2,001	2,382
Total current liabilities	7,531	7,627
Commitments and contingencies (Note 6)	—	—
Stockholders' equity		
Common stock, no par value, 400,000,000 shares authorized and 43,524,894 issued and outstanding at March 31, 2023 and 400,000,000 shares authorized and 43,518,724 issued and outstanding at December 31, 2022	—	—
Paid-in capital	270,052	269,626
Accumulated deficit	(266,108)	(259,154)
Accumulated other comprehensive loss	(19)	(20)
Total stockholders' equity	3,925	10,452
Total liabilities and stockholders' equity	\$ 11,456	\$ 18,079

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Cyclerion Therapeutics, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands except per share data)  
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
<b>Revenues:</b>		
Revenue from development agreement	—	225
Revenue from grants	—	486
Total revenues	—	711
<b>Cost and expenses:</b>		
Research and development	3,773	9,743
General and administrative	3,269	3,952
Total cost and expenses	7,042	13,695
Loss from operations	(7,042)	(12,984)
Interest and other income (expenses), net	88	6
Net loss	\$ (6,954)	\$ (12,978)
<b>Net loss per share:</b>		
Basic and diluted net loss per share	\$ (0.16)	\$ (0.30)
<b>Weighted average shares used in calculating:</b>		
Basic and diluted net loss per share	43,521	43,425
<b>Other comprehensive loss:</b>		
Net loss	\$ (6,954)	\$ (12,978)
<b>Other comprehensive loss:</b>		
Foreign currency translation adjustment gain	1	—
Comprehensive loss	\$ (6,953)	\$ (12,978)

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Cyclerion Therapeutics, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
(In thousands except share data)  
(Unaudited)

	Common Stock		Paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total Stockholders' equity
	Shares	Amount				
<b>Balance at December 31, 2021</b>	43,410,185	\$ —	\$ 263,345	\$ (215,076)	\$ (23)	\$ 48,246
Net loss	—	—	—	(12,978)	—	(12,978)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	38,175	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,476	—	—	1,476
Share-based compensation expense related to issuance of stock options to non-employees	—	—	291	—	—	291
Foreign currency translation adjustment	—	—	—	—	(1)	(1)
<b>Balance at March 31, 2022</b>	<u>43,448,360</u>	<u>\$ —</u>	<u>\$ 265,112</u>	<u>\$ (228,054)</u>	<u>\$ (24)</u>	<u>\$ 37,034</u>

**Cyclerion Therapeutics, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
(In thousands except share data)  
(Unaudited)

	Common Stock		Paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total Stockholders' equity
	Shares	Amount				
<b>Balance at December 31, 2022</b>	43,518,724	\$ —	\$ 269,626	\$ (259,154)	\$ (20)	\$ 10,452
Net loss	—	—	—	(6,954)	—	(6,954)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	6,170	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	416	—	—	416
Share-based compensation expense related to issuance of stock options to non-employees	—	—	10	—	—	10
Foreign currency translation adjustment	—	—	—	—	1	1
<b>Balance at March 31, 2023</b>	<u>43,524,894</u>	<u>\$ —</u>	<u>\$ 270,052</u>	<u>\$ (266,108)</u>	<u>\$ (19)</u>	<u>\$ 3,925</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.



**Cyclerion Therapeutics, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
(In thousands)  
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (6,954)	\$ (12,978)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	—	48
Share-based compensation expense	426	1,767
Changes in operating assets and liabilities:		
Accounts receivable	—	(127)
Prepaid expenses	238	(79)
Other current assets	34	(9)
Operating lease assets	47	46
Other assets	91	91
Accounts payable	955	691
Accrued research and development costs	(670)	(1,815)
Accrued expenses and other current liabilities	(381)	(470)
<b>Net cash (used in) operating activities</b>	<b>(6,214)</b>	<b>(12,835)</b>
Effect of exchange rate changes on cash and cash equivalents	1	(1)
Net decrease in cash, cash equivalents and restricted cash	(6,213)	(12,836)
Cash, cash equivalents and restricted cash, beginning of period	13,382	53,961
Cash, cash equivalents and restricted cash, end of period	<u>\$ 7,169</u>	<u>\$ 41,125</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Cyclerion Therapeutics, Inc.**  
**Notes to the Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Nature of Business**

**Nature of Operations**

Cyclerion Therapeutics, Inc. ("Cyclerion", the "Company" or "we") is a biopharmaceutical company on a mission to develop treatments for serious diseases. Our portfolio includes novel soluble guanylate cyclase ("sGC") stimulators that modulate a key node in a fundamental signaling network in both the central nervous system ("CNS") and the periphery. 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. The NO-sGC-cGMP pathway, regulates diverse and critical biological functions including mitochondrial function, neuronal function, inflammation, and hemodynamics. Although this pathway has been successfully targeted with several drugs in the periphery, this mechanism has yet to be fully leveraged therapeutically, particularly 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.

Zagociguat is a clinical-stage CNS-penetrant sGC stimulator that has shown rapid improvement in cerebral blood flow, functional brain connectivity, brain response to visual stimulus, cognitive performance, and biomarkers associated mitochondrial function and inflammation in clinical studies. CY 3018 is a CNS-targeted sGC stimulator that preferentially localizes to the brain and has a pharmacology profile that suggests its potential for the treatment of neuropsychiatric diseases and disorders. Praliciguat is a systemic sGC stimulator that is licensed to Akebia Therapeutics, Inc. ("Akebia") and being advanced in rare kidney disease. Olinciguat is a clinical-stage vascular sGC stimulator that the Company intends to out-license for cardiovascular diseases. Cyclerion is actively evaluating the best combination of capital, capabilities, and transactions available to it to advance the development of zagociguat and its other clinical development candidates and to maximize shareholder value.

Cyclerion GmbH, a wholly owned subsidiary, was incorporated in Zug, Switzerland on May 3, 2019. The functional currency is the Swiss franc.

Cyclerion Securities Corporation, a wholly owned subsidiary, was incorporated in Massachusetts on November 15, 2019 and was granted securities corporation status in Massachusetts for the 2019 tax year. Cyclerion Securities Corporation has no employees.

**Company Overview**

The Company's mission is to develop treatments for serious CNS diseases.

Zagociguat is an orally administered CNS-penetrant sGC stimulator. As an sGC stimulator, zagociguat amplifies endogenous NO signaling by acting as a positive allosteric modulator to sensitize the sGC enzyme to NO and increase the production of cGMP, and thereby amplify endogenous NO signaling. By compensating for deficient NO-sGC-cGMP signaling zagociguat may have broad therapeutic potential as a treatment for people with serious diseases.

On January 13, 2020, we announced positive results from our Phase 1 first-in-human study that provided the foundation for continued development of zagociguat. The results from this study indicate that zagociguat was well tolerated. Pharmacokinetic data, obtained from both blood and cerebral spinal fluid ("CSF"), support once-daily dosing, with or without food, and demonstrated zagociguat penetration of the blood-brain-barrier with CSF concentrations expected to be pharmacologically active.

On October 14, 2020, we announced positive topline results from our zagociguat Phase 1 translational pharmacology study in healthy elderly participants. Treatment with zagociguat for 15-days in this 24-subject study confirmed and extended results seen in the earlier first-in-human Phase 1 study: once daily oral treatment demonstrated blood-brain barrier penetration with expected CNS exposure and target engagement. Results also showed significant improvements in neurophysiological and objective performance measures as well as decreases in

inflammatory biomarkers associated with aging and neurodegenerative diseases. Zagociguat was safe and generally well tolerated in the study. These results, together with nonclinical data, supported the continued development of zagociguat as a potential new medicine for serious diseases involving the CNS.

On June 10, 2022, we announced positive topline clinical data for zagociguat in our signal-seeking clinical study for the potential treatment of Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes ("MELAS"). In this open-label, single-arm study of the oral, once-daily sGC stimulator in eight adults aged 18 or older with MELAS, improvements were seen across a range of endpoints reflecting multiple domains of disease activity, including mitochondrial disease-associated biomarkers such as lactate and GDF-15, a broad panel of inflammatory biomarkers, cerebral blood flow, and functional connectivity between neural networks. These positive effects after 29 days of dosing were supported by correlations among several endpoints with each other and with zagociguat plasma concentrations. Zagociguat was well tolerated with no serious or severe adverse events and no events leading to discontinuation. Pharmacokinetics were consistent with the Phase 1 studies in healthy volunteers. The positive data from this study support the potential of zagociguat to provide therapeutic benefit to people living with mitochondrial diseases, including MELAS.

On July 28, 2022, we announced positive topline data from our signal-seeking clinical study of zagociguat for the potential treatment of Cognitive Impairment Associated with Schizophrenia ("CIAS"). Data from the 14-day, double blind, randomized, placebo-controlled, multiple-ascending-dose study in 48 adults aged 18-50 with stable schizophrenia on a stable, single atypical antipsychotic regimen demonstrated that once-daily zagociguat was safe and well tolerated, with no reports of serious adverse events, severe adverse events, or treatment discontinuation due to adverse events. We further announced that study data demonstrated a strong effect on cognitive performance after two weeks of 15mg once-daily dosing and that positive movements on inflammatory biomarkers were also observed. These signals on exploratory endpoints are consistent with pro-cognitive and anti-inflammatory effects of zagociguat observed in preclinical studies and prior clinical trials and support the further development of oral, once-daily zagociguat.

In October 2022, the WHO International Nonproprietary Names committee and the United States Adopted Name council selected zagociguat as a nonproprietary name for CY6463.

On March 22, 2023, we announced that given the significant capital and capabilities necessary to ensure that the MELAS Phase 2b study is executed efficiently and with the highest quality, and the currently unfavorable capital market conditions, we are actively evaluating the best combination of capital, capabilities, and transactions available to us to advance the development of zagociguat and our other clinical development candidates and to maximize shareholder value.

On March 31, 2023, we entered into a stock purchase agreement with the Company's Chief Executive Officer (the "CEO") pursuant to which the CEO will make an equity investment in the Company of \$5 million in cash for common stock or nonvoting convertible preferred stock of the Company, the purchase price, consistent with Nasdaq rules, to be at or above the market price at the time of signing that agreement. The closing of the equity investment will take place six business days after the signing of the Asset Purchase Agreement (as defined below), or May 11, 2023.

On May 11, 2023, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with an investor group which includes Peter Hecht, the Company's Chief Executive Officer ("CEO"), JW Celtics Investment Corp. ("Buyer Parent") and JW Cycler Inc. ("Buyer"). Pursuant to the terms of the Asset Purchase Agreement and subject to the approval by the Company's shareholders, the Company will receive proceeds of \$8 million as cash consideration, reimbursement for certain operating expenses related to zagociguat and CY3018 for the period between signing and closing of the transaction and 10% of all of Buyer Parent's outstanding equity securities upon the successful closing of the transaction.

On May 11, 2023, we announced topline data from our signal-seeking clinical study of zagociguat for the potential treatment of Alzheimer's disease with vascular pathology ("ADv"), which study was supported in part by a \$2 million grant from the Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program (the "PTC Grant"). This exploratory, randomized, placebo-controlled, study of oral once-daily zagociguat was designed to evaluate safety, tolerability, and pharmacokinetics as well as explore the impact of zagociguat on biomarkers and

cognitive performance over a twelve-week dosing period. The total number of enrolled participants was capped at 12 participants due to challenges associated with enrollment. Data from this study show that the safety and tolerability of profile once-daily zagociguat was consistent with prior studies. Given the small number of participants we are unable to draw any conclusions from the data generated in the study.

CY3018 is a CNS-targeted sGC stimulator in preclinical development that preferentially localizes to the brain and has a pharmacology profile that suggests its potential for the treatment of neuropsychiatric diseases and disorders.

Praliguat is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into a license agreement with Akebia relating to the exclusive worldwide license to Akebia of our rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing praliguat and other related products and forms thereof enumerated in such agreement. Cycleron is eligible to receive up to \$585 million in total potential future development, regulatory, and commercialization milestone payments. Cycleron is also eligible to receive tiered, sales-based royalties ranging from single-digit to high-teen percentages.

Olinciguat is an orally administered, once-daily, vascular sGC stimulator that was evaluated in a Phase 2 study of participants with sickle cell disease. We released topline results from this study in October 2020. We intend to out-license olinciguat to an entity with strong cardiovascular and/or cardiopulmonary capabilities.

### **At-the-Market Offering**

On July 24, 2020, the Company filed a Registration Statement on Form S-3 (the "Shelf") with the Securities and Exchange Commission (the "SEC") in relation to the registration of common stock, preferred stock, debt securities, warrants and units of any combination thereof for an aggregate initial offering price not to exceed \$150.0 million. The Shelf was declared effective as of July 31, 2020. On September 3, 2020, the Company entered into a Sales Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") with respect to an at-the-market offering (the "ATM Offering") under the Shelf. Under the ATM Offering, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to \$50.0 million through Jefferies as its sales agent. The Company will pay Jefferies cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. The Company has sold 3,353,059 shares of its common stock for net proceeds of \$12.5 million under the ATM Offering since entering into the Sales Agreement. No shares of common stock have been issued or sold under the ATM Offering during the three months ended March 31, 2023.

### **Basis of Presentation**

The condensed consolidated financial statements and the related disclosures are unaudited and have been prepared in accordance with accounting principles generally accepted in the U.S. Additionally, certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which was filed with the Securities and Exchange Commission on March 22, 2023.

In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all normal recurring adjustments considered necessary for a fair presentation of the Company's financial position and the results of its operations for the interim periods presented. The results of operations for the three months ended March 31, 2023 and 2022 are not necessarily indicative of the results that may be expected for the full year or any other subsequent interim period.

The condensed consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries, Cycleron GmbH, and Cycleron Securities Corporation. All significant intercompany accounts and transactions have been eliminated in the preparation of the accompanying condensed consolidated financial statements.

### **Going Concern**

At each reporting period, in accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company's evaluation entails analyzing prospective operating budgets and forecasts for expectations of the Company's cash needs and comparing those needs to the current cash and cash equivalent balances. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by the Company's plans or when its plans alleviate substantial doubt about the Company's ability to continue as a going concern.

This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. In performing its analysis, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future partnerships, equity or debt issuances and the potential milestones from the Akebia agreement cannot be considered probable at this time because these plans are not entirely within the Company's control and/or have not been approved by the Board of Directors as of the date of these consolidated financial statements.

The Company's expectation to generate negative operating cash flows in the future and the need for additional funding to support its planned operations, raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that these consolidated financial statements are issued. Management's plans to alleviate the conditions that raise substantial doubt include reduced spending, and the pursuit of additional capital. Management has concluded the likelihood that its plan to successfully obtain sufficient funding from one or more of these sources, or adequately reduce expenditures, while reasonably possible, is less than probable. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

### **Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard**

On June 1, 2022, the Company received a notice from the Nasdaq Stock Market ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common stock listed on Nasdaq has been below the minimum \$1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided a period of 180 calendar days, or until November 28, 2022, to regain compliance with the Bid Price Requirement. The Company did not regain compliance with the Bid Price Requirement by the initial compliance date. On November 29, 2022, Nasdaq notified the Company that it is eligible for an additional 180 calendar day period, or until May 29, 2023 (the "Extended Compliance Date"), to regain compliance with the Bid Price Requirement. Nasdaq's determination was

based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market with the exception of the Bid Price Requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. Effective November 25, 2022, the Company transferred its listing of the Company's common stock from the Nasdaq Global Market to the Nasdaq Capital Market, a continuous trading market that operates in substantially the same manner as the Nasdaq Global Market. The Company's common stock continues to trade under the symbol "CYCN".

To date, the Company has not regained compliance with the Bid Price Requirement. If at any time before May 29, 2023, the bid price of the Company's common stock closes at a \$1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will provide written notification to the Company that it has regained compliance with the Bid Price Requirement. If the Company does not regain compliance with the Bid Price Requirement by the end of the second compliance period, the Company's stock will be subject to delisting.

On April 3, 2023, the Company filed with the SEC a definitive proxy statement for its annual meeting of stockholders to be held on May 15, 2023, at which meeting the Company is seeking stockholder approval of a reverse stock split with the primary intent of increasing the price of its common stock to meet the price criteria for continued listing on Nasdaq. The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement, including initiating a reverse stock split. However, there can be no assurance on how stockholders will vote on such proposal or that the Company will be able to regain compliance with the Bid Price Requirement or will otherwise be in compliance with other Nasdaq Listing Rules.

## **2. Summary of Significant Accounting Policies**

The accounting policies of the Company are set forth in Note 2. *Summary of Significant Accounting Policies* to the consolidated financial statements contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

### **Use of Estimates**

The preparation of consolidated financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") requires the Company's management to make estimates and judgments that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the amounts of expenses during the reported periods. On an ongoing basis, the Company's management evaluates its estimates, judgments, and methodologies. Significant estimates and assumptions in the consolidated financial statements include those related to revenue, impairment of long-lived assets, valuation procedures for right-of-use ("ROU") assets and operating lease liabilities, income taxes, including the valuation allowance for deferred tax assets, research and development expenses, contingencies, share-based compensation and going concern. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

### **New Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Except as discussed elsewhere in the notes to the consolidated financial statements, the Company did not adopt any new accounting pronouncements during the three months ended March 31, 2023 that had a material effect on its condensed consolidated financial statements.

In June 2016 the FASB issued ASU 2016-13, Financial Instruments-Credit Losses. This standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. As a smaller reporting company, ASU 2016-13 will become effective for the Company for fiscal years beginning after December 15, 2022, and early

adoption is permitted. The Company adopted ASU 2016-13 in the first quarter of 2023, and the adoption of this standard did not have any impact on the Company's financial position or results of operations

No other accounting standards known by the Company to be applicable to it that have been issued by the FASB or other standard-setting bodies and that do not require adoption until a future date are expected to have a material impact on the Company's condensed consolidated financial statements upon adoption.

### 3. Fair Value of Financial Instruments

The Company's cash equivalents are generally classified within Level 1 of the fair value hierarchy. The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values as of March 31, 2023 and December 31, 2022 (in thousands):

	Fair Value Measurements as of March 31, 2023:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 6,079	\$ —	\$ —	\$ 6,079
Cash equivalents	<u>\$ 6,079</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,079</u>
	Fair Value Measurements as of December 31, 2022:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 12,357	\$ —	\$ —	\$ 12,357
Cash equivalents	<u>\$ 12,357</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 12,357</u>

During the three months ended March 31, 2023 and 2022, there were no transfers between levels. The fair value of the Company's cash equivalents, consisting of money market funds, is based on quoted market prices in active markets with no valuation adjustment.

The Company believes the carrying amounts of its prepaid expenses and other current assets, restricted cash, accounts receivable, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of these amounts.

### 4. Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Software	2,174	\$ 2,174
Computer equipment	—	7
Leasehold improvements	—	—
Property and equipment, gross	2,174	2,181
Less: accumulated depreciation and amortization	(2,174)	(2,181)
Property and equipment, net	<u>\$ —</u>	<u>\$ —</u>

As of March 31, 2023, and December 31, 2022, the Company's property and equipment was primarily located in Boston, Massachusetts.

During the three months ended March 31, 2023, the Company did not record depreciation and amortization expenses. The company recorded approximately \$0.1 million of depreciation and amortization expenses for the three months ended March 31, 2022.

## 5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued incentive compensation	\$ 362	\$ 238
Salaries	248	246
Accrued vacation	186	186
Professional fees	924	835
Accrued severance and benefit costs	141	809
Other	140	68
Accrued expenses and other current liabilities	<u>\$ 2,001</u>	<u>\$ 2,382</u>

## 6. Commitments and Contingencies

### *Other Funding Commitments*

In the normal course of business, the Company enters into contracts with clinical research organizations and other third parties for clinical and preclinical research studies and other services and products for operating purposes. These contracts are generally cancellable, with notice, at the Company's option and do not have any significant cancellation penalties.

### *Guarantees*

On September 6, 2018, Cycleron was incorporated in Massachusetts and its officers and directors are indemnified for certain events or occurrences while they are serving in such capacity.

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, clinical sites and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreements. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal. Accordingly, the Company did not have any liabilities recorded for these obligations as of March 31, 2023 and December 31, 2022.

## 7. Leases

In May 2021, the Company signed a 12-month membership agreement to lease space with WeWork at 501 Boylston Street, Boston, Massachusetts, commencing on August 1, 2021. The agreement was extended for six months on August 1, 2022. The 12-month agreement and 6-month extension are accounted for as short-term leases. The Company recorded a de minimis amount and approximately \$0.1 million, in lease expense associated with the membership agreement during the three months ended March 31, 2023 and 2022, respectively.

On September 15, 2020, the Company entered into a Sublease Termination Agreement (the "Sublease Termination Agreement") to terminate its sublease of 15,700 rentable square feet of its leased premises under the Head Lease. Under the terms of the Sublease Termination Agreement, the subtenant was relieved of its obligation to provide future cash rental payments to the Company. The agreements requiring the former subtenant to provide licensed rooms and services to the Company free of charge through the original sublease term survived the sublease termination. The Company gained access to the licensed rooms and services beginning in the third quarter of 2021. The letter of credit security deposit related to the sublease was released.

The Company determined that the Sublease Termination Agreement constituted a non-monetary exchange under ASC 845 Nonmonetary Transactions ("ASC 845") where, in return for the free rooms and the services, the



Company agreed to terminate its rights and obligations under the sublease agreement. In accordance with ASC 845, the Company determined that the accounting for the transaction should be based on the fair value of assets or services involved. The Company estimated the fair value of the rooms and services to be approximately \$1.5 million and \$2.9 million, respectively.

The Company determined that the licensed rooms represent a lease under ASC Topic 842, Leases. The Company obtained control of the rooms in the third quarter of 2021 and the prepaid rooms balance of approximately \$1.4 million was reclassified from other assets to a ROU asset. The related lease expense is recognized on a straight-line basis over the lease term of 8.88 years. The Company recorded \$0.1 million and \$0.1 million of lease expense during the three months ended March 31, 2023 and 2022, respectively. The Company determined that the licensed services represent a non-lease component, which is recognized separately from the lease component for this asset class. The expense related to the licensed services is recognized on a straight-line basis over the period the services are received. The Company recorded \$0.1 million and \$0.1 million for the three months ended March 31, 2023 and 2022, respectively. Both the lease expense and services expense are recognized as a component of research and development costs in the condensed consolidated statements of operations and comprehensive loss.

## 8. Share-based Compensation Plans

In 2019, Cycleron adopted share-based compensation plans. Specifically, Cycleron adopted the 2019 Employee Stock Purchase Plan ("2019 ESPP") and the 2019 Equity Incentive Plan ("2019 Equity Plan"). Under the 2019 ESPP, eligible employees may use payroll deductions to purchase shares of stock in offerings under the plan, and thereby acquire an interest in the future of the Company. The 2019 Equity Plan provides for stock options and restricted stock units ("RSUs").

Cycleron mirrored two of Ironwood Pharmaceuticals, Inc's ("Ironwood") existing plans, the Amended and Restated 2005 Stock Incentive Plan ("2005 Equity Plan") and the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan ("2010 Equity Plan"). These mirror plans were adopted to facilitate the exchange of Ironwood equity awards for Cycleron equity awards upon the tax-free spin-off of Ironwood's sGC business (the "Separation") as part of the equity conversion. As a result of the Separation and in accordance with the Employee Matters Agreement between Ironwood and Cycleron entered into as part of the Separation, employees of both companies retained their existing Ironwood vested options and received a pro-rata share of Cycleron options, regardless of which company employed them post-Separation. For employees that were ultimately employed by Cycleron, unvested Ironwood options and RSUs were converted to unvested Cycleron options and RSUs.

The following table provides share-based compensation reflected in the Company's condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 229	\$ 830
General and administrative	197	937
	<u>\$ 426</u>	<u>\$ 1,767</u>

A summary of stock option activity for the three months ended March 31, 2023, is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Average Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	7,311,893	\$ 9.23	5.8	20
Granted	—	0.00		
Exercised	—	0.00		
Cancelled or forfeited	(600,887)	14.29		
Outstanding as of March 31, 2023	<u>6,711,006</u>	<u>\$ 8.77</u>	<u>6.1</u>	<u>\$ 0</u>
Exercisable at March 31, 2023	<u>4,867,431</u>	<u>\$ 11.30</u>	<u>5.2</u>	<u>\$ 0</u>

As of March 31, 2023, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested time-based stock options held by the Company's employees is \$1.8 million and the weighted average period over which that expense is expected to be recognized is 3.2 years.

A summary of RSU activity for the three months ended March 31, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2022	815,587	\$ 0.77
Granted	—	—
Vested	(6,170)	14.20
Forfeited	—	—
Unvested as of March 31, 2023	<u>809,417</u>	<u>\$ 0.66</u>

As of March 31, 2023, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested restricted stock units by the Company's employees is \$0.3 million and the weighted-average period over which that expense is expected to be recognized is 0.52 years.

The Company has granted to certain employees stock options containing market conditions that vest upon the achievement of specified price targets of the Company's share price for a period through December 31, 2024. Vesting is measured based upon the average closing price of the Company's share price for any thirty consecutive trading days, subject to certain service requirements. Stock compensation cost is expensed on a straight-line basis over the derived service period for each stock price target within the award, ranging from approximately 4.0 to 4.6 years. The Company accelerates expense when a stock price target is achieved prior to the derived service period. As of March 31, 2023 there were 300,000 outstanding stock options containing market conditions with a weighted average exercise price of \$2.01. As of March 31, 2023 there was \$0.1 million of unrecognized compensation costs related to stock options containing market conditions, which is expected to be recognized over a weighted-average period of 1 year.

## 9. Loss per share

Basic and diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period as follows:

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net loss (in thousands)	\$ (6,954)	\$ (12,978)
Denominator:		
Weighted average shares used in calculating net loss per share — basic and diluted (in thousands)	43,521	43,425
Net loss per share — basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.30)</u>

We exclude shares of common stock related to stock options and RSUs from the calculation of diluted net loss per share since the inclusion of such shares would be anti-dilutive. The following table sets forth potential shares that were considered anti-dilutive for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,	
	2023	2022
Stock Options	\$ 6,711,006	\$ 8,270,398
RSUs	809,417	54,629
	<u>\$ 7,520,423</u>	<u>\$ 8,325,027</u>

## 10. Defined Contribution Plan

Subsequent to the Separation, the Company adopted a defined contribution 401(k) Savings Plan similar to the plan in place at Ironwood. The plan assets under the Ironwood defined contribution 401(k) Savings Plan were transferred to the Company's plan.

Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. The Company's contributions to the plan are at the sole discretion of the board of directors. Currently, the Company provides a matching contribution of 75% of the employee's contributions, up to \$6,000 annually.

Included in compensation expense is approximately \$0.1 million and \$0.2 million related to the defined contribution 401(k) Savings Plan for the three months ended March 31, 2023 and 2022, respectively.

## 11. Workforce Reduction

### 2022 Workforce Reduction

On October 6, 2022, the Company began a reduction of its current workforce by thirteen (13) full-time employees to align its resources with its current priorities of focusing on a mitochondrial disease-focused strategy. The workforce reduction was completed in the fourth quarter of 2022.

The Company recorded total costs related to the 2022 Workforce Reduction of approximately \$1.3 million, including a de minimis amount of stock-based compensation from the modification of certain share-based equity awards.

The following table summarizes the accrued liabilities activity recorded in connection with the reduction in workforce for the three months ended March 31, 2023 (in thousands):

	Amounts accrued at December 31, 2022	Charges	Amount paid	Adjustments	Amounts accrued at March 31, 2023
2022 workforce reduction	\$ (809)	\$ —	\$ 668	\$ —	\$ (141)
Total	<u>\$ (809)</u>	<u>\$ —</u>	<u>\$ 668</u>	<u>\$ —</u>	<u>\$ (141)</u>

## 12. License Agreement

### Akebia License Agreement

On June 3, 2021, the Company and Akebia entered into a License Agreement (the "Akebia License Agreement") relating to the exclusive worldwide license by the Company to Akebia of our 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 License Agreement (collectively, the "Products"). Pursuant to the Akebia License Agreement, Akebia will be responsible for all future research, development, regulatory, and commercialization activities for the Products.

Akebia paid a \$3.0 million up-front payment to the Company upon signing of the Akebia License Agreement and the Company is eligible to receive additional milestone cash payments of up to \$12.0 million upon initiation of a Phase 2 clinical trial. Further milestone cash payments by Akebia are scheduled in the Akebia License 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 the Company 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.

Pursuant to the Akebia License Agreement, the Company determined the Akebia License Agreement represents a service arrangement under the scope of ASC 606. Given the reversion of the rights under the Akebia License Agreement represents a penalty in substance for a termination by Akebia, the contract term would be the stated term of the Akebia License Agreement.

The Company determined that the grant of license to our patents and trademarks, know how transfer, the assignment of regulatory submissions and trademarks and additional knowledge transfer assistance obligations represent a single promise and performance obligation to be transferred to Akebia over time due to the nature of the promises in the contract. The provision of development materials on hand was identified as a separate performance obligation. However, it is immaterial in the context of the contract as the development materials are low value and do not have an alternative use to the Company.

The consideration related to sales-based milestone payments, including royalties, will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license. The Company will re-evaluate the probability of achievement of the milestones and any related constraints each reporting period.

### Akebia Supply Agreement

On August 3, 2021, the Company and Akebia entered into a Supply Agreement (the "Supply Agreement") relating to the manufacturing by the Company of the Initial Supply of the Drug Product and placebo ("Initial Supply") for Akebia's use pursuant to the Akebia License Agreement. Akebia will pay the Company for the manufacturing costs at mutually agreed upon rates.

The Company determined the Supply Agreement has stand-alone value under the scope of ASC 606 and should not be combined with the Akebia License Agreement. Given that the Supply Agreement can be terminated at any time without cause with 30 days notice, the Company deemed the Supply Agreement to be a month-to-month contract. The manufacturing of the Initial Supply by the Company represents a single performance obligation and consideration related to the manufacturing costs will be recognized over time as costs are incurred. The Company recorded approximately \$0.2 million as revenue from the Supply Agreement in the three months ended March 31, 2022. There was no revenue recognized as part of the Supply Agreement in the three months ended March 31, 2023.

### **13. Grant Revenue**

In August 2021, the Company was approved to receive funding from the PTC Grant for the Phase 2 study of CNS sGC stimulation in AD with vascular features. The granting period was July 1, 2021, to December 31, 2022, and the Company received an award of \$2 million. The Company determined that this transaction is non-reciprocal as there is not considered to be a commensurate value exchanged with the Alzheimer's Association as the funding provider. Where commensurate value is not exchanged for goods and services provided, a recipient assesses whether the grant is conditional or unconditional. The Company considered all conditions and barriers associated with this grant and determined the grant is conditional and revenue will be recognized upon achieving certain milestones and incurring internal costs specifically covered by this grant. Under ASC 958-605, revenues will be recognized as the Company incurs expenses related to the PTC Grant.

The Company has incurred no costs associated with the grant for the three months ended March 31, 2023, compared to approximately \$0.5 million of expenses associated with the grant for the three months ended March 31, 2022. The Company had a deferred revenue balance of approximately \$0.1 million related to advance billings as of March 31, 2023.

### **14. Subsequent Events**

On May 11, 2023, the Company entered into the Asset Purchase Agreement with an investor group which includes the Company's CEO, Buyer Parent and Buyer. Pursuant to the terms of the Asset Purchase Agreement and subject to the approval by the Company's shareholders, the Company will receive proceeds of \$8 million as cash consideration, reimbursement for certain operating expenses related to zagociguat and CY3018 for the period between signing and closing of the transaction and 10% of all of Buyer Parent's outstanding equity securities upon the successful closing of the transaction. The Company will also receive net proceeds of \$5 million pursuant to a stock purchase agreement with the Company's CEO, which will take place six business days after the signing of the Asset Purchase Agreement.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the corresponding notes included in this Quarterly Report on Form 10-Q, as well as the audited condensed consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those referenced or set forth under "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

### Overview

We are a biopharmaceutical company on a mission to develop treatments for serious diseases. Zagociguat is a pioneering 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. sGC stimulators are small molecules that act synergistically with NO as positive allosteric modulators of sGC to boost production of cGMP. cGMP is a key second messenger that, when produced by sGC, regulates diverse and critical biological functions such as mitochondrial function, neuronal function, inflammation, and vascular dynamics.

We operate in one reportable business segment—human therapeutics.

### Financial Overview

*Research and Development Expense.* Research and development expenses are incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of the following costs: compensation, benefits and other employee-related expenses, research and development related facilities, third-party contracts relating to nonclinical study and clinical trial activities. All research and development expenses are charged to operations as incurred.

Zagociguat is an orally administered CNS-penetrant sGC stimulator. NO-sGC-cGMP is a fundamental signaling network, including in the brain where it is critical to basic CNS functions. Deficient NO-sGC-cGMP signaling is believed to play an important role in the pathogenesis of many neurological disorders. As an sGC stimulator, zagociguat amplifies endogenous NO signaling by acting as a positive allosteric modulator to sensitize the sGC enzyme to NO, and increase the production of cGMP. By compensating for deficient NO-sGC-cGMP signaling, zagociguat may have broad therapeutic potential as a treatment for people with serious diseases.

In January 2020, we announced positive results from our Phase 1 first-in-human study that provided the first clinical data supporting the development of zagociguat. The results from this study indicate that zagociguat was well tolerated. Pharmacokinetic data, obtained from both blood and cerebral spinal fluid, support once-daily dosing with or without food and demonstrated zagociguat penetration of the blood-brain-barrier with concentrations in the CSF expected to be pharmacologically active.

In October 2020, we announced positive topline results from our zagociguat Phase 1 translational pharmacology study in healthy elderly participants. Treatment with zagociguat for 15 days in this 24-subject study confirmed and extended results seen in the earlier first-in-human Phase 1 study: once-daily oral treatment demonstrated blood-brain barrier penetration with expected CNS exposure and target engagement. Results also showed significant improvements in neurophysiological and objective performance measures as well as decreases in inflammatory biomarkers associated with aging and neurodegenerative diseases. Zagociguat was safe and generally well tolerated in the study. These results, together with nonclinical data, support continued development of zagociguat as a potential new medicine for serious CNS diseases.

In June 2022, we announced positive topline clinical data for zagociguat in our signal-seeking clinical study for the potential treatment of MELAS. In this open-label, single-arm study of the oral, once-daily sGC stimulator in eight adults aged 18 or older with MELAS, improvements were seen across a range of endpoints reflecting multiple domains of disease activity, including mitochondrial disease-associated biomarkers such as

lactate and GDF-15, a broad panel of inflammatory biomarkers, cerebral blood flow, and functional connectivity between neural networks. These positive effects after 29 days of dosing were supported by correlations among several endpoints with each other and with zagociguat plasma concentrations. Zagociguat was well tolerated with no serious or severe adverse events and no events leading to discontinuation. Pharmacokinetics were consistent with the Phase 1 studies in healthy volunteers. The positive data from this study supports the potential of zagociguat to provide therapeutic benefit to people living with mitochondrial diseases, including MELAS.

In July 2022, we announced positive topline data from our signal-seeking clinical study of zagociguat for the potential treatment of CIAS. Data from the 14-day, double blind, randomized, placebo-controlled, multiple-ascending-dose study in 48 adults aged 18-50 with stable schizophrenia on a stable, single, atypical antipsychotic regimen demonstrated that once-daily zagociguat was safe and well tolerated, with no reports of serious adverse events, severe adverse events, or treatment discontinuation due to adverse events. We further announced that study data demonstrated a strong effect on cognitive performance after two weeks of 15mg once-daily dosing and that positive movement on inflammatory biomarkers was also observed. These signals on exploratory endpoints are consistent with the pro-cognitive and anti-inflammatory effects of zagociguat observed in preclinical studies and prior clinical trials and support the further development of oral, once-daily zagociguat.

In October 2022, the WHO International Nonproprietary Names committee and the United States Adopted Name Council selected zagociguat as a nonproprietary name for CY6463.

In March 2023, we announced that given the significant capital and capabilities necessary to ensure that the MELAS Phase 2b study is executed efficiently and with the highest quality, and the currently unfavorable capital market conditions, we are actively evaluating the best combination of capital, capabilities, and transactions available to us to advance the development of zagociguat and our other clinical development candidates and to maximize shareholder value.

On March 31, 2023, we entered into a stock purchase agreement with the Company's Chief Executive Office ("CEO") pursuant to which the CEO will make an equity investment in the Company of \$5 million in cash for common stock or nonvoting convertible preferred stock of the Company, the purchase price, consistent with Nasdaq rules, to be at or above the market price at the time of signing that agreement. The closing of the equity investment will take place six business days after the signing of the Asset Purchase Agreement, or May 11, 2023.

On May 11, 2023, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with an investor group which includes the CEO, JW Celtics Investment Corp. ("Buyer Parent") and JW Cyclor Inc. ("Buyer"). Pursuant to the terms of the Asset Purchase Agreement and subject to the approval by Company's shareholders, the Company will receive proceeds of \$8 million as cash consideration, reimbursement for certain operating expenses related to zagociguat and CY3018 for the period between signing and closing of the transaction and 10% of all of Buyer's Parent outstanding equity securities upon the successful closing of the transaction.

On May 11, 2023, we announced topline data from our signal-seeking clinical study of zagociguat for the potential treatment of Alzheimer's disease with vascular pathology ("ADv"), which study was supported in part by a \$2 million grant from the Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program (the "PTC Grant"). This exploratory, randomized, placebo-controlled, study of oral once-daily zagociguat was designed to evaluate safety, tolerability, and pharmacokinetics as well as explore the impact of zagociguat on biomarkers and cognitive performance over a twelve-week dosing period. The total number of enrolled participants was capped at 12 participants due to challenges associated with enrollment. Data from this study show that the safety and tolerability of profile once-daily zagociguat was consistent with prior studies. Given the small number of participants we are unable to draw any conclusions from the data generated in the study.

CY3018 is a CNS-targeted sGC stimulator in preclinical development that preferentially localizes to the brain and has a pharmacology profile that suggests its potential for the treatment of neuropsychiatric diseases and disorders.

Praliguat is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into a license agreement with Akebia relating to the exclusive worldwide license to Akebia of our rights to the

development, manufacture, medical affairs and commercialization of pharmaceutical products containing praliguat and other related products and forms, thereof enumerated in such agreement. Cycleron is eligible to receive up to \$585 million in total potential future development, regulatory, and commercialization milestone payments. Cycleron is also eligible to receive tiered, sales-based royalties ranging from single-digit to high-teen percentages.

Olinciguat is an orally administered, once-daily, vascular sGC stimulator that was evaluated in a Phase 2 study of participants with sickle cell disease. We released topline results from this study in October 2020. We intend to out-license olinciguat to an entity with strong cardiovascular and/or cardiopulmonary capabilities.

The following table summarizes our research and development expenses, employee and facility related costs allocated to research and development expense, and discovery and pre-clinical phase programs, for the three months ended March 31, 2023 and 2022. The product pipeline expenses relate primarily to external costs associated with nonclinical studies and clinical trial costs, which are presented by development candidates.

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
<b>Product pipeline external costs:</b>		
Zagociguat	2,294	4,452
CY3018	58	933
Discovery research	30	178
<b>Total product pipeline external costs</b>	<b>2,382</b>	<b>5,563</b>
Personnel and related internal costs	1,073	3,284
Facilities and other	318	896
<b>Total research and development expenses</b>	<b>\$ 3,773</b>	<b>\$ 9,743</b>

Securing regulatory approvals for new drugs is a lengthy and costly process. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product candidate development efforts and our business overall.

Given the inherent uncertainties of pharmaceutical product development, we cannot estimate with any degree of certainty how our programs will evolve, and therefore the amount of time or money that would be required to obtain regulatory approval to market them. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, our discovery and development candidates will be approved. We invest carefully in our pipeline, and the commitment of funding for each subsequent stage of our development programs is dependent upon the receipt of clear, supportive data.

The successful development of our product candidates is highly uncertain and subject to a number of risks including, but not limited to:

- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms, or if at all. Failure to obtain necessary capital may force us to delay, limit or terminate our development efforts or other operations.
- Cycleron works closely with its clinical trial sites and investigators to deliver trials in a manner consistent with the safety of study participants and healthcare professionals.
- The duration of clinical trials may vary substantially according to the type and complexity of the product candidate and may take longer than expected.
- The United States FDA and comparable agencies outside the United States. impose substantial and varying requirements on the introduction of therapeutic pharmaceutical products, which typically require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures.



- Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.
- The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a product candidate and are difficult to predict.
- The costs, timing and outcome of regulatory review of a product candidate may not be favorable, and, even if approved, a product may face post-approval development and regulatory requirements.
- The emergence of competing technologies and products and other adverse market developments may reduce or eliminate the potential value of our pipeline.
- The continuing impact of COVID-19, which could continue to adversely affect our programs and operations, including our development activities, corporate development, and other activities.

As a result of the factors listed in the “Risk Factors” section in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and elsewhere in this Quarterly Report on Form 10-Q, we are unable to determine the duration and costs to complete current or future nonclinical and clinical stages of our product candidates, including as licensed to third parties, or when, or to what extent, we may generate revenues from the commercialization and sale of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the data from the studies of each product candidate, the competitive landscape and ongoing assessments of such product candidate’s commercial potential.

*General and Administrative Expense.* General and administrative expenses consists primarily of compensation, benefits and other employee-related expenses for personnel in our administrative, finance, legal, information technology, business development, and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs, insurance costs and professional fees for accounting and legal services. We record all general and administrative expenses as incurred.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the amounts of expenses during the reported periods. We base our estimates on our historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ materially from our estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

We believe that our application of accounting policies requires significant judgments and estimates on the part of management and is the most critical to aid in fully understanding and evaluating our reported financial results. Our significant accounting policies are more fully described in Note 2, *Summary of Significant Accounting Policies*, of the consolidated financial statements elsewhere in this Quarterly Report on Form 10-Q.

All research and development expenses are expensed as incurred. We defer and capitalize nonrefundable advance payments we make for research and development activities until the related goods are received or the related services are performed. A discussion of our critical accounting policies and estimates may be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 in Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* under the heading *Critical Accounting Policies and Estimates*.

## Results of Operations

The revenue and expenses reflected in the consolidated financial statements may not be indicative of revenue and expenses that will be incurred by us in the future. The following discussion summarizes the key factors we believe are necessary for an understanding of our consolidated financial statements.

### Revenues and Expenses

	Three Months Ended March 31,		Change	
	2023	2022	\$	%
(dollars in thousands)				
<b>Revenues:</b>				
Revenue from development agreement	—	225	(225)	(100)%
Revenue from grants	—	486	(486)	(100)%
Total revenues	—	711	(711)	(100)%
<b>Cost and expenses:</b>				
Research and development	3,773	9,743	(5,970)	(61)%
General and administrative	3,269	3,952	(683)	(17)%
Total cost and expenses	7,042	13,695	(6,653)	(49)%
Loss from operations	(7,042)	(12,984)	5,942	(46)%
Interest and other income (expenses), net	88	6	82	1367%
Net loss	<u>\$ (6,954)</u>	<u>\$ (12,978)</u>	<u>\$ 6,024</u>	<u>(46)%</u>

*Revenues.* The decrease in revenue of approximately \$0.7 million for the three months ended March 31, 2023, compared to the three months ended March 31, 2022, can be attributed to the revenue from the PTC Grant and the Akebia Supply Agreement recognized in 2022.

*Research and development expense.* The decrease in research and development expense of approximately \$6.0 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 was driven by a decrease of approximately \$2.2 million in external research costs related to the completion of the zagociguat clinical trials in CIAS and MELAS in 2022, a decrease of approximately \$0.9 million for CY3018 costs, a decrease of approximately \$0.1 million in discovery research, a decrease of approximately \$1.6 million in other employee-related expenses primarily due to the workforce reduction in November 2022, a decrease of approximately \$0.6 million in non-cash stock-based compensation, and a decrease of approximately \$0.6 million in professional services.

*General and administrative expense.* The decrease in general and administrative expenses of approximately \$0.7 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 was primarily driven by a decrease in non-cash stock-based compensation.

*Interest and other income (expenses), net.* Interest and other income (expenses), net increased by approximately \$0.1 million for the three months ended March 31, 2023, compared to the three months ended March 31, 2022 due to an increase in interest income driven by higher interest rates.

### Liquidity and Capital Resources

On September 3, 2020, the Company entered into the Sales Agreement with Jefferies with respect to the ATM Offering under the Shelf. Under the ATM Offering, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to \$50.0 million through Jefferies as its sales agent. The Company will pay Jefferies cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. The Company has sold 3,353,059 shares of its common stock for net proceeds of \$12.5 million under the ATM Offering since entering into the Sales Agreement, with no shares of common stock issued or sold under the ATM Offering during the three months ended March 31, 2023.

On June 7, 2021, we closed on a private placement of 5,735,988 shares of our common stock, pursuant to a Common Stock Purchase Agreement, for total gross proceeds of approximately \$18 million. There were no material

fees or commissions related to the transaction. The Company intends to use the proceeds to fund working capital and other general corporate purposes.

Our ability to continue to fund our operations and meet capital needs will depend on our ability to generate cash from operations and access to capital markets and other sources of capital, as further described below. We anticipate that our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures and other general corporate purposes.

On March 31, 2023, we had approximately \$7.2 million of unrestricted cash and cash equivalents. Our cash equivalents include amounts held in U.S. government money market funds. We invest cash in excess of immediate requirements in accordance with our investment policy, which requires all investments held by us to be at least "AAA" rated or equivalent, with a remaining final maturity when purchased of less than twelve months, so as to primarily achieve liquidity and capital preservation.

### **Going Concern**

The Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. In performing its analysis, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future partnerships, equity or debt issuances, and the potential milestones from the Akebia agreement cannot be considered probable at this time because these plans are not entirely within the Company's control and/or have not been approved by the Board of Directors as of the date of these consolidated financial statements.

The Company has incurred recurring losses since its inception, including a net loss of \$7.0 million for the three months ended March 31, 2023. In addition, as of March 31, 2023, the Company had an accumulated deficit of \$266.1 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its cash, cash equivalents and marketable securities as of March 31, 2023 will not be sufficient to fund operations for at least the next twelve months from the date of issuance of these consolidated financial statements and the Company will need to obtain additional funding. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

### **Continued Nasdaq Listing**

On June 1, 2022, the Company received a notice from the Nasdaq Stock Market ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common stock listed on Nasdaq has been below the minimum \$1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided a period of 180 calendar days, or until November 28, 2022, to regain compliance with the Bid Price Requirement. The Company did not regain compliance with the Bid Price Requirement by the initial compliance date. On November 29, 2022,

Nasdaq notified the Company that it is eligible for an additional 180 calendar day period, or until May 29, 2023 (the "Extended Compliance Date"), to regain compliance with the Bid Price Requirement. Nasdaq's determination was based on the Company meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market with the exception of the Bid Price Requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. Effective November 25, 2022, the Company transferred its listing of the Company's common stock from the Nasdaq Global Market to the Nasdaq Capital Market, a continuous trading market that operates in substantially the same manner as the Nasdaq Global Market. The Company's common stock continues to trade under the symbol "CYCN".

To date, the Company has not regained compliance with the Bid Price Requirement. If at any time before May 29, 2023, the bid price of the Company's common stock closes at a \$1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will provide written notification to the Company that it has regained compliance with the Bid Price Requirement. If the Company does not regain compliance with the Bid Price Requirement by the end of the second compliance period, the Company's stock will be subject to delisting.

On April 3, 2023, the Company filed with the SEC a definitive proxy statement for its annual meeting of stockholders to be held on May 15, 2023, at which meeting the Company is seeking stockholder approval of a reverse stock split with the primary intent of increasing the price of its common stock to meet the price criteria for continued listing on Nasdaq. The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement, including initiating a reverse stock split. However, there can be no assurance on how stockholders will vote on such proposal or that the Company will be able to regain compliance with the Bid Price Requirement or will otherwise be in compliance with other Nasdaq Listing Rules.

## Cash Flows

The following is a summary of cash flows for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		Change	
	2023	2022	\$	%
	(dollars in thousands)			
Net cash used in operating activities	\$ (6,214)	\$ (12,835)	\$ 6,621	(52)%

## Cash Flows from Operating Activities

Net cash used in operating activities was \$6.2 million for the three months ended March 31, 2023 compared to \$12.8 million for the three months ended March 31, 2022. The decrease in net cash used in operations of \$6.6 million primarily relates to a decrease in our net loss of \$6.0 million, a decrease in working capital accounts of \$2.0 million, partially offset by a decrease of stock-based compensation of \$1.4 million.

## Funding Requirements

We expect our expenses to fluctuate as we engage in preclinical activities and clinical trials of our product candidates, continue to maintain out-license opportunities and seek to broaden our portfolio through in-licensing of complementary CNS assets. Based on our cash and cash equivalents position as of March 31, 2023 and our planned operating expenses and capital expenditure requirements there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date of this Quarterly Report on Form 10-Q. We will need to raise additional capital in upcoming periods which may not be available on acceptable terms, if at all. Failure to obtain necessary capital when needed may delay current development of our product candidates, halt new development phases, or other operations.

Because of the many risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our

expenses will fluctuate, and our future funding requirements will depend on, and could increase or decrease significantly as a result of many factors including the:

- scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- costs, timing and outcome of regulatory review of our product candidates;
- costs of future activities, including medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- cost and timing of necessary actions to support our strategic objectives;
- costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

A change in any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing of the development of that product candidate.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, outstanding equity ownership may be materially diluted, and the terms of securities sold in such transactions could include liquidation or other preferences that adversely affect the rights of holders of common stock. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

## **Contractual Commitments and Obligations**

### ***Tax-related Obligations***

We exclude assets, liabilities or obligations pertaining to uncertain tax positions from our summary of contractual commitments and obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of March 31, 2023, we had no uncertain tax positions.

### ***Other Funding Commitments***

As of March 31, 2023, we had, and continue to have, several ongoing studies in various clinical trial stages. Our most significant clinical trial spending is with clinical research organizations, or CROs. The contracts with CROs generally are cancellable, with notice, at our option and do not have any significant cancellation penalties.

### **Off-Balance Sheet Arrangements**

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance.

## **New Accounting Pronouncements**

For a discussion of new accounting pronouncements see Note 2, *Summary of Significant Accounting Policies*, of the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and are not required to provide the information required under this item.

## **Item 4. Controls and Procedures.**

### *Evaluation of Disclosure Controls and Procedures*

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Because there are inherent limitations in all control systems, a control system, no matter how well conceived and operated, can provide only reasonable, as opposed to absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

### *Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II

### **Item 1. Legal Proceedings**

We are not a party to any material legal proceedings at this time. From time to time we may be subject to various legal proceedings and claims, which may have a material adverse effect on our financial position or results of operations.

### **Item 1A. Risk Factors**

You should carefully review and consider the information regarding certain factors which could materially affect our business, financial condition or future results set forth under the heading “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. There have been no material changes from the risk factors previously disclosed therein.

### **Item 5. Other Information**

Not applicable.

### **Item 6. Exhibits**

See the Exhibit Index on the following page of this Quarterly Report on Form 10-Q.

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>10.1</u></a>	<a href="#"><u>Stock Purchase Agreement, incorporated by reference to Exhibit 1 to Amendment No. 3 to Schedule 13D filed by Peter M. Hecht on April 3, 2023</u></a>
<a href="#"><u>31.1</u></a>	<a href="#"><u>Certificate of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>31.2</u></a>	<a href="#"><u>Certificate of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>32.1</u></a>	<a href="#"><u>Certificate of Chief Executive Officer (Principal Executive Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>32.2</u></a>	<a href="#"><u>Certificate of Chief Financial Officer (Principal Financial Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
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, thereunto duly authorized.

CYCLERION THERAPEUTICS, INC.

By: /s/ Peter M. Hecht  
Name: Peter M. Hecht  
Title: *Chief Executive Officer (Principal Executive Officer)*

By: /s/ Anjeza Gjino  
Name: Anjeza Gjino  
Title: *Chief Financial Officer (Principal Financial and Accounting Officer)*

Date: May 11, 2023



CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter M. Hecht, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cycleron Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

By: /s/ Peter M. Hecht

Name: Peter M. Hecht

Title: Chief Executive Officer (Principal Executive Officer)

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CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Anjeza Gjino, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cycleron Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 11, 2023

By: /s/ Anjeza Gjino  
Name: Anjeza Gjino  
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter M. Hecht, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Cycleron Therapeutics, Inc. for the period ended March 31, 2023 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Cycleron Therapeutics, Inc.

Date: May 11, 2023

By: /s/ Peter M. Hecht  
Name: Peter M. Hecht  
Title: Chief Executive Officer (Principal Executive Officer)

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Anjeza Gjino, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Cycleron Therapeutics, Inc. for the period ended March 31, 2023 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Cycleron Therapeutics, Inc.

Date: May 11, 2023

By: /s/ Anjeza Gjino  
Name: Anjeza Gjino  
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

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