

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 September 30, 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, 18th 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 November 9, 2023, the registrant had 2,445,096 shares of common stock, no par value, outstanding.

CYCLERION PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2023
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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:

- 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 any current or future product candidates;
- the uncertainty as to any liquidity or monetizable value of our equity interest in Tisento, which faces all the risks of an early-stage pharmaceutical development company;
- 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;
- whether the pralicigat 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;
- a determination that we constitute an investment company under the Investment Company Act of 1940, as amended, and if we are required to register thereunder, would have a material adverse effect on us;
- our or our partners' plans with respect to the development, manufacture or sale of any current or future 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 any current or future product candidates;
- the efficacy and perceived therapeutic benefits of any current or future product candidates, their potential indications and their market potential;

- U.S. and non-U.S. regulatory requirements for any current or future product candidates, including any post-approval development and regulatory requirements, and the ability of any current or future 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, and concentration of voting control, as well as the timing and drivers thereof, and our ability to maintain effective 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 any current or future product candidates;
- the impact of government regulation in the life sciences industry, particularly with respect to healthcare reform;
- the potential we could be delisted from Nasdaq;
- 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 in our Quarterly Report on Form 10-Q for the period ended June 30, 2023 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 data)
(Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,108	\$ 13,382
Accounts receivable	—	96
Prepaid expenses	726	805
Other current assets	30	537
Total current assets	9,864	14,820
Operating lease right-of-use asset	—	1,218
Other investment	5,350	—
Other assets	—	2,041
Total assets	<u>\$ 15,214</u>	<u>\$ 18,079</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 814	\$ 2,970
Accrued research and development costs	362	2,275
Accrued expenses and other current liabilities	1,165	2,382
Total current liabilities	2,341	7,627
Commitments and contingencies (Note 8)	—	—
Stockholders' equity		
Preferred shares, no par value, 500,000 shares authorized and 351,037 series A convertible preferred stock issued and outstanding at September 30, 2023	—	—
Common stock, no par value, 20,000,000 shares authorized and 2,445,096 issued and outstanding at September 30, 2023 and 20,000,000 shares authorized and 2,175,936 issued and outstanding at December 31, 2022 (*)	—	—
Paid-in capital	275,614	269,626
Accumulated deficit	(262,723)	(259,154)
Accumulated other comprehensive loss	(18)	(20)
Total stockholders' equity	12,873	10,452
Total liabilities and stockholders' equity	<u>\$ 15,214</u>	<u>\$ 18,079</u>

*Adjusted retroactively for reverse stock split - see Note 1

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Revenue from development agreement	\$ —	\$ —	\$ —	\$ 297
Total revenues	<u>—</u>	<u>—</u>	<u>—</u>	<u>297</u>
Cost and expenses:				
Research and development	580	1,414	1,491	4,803
General and administrative	2,131	3,104	6,361	9,579
Impairment loss	3,304	—	3,304	—
Total cost and expenses	<u>6,015</u>	<u>4,518</u>	<u>11,156</u>	<u>14,382</u>
Loss from operations	<u>(6,015)</u>	<u>(4,518)</u>	<u>(11,156)</u>	<u>(14,085)</u>
Interest and other income, net	107	111	257	162
Net loss from continuing operations	<u>(5,908)</u>	<u>(4,407)</u>	<u>(10,899)</u>	<u>(13,923)</u>
Discontinued operations:				
Gain (loss) from discontinued operations	13,474	(6,089)	7,330	(22,939)
Net gain (loss)	<u>\$ 7,566</u>	<u>\$ (10,496)</u>	<u>\$ (3,569)</u>	<u>\$ (36,862)</u>
Net gain (loss) per share - basic:				
Net loss per share from continuing operations - basic	\$ (2.43)	\$ (2.03)	\$ (4.74)	\$ (6.41)
Net gain (loss) per share from discontinued operations - basic	5.53	(2.80)	3.19	(10.56)
Basic net gain (loss) per share (*)	<u>\$ 3.11</u>	<u>\$ (4.83)</u>	<u>\$ (1.55)</u>	<u>\$ (16.96)</u>
Net gain (loss) per share - diluted:				
Net loss per share from continuing operations - diluted	\$ (2.12)	\$ (2.03)	\$ (4.74)	\$ (6.41)
Net gain (loss) per share from discontinued operations - diluted	4.84	(2.80)	3.19	(10.56)
Diluted net gain (loss) per share (*)	<u>\$ 2.72</u>	<u>\$ (4.83)</u>	<u>\$ (1.55)</u>	<u>\$ (16.96)</u>
Weighted average shares used in calculating:				
Basic shares	2,435	2,174	2,299	2,173
Diluted shares	2,786	2,174	2,299	2,173
Other comprehensive loss:				
Net gain (loss)	\$ 7,566	\$ (10,496)	\$ (3,569)	\$ (36,862)
Other comprehensive loss:				
Foreign currency translation adjustment loss (gain)	(2)	(3)	2	(5)
Comprehensive gain (loss)	<u>\$ 7,564</u>	<u>\$ (10,499)</u>	<u>\$ (3,567)</u>	<u>\$ (36,867)</u>

*Adjusted retroactively for reverse stock split - see Note 1

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				
Balance at December 31, 2021	2,170,509	\$ —	\$ 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	1,909	—	—	—	—	—
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)
Balance at March 31, 2022	2,172,418	\$ —	\$ 265,112	\$ (228,054)	\$ (24)	\$ 37,034
Net loss	—	—	—	(13,388)	—	(13,388)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	1,574	—	17	—	—	17
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,410	—	—	1,410
Share-based compensation expense related to issuance of stock options to non-employees	—	—	289	—	—	289
Foreign currency translation adjustment	—	—	—	—	(1)	(1)
Balance at June 30, 2022	2,173,992	\$ —	\$ 266,828	\$ (241,442)	\$ (25)	\$ 25,361
Net loss	—	—	—	(10,496)	—	(10,496)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	717	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,372	—	—	1,372
Share-based compensation expense related to issuance of stock options to non-employees	—	—	290	—	—	290
Foreign currency translation adjustment	—	—	—	—	(3)	(3)
Balance at September 30, 2022	2,174,709	\$ —	\$ 268,490	\$ (251,938)	\$ (28)	\$ 16,524

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

	Common Stock (*)		Preferred Stock		Paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total Stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	2,175,936	\$ —	—	\$ —	\$ 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	309	—	—	—	—	—	—	—
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
Balance at March 31, 2023	2,176,245	\$ —	—	\$ —	\$ 270,052	\$ (266,108)	\$ (19)	\$ 3,925
Net loss	—	—	—	—	—	(4,181)	—	(4,181)
Issuance of common stock	225,000	—	—	—	1,953	—	—	1,953
Issuance of preferred shares	—	—	351,037	—	3,047	—	—	3,047
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	6,618	—	—	—	24	—	—	24
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	—	—	373	—	—	373
Share-based compensation expense related to issuance of stock options to non-employees	—	—	—	—	6	—	—	6
Foreign currency translation adjustment	—	—	—	—	—	—	3	3
Fractional shares issuance	(67)	—	—	—	—	—	—	—
Balance at June 30, 2023	2,407,796	\$ —	351,037	\$ —	\$ 275,455	\$ (270,289)	\$ (16)	\$ 5,150
Net gain	—	—	—	—	—	7,566	—	7,566
Issuance of common stock upon vesting of RSUs	37,300	—	—	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and RSUs to employees	—	—	—	—	154	—	—	154
Share-based compensation expense related to issuance of stock options to non-employees	—	—	—	—	5	—	—	5
Foreign currency translation adjustment	—	—	—	—	—	—	(2)	(2)
Balance at September 30, 2023	2,445,096	\$ —	351,037	\$ —	\$ 275,614	\$ (262,723)	\$ (18)	\$ 12,873

*Adjusted retroactively for reverse stock split - see Note 1

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)

	Nine Months Ended September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (3,569)	\$ (36,862)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of discontinued operations	(15,752)	—
Depreciation and amortization	—	65
Impairment loss	3,304	—
Share-based compensation expense	964	5,128
Changes in operating assets and liabilities:		
Accounts receivable	96	(127)
Prepaid expenses	79	392
Other current assets	140	(20)
Operating lease assets	107	138
Other assets	213	274
Accounts payable	(2,157)	(183)
Accrued research and development costs	(1,912)	(2,037)
Accrued expenses and other current liabilities	(1,217)	(336)
Net cash used in operating activities	(19,704)	(33,568)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from disposal of discontinued operations	10,402	—
Net cash provided by investing activities	10,402	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from stock purchase agreement	5,000	—
Proceeds from exercises of stock options and ESPP	24	17
Net cash provided by financing activities	5,024	17
Effect of exchange rate changes on cash and cash equivalents	4	(5)
Net decrease in cash and cash equivalents	(4,274)	(33,556)
Cash and cash equivalents, beginning of period	13,382	53,961
Cash and cash equivalents, end of period	<u>\$ 9,108</u>	<u>\$ 20,405</u>
Supplemental cash flow disclosure:		
Non-cash gain on disposal of discontinued operations	\$ 5,350	\$ —

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 and has been successfully targeted with several drugs.

Pralicyguat 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. 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. CY3018 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. On July 28, 2023, the Company sold Zagociguat and CY3018 to Tisento Therapeutics, Inc. ("Tisento"), a newly formed private company focused on their development, in which Cyclerion currently holds a 10% equity stake received in partial consideration of such sale. See "Asset Purchase Agreement" and "Note 4" below. Cyclerion is actively evaluating other activities aimed at enhancing shareholder value, which may potentially include collaborations, licenses, mergers, acquisitions and/or other targeted investments.

Cyclerion GmbH, a wholly owned subsidiary, was incorporated in Zug, Switzerland on May 3, 2019. The functional currency is the Swiss franc. Subsequent to September 30, 2023, the liquidation process for Cyclerion GmbH has been concluded and the subsidiary is pending deregistration from the commercial registry.

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 diseases.

Pralicyguat is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, Cyclerion entered into a license agreement (as defined below) 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 pralicyguat and other related products and forms thereof enumerated in such agreement. Cyclerion is eligible to receive up to \$585 million in total potential future development, regulatory, and commercialization milestone payments. Cyclerion 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. The Company released topline results from this study in October 2020. Cyclerion intends to out-license olinciguat to an entity with strong cardiovascular and/or cardiopulmonary capabilities.

Zagociguat and CY3018 are orally administered CNS-penetrant sGC stimulators. On July 28, 2023, the Company sold zagociguat and CY3018 to Tisento in exchange for \$8.0 million in cash consideration, \$2.4 million as 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 Tisento's parent's outstanding equity securities. See "Asset Purchase Agreement" and "Note 4" below.

Cyclerion continues to evaluate other activities aimed at enhancing shareholder value, which may potentially include collaborations, licenses, mergers, acquisitions and/or other targeted investments. No such activities are currently pending as of the date of the filing.

Stock Purchase Agreement

In March 2023, we entered into a stock purchase agreement with the Company's Chief Executive Officer (the "CEO") pursuant to which he invested \$5 million in cash for 225,000 shares of common stock and 351,037 shares of Series A Convertible Preferred Stock of the Company at a price of \$8.68 per share (after giving effect to the 1-for-20 reverse stock split the Company implemented on May 15, 2023). Such Series A Convertible Preferred Stock is convertible into shares of our common stock on a one-to-one basis. The closing of the equity investment took place on May 19, 2023, and (to comply with Nasdaq listing requirements) our shareholders approved such convertibility on July 19, 2023.

Asset Purchase Agreement

On May 11, 2023, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with an investor group that included the CEO, JW Celtics Investment Corp and JW Cycle Inc. which subsequently changed their names to Tisento Therapeutics Holdings Inc. ("Tisento Parent") and Tisento Therapeutics Inc. ("Tisento"). Upon the closing on July 28, 2023, of the transactions contemplated by the Asset Purchase Agreement, the Company sold to Tisento specified assets relating to the Company's zagociguat and CY3018 programs (the "Program Assets") and Tisento assumed certain liabilities relating thereto, including, but not limited to (i) liabilities, costs and expenses arising after the date of the Asset Purchase Agreement relating to the employment of certain Cyclerion employees and the conduct of certain preclinical and clinical trial activities prior to the closing of the transactions contemplated by the Asset Purchase Agreement, and (ii) liabilities relating to such assets to the extent relating to the period after the closing of the transaction. In consideration for such sale and assumption, at such closing the Company received proceeds of \$8.0 million as cash consideration, \$2.4 million as reimbursement for certain operating expenses related to such assets for the period between signing and closing of the Asset Purchase Agreement, and shares of common stock of Tisento Parent comprising 10% of the then issued and outstanding equity securities of Tisento Parent immediately following such closing, subject to certain protections against dilution.

Reverse Stock Split

On May 15, 2023, the Company filed Articles of Amendment to the Company's Restated Articles of Organization with the Secretary of Commonwealth of Massachusetts to effect a 1-for-20 reverse stock split of the Company's issued and outstanding shares of common stock. The reverse stock split was reflected on the Nasdaq Capital Market beginning with the opening of trading on May 16, 2023. No fractional shares were issued in connection with the reverse stock split. All share amounts and per share amounts disclosed in this Quarterly Report on Form 10-Q have been adjusted retroactively to reflect the reverse stock split for all periods presented.

At-the-Market Shelf Registration Statement

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. The Shelf expired in July 31, 2023. 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 could 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 agreed to pay Jefferies cash commissions of 3.0 percent of the gross proceeds of sales of common stock which could be sold under the Sales Agreement. Prior to January 1, 2022, the Company 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 in 2022 or 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 and nine months ended September 30, 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, Cyclerion GmbH, and Cyclerion 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, certain cost reduction measures 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 expects that its cash, cash equivalents and marketable securities as of September 30, 2023, will be sufficient to fund operations into 2025, however the Company will need to obtain additional funding to sustain operations as it expects to continue to generate operating losses for the foreseeable future. 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. 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, 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.

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.

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 2022 Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Discontinued Operations

In accordance with ASC 205-20 "Presentation of Financial Statements: Discontinued Operations", a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. In the period in which the component meets held-for-sale or discontinued operations criteria the major current assets, non-current assets, current liabilities, and non-current liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations and disclosed in the notes to financial statements. At the same time, the results of all discontinued operations, less applicable income taxes, shall be reported as components of net loss separate from the net income (loss) of continuing operations.

The Program Assets met the definition of a discontinued operation. Accordingly, the Company has classified the results of the Program Assets as discontinued operations in its unaudited condensed consolidated statements of operations for all periods presented. All assets and liabilities associated with the Program Assets were classified as assets and liabilities of discontinued operations in the Note 4, "Discontinued Operations". All amounts included in the notes to the unaudited condensed consolidated financial statements relate to continuing operations unless otherwise noted. For additional information, see Note 4, "Discontinued Operations".

Investment

The Company accounts for investments in equity securities without a readily determinable fair value at cost, minus impairment. If the Company identifies observable price changes in orderly transactions for an identical or a similar investment of the same issuer, the Company will measure the equity security at fair value as of the date that the observable transaction occurred in accordance with ASC Topic 321, *Investments-Equity Securities*.

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, fair value determination of other investment, 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 nine months ended September 30, 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 became effective for the Company for fiscal years beginning after December 15, 2022. 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 September 30, 2023, and December 31, 2022 (in thousands):

	Fair Value Measurements as of September 30, 2023:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 8,237	\$ —	\$ —	\$ 8,237
Cash equivalents	\$ 8,237	\$ —	\$ —	\$ 8,237

	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	\$ 12,357	\$ —	\$ —	\$ 12,357

During the nine months ended September 30, 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, accounts receivable, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of these amounts.

4. Discontinued Operations

On May 11, 2023, the Company entered into the Purchase Agreement with Tisento for Tisento's acquisition of substantially all of the assets comprising the Company's zagociguat and CY3018 programs, in exchange for consideration at closing of \$8.0 million, the reimbursement of employee expenses or R&D expenses of \$2.4 million that Tisento reimbursed the Company for upon closing, and 10% of the issued and outstanding shares of Tisento Parent (Note 5). Upon closing of the transaction, the Company transferred certain fully depreciated software included within property and equipment to Tisento.

The carrying value of the disposal group was lower than its fair value, less costs to sell, and accordingly, a gain on disposal was recorded during the three and nine months ended September 30, 2023. The operations of the Program Assets are presented as discontinued for all periods presented. The transaction closed on July 28, 2023.

The following table presents the results of the discontinued operations for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Revenue from grants	\$ 50	\$ —	\$ 50	\$ 720
Total revenues	50	—	50	720
Cost and expenses:				
Research and development	691	5,668	4,439	22,240
General and administrative	1,637	421	4,033	1,419
Total cost and expenses	2,328	6,089	8,472	23,659
Loss from operations	(2,278)	(6,089)	(8,422)	(22,939)
Gain on disposal of discontinued operations	15,752	—	15,752	—
Net gain (loss) from discontinued operations	\$ 13,474	\$ (6,089)	\$ 7,330	\$ (22,939)

The following table summarizes the carrying amounts of major classes of assets and liabilities of discontinued operations as of December 31, 2022 (in thousands).

	December 31, 2022
Prepaid expenses	\$ 3
Other current assets	20
Total current assets of discontinued operations	23
Total assets of discontinued operations	23
Accounts payable	2,389
Accrued research and development costs	2,233
Accrued expenses and other current liabilities	155
Total current liabilities of discontinued operations	4,777
Total liabilities of discontinued operations	4,777
Net liabilities of discontinued operations	\$ (4,754)

The following table presents the significant non-cash item for the discontinued operations that are included in the accompanying unaudited condensed consolidated statements of cash flows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cash flows from operating activities:				
Share-based compensation expense	\$ —	\$ 306	\$ 505	\$ 937

The transaction consideration received from the sale of the Program Assets were as follows (in thousands):

	Amount
Closing payment	\$ 8,000
Expense reimbursement	2,402
Investment in Tisento Parent	5,350
Gross transaction consideration from the sale	15,752
Net assets sold	—
Gain on disposal of discontinued operations	\$ 15,752

During the three and nine months ended September 30, 2023, the Company incurred \$1.3 million in closing costs associated with the sale of the Program Assets. The Company also incurred \$0.2 and \$0.9 million in transaction costs associated with the sale of the Program Assets during the three and nine months ended September 30, 2023, respectively. All of the closing and transaction costs were recognized as part of discontinued operations - general and administrative.

5. Other Investment

On July 28, 2023, the Company closed the transactions contemplated by the Asset Purchase Agreement receiving proceeds of \$8.0 million as cash consideration, approximately \$2.4 million as reimbursement for certain operating expenses related to zagociguat and CY3018 programs for the period between signing and closing of the transaction, and 10% of all of Tisento Parent's outstanding equity securities which fair value was determined to be \$5.3 million at the time of closing. The Company's investment in Tisento Parent does not provide it with significant influence over Tisento Parent.

The investment does not have a readily determinable fair value and therefore will be measured at cost minus impairment adjusted by observable price changes in orderly transactions for the identical or a similar investment of the same issuer. This investment will be measured at fair value on a nonrecurring basis when there are events or changes in circumstances that may have a significant adverse effect. An impairment loss is recognized in the consolidated statements of operations and comprehensive loss equal to the amount by which the carrying value exceeds the fair value of the investment. As of September 30, 2023, no impairment loss was recognized.

The initial fair value of the investment in Tisento Parent was determined by reference to the risk-adjusted net assets value using the discounted cash flow method. The estimated net assets value of Tisento Parent includes the cash generated/used from the operations and the proceeds from equity financing. Valuations were derived by reference to observable valuation measures for comparable companies or transactions, including weighted average cost of capital (21% to 23%), terminal decline rate (25% to 75%) and the discount rate referenced by a two-year treasury rate of 4.01%.

6. Property and Equipment

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

	September 30, 2023	December 31, 2022
Software	\$ 126	\$ 2,174
Computer equipment	—	7
Property and equipment, gross	126	2,181
Less: accumulated depreciation and amortization	(126)	(2,181)
Property and equipment, net	<u>\$ —</u>	<u>\$ —</u>

As of September 30, 2023, and December 31, 2022, the Company's property and equipment was primarily located in Boston, Massachusetts.

During the three and nine months ended September 30, 2023, the Company did not record depreciation and amortization expenses. The Company recorded a de minimis amount and approximately \$0.1 million of depreciation and amortization expenses for the three and nine months ended September 30, 2022.

7. Accrued Expenses and Other Current Liabilities

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

	September 30, 2023	December 31, 2022
Accrued incentive compensation	\$ —	\$ 238
Salaries	14	246
Accrued vacation	17	186
Professional fees	676	835
Accrued severance and benefit costs	300	809
Other	158	68
Accrued expenses and other current liabilities	<u>\$ 1,165</u>	<u>\$ 2,382</u>

8. Commitments and Contingencies

Guarantees

On September 6, 2018, Cyclorion 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 September 30, 2023 and December 31, 2022.

9. 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 agreements and 6-month extension are accounted for as short-term leases. The lease agreement was terminated during the three months ended March 31, 2023. The Company recorded a de minimis amount of lease expense associated with the membership agreement during the nine months ended September 30, 2023.

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 at 301 Binney Street, Cambridge, Massachusetts. 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 a de minimis amount, and \$0.1 million of lease expense during the three and nine months ended September 30, 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 a \$0.1 million and \$0.2 million for the three and nine months ended September 30, 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.

After the closing of the Asset Purchase Agreement, the Company had no plans in the foreseeable future to use the licensed rooms and the Company is restricted from subleasing the rooms. In August 2023, the ROU asset and other assets were fully impaired and the Company recognized a \$3.3 million impairment loss during the three and nine months ended September 30, 2023.

10. 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 and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	\$ (19)	\$ 773	\$ 391	\$ 2,396
General and administrative	178	889	573	2,732
	<u>\$ 159</u>	<u>\$ 1,662</u>	<u>\$ 964</u>	<u>\$ 5,128</u>

A summary of stock option activity for the nine months ended September 30, 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	365,216	\$ 184.45	5.8	20
Granted	4,000	3.82		
Exercised	—	0.00		
Cancelled or forfeited	(49,109)	192.07		
Outstanding as of September 30, 2023	<u>320,107</u>	<u>\$ 181.02</u>	<u>4.9</u>	<u>\$ —</u>
Exercisable at September 30, 2023	<u>262,967</u>	<u>\$ 210.43</u>	<u>4.3</u>	<u>\$ —</u>

As of September 30, 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 \$0.9 million and the weighted average period over which that expense is expected to be recognized is 3.3 years.

A summary of RSU activity for the nine months ended September 30, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2022	40,772	\$ 15.30
Granted	—	—
Vested	(37,675)	15.11
Forfeited	(3,097)	17.50
Unvested as of September 30, 2023	<u>—</u>	<u>\$ —</u>

The Company has granted to certain employees stock options 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 September 30, 2023, there were 11,250 outstanding stock options containing market conditions with a weighted average exercise price of \$40.20. As of September 30, 2023, there was a de minimis amount of unrecognized compensation costs related to stock options containing market conditions, which is expected to be recognized over a weighted-average period of 0.54 years.

11. Gain (loss) per share

Basic and diluted net gain (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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss from continuing operations (in thousands)	\$ (5,908)	\$ (4,407)	\$ (10,899)	\$ (13,923)
Net gain (loss) from discontinued operations (in thousands)	13,474	(6,089)	7,330	(22,939)
Total net gain (loss) (in thousands)	<u>7,566</u>	<u>(10,496)</u>	<u>(3,569)</u>	<u>(36,862)</u>
Denominator:				
Weighted average shares used in calculating net gain (loss) per share — basic (in thousands)	<u>2,435</u>	<u>2,174</u>	<u>2,299</u>	<u>2,173</u>
Weighted average shares used in calculating net gain (loss) per share — diluted (in thousands)	<u>2,786</u>	<u>2,174</u>	<u>2,299</u>	<u>2,173</u>
Net gain (loss) per share — basic				
Net loss per share from continuing operations	\$ (2.43)	\$ (2.03)	\$ (4.74)	\$ (6.41)
Net gain (loss) per share from discontinued operations	5.53	(2.80)	3.19	(10.56)
Total gain (loss) per share	<u>\$ 3.11</u>	<u>\$ (4.83)</u>	<u>\$ (1.55)</u>	<u>\$ (16.96)</u>
Net gain (loss) per share — diluted				
Net loss per share from continuing operations	\$ (2.12)	\$ (2.03)	\$ (4.74)	\$ (6.41)
Net gain (loss) per share from discontinued operations	4.84	(2.80)	3.19	(10.56)
Total gain (loss) per share	<u>\$ 2.72</u>	<u>\$ (4.83)</u>	<u>\$ (1.55)</u>	<u>\$ (16.96)</u>

Except for the three months ended September 30, 2023, we exclude shares of preferred stock, 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 in each period. During the three months ended September 30, 2023, 351,037 shares of preferred stock are dilutive and included in the diluted shares. There was no preferred stock issued and outstanding during the three and nine months ended September 30, 2022.

The following table sets forth potential shares that were considered anti-dilutive for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Preferred Stock	—	—	351,037	—
Stock Options	320,107	420,666	320,107	420,666
RSUs	—	2,624	—	2,624
	<u>320,107</u>	<u>423,290</u>	<u>671,144</u>	<u>423,290</u>

12. 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 a de minimis amount and approximately \$0.1 million related to the defined contribution 401(k) Savings Plan for the three and nine months ended September 30, 2023, respectively, and a de minimis amount, and approximately \$0.2 million for the three and nine months ended September 30, 2022, respectively.

13. 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 nine months ended September 30, 2023 (in thousands):

	Amounts accrued at December 31, 2022	Charges	Amount paid	Adjustments	Amounts accrued at September 30, 2023
Workforce reduction	\$ (809)	\$ (565)	\$ 1,074	\$ —	\$ (300)
Total	<u>\$ (809)</u>	<u>\$ (565)</u>	<u>\$ 1,074</u>	<u>\$ —</u>	<u>\$ (300)</u>

14. 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 did not record any revenue for the three months ended September 30, 2023 and 2022 and the nine months ended September 30, 2023. The Company recorded \$0.3 million as revenue from the Supply Agreement in the nine months ended September 30, 2022.

15. Grant Revenue

In August 2021, the Company was approved to receive funding from Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program (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 receive 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 were recognized as the Company incurred expenses related to the PTC Grant.

The Company incurred approximately \$0.1 million of expenses associated with the grant for the three and nine months ended September 30, 2023, compared to approximately \$0.7 million of expenses associated with the grant for the nine months ended September 30, 2022. There is no cost incurred associated with the grant during the three months ended September 30, 2022.

16. Subsequent Events

The Company has evaluated all events and transactions that occurred after the balance sheet date through the date the consolidated financial statements were issued and determined that there were no such events requiring recognition or disclosure in the consolidated financial statements.

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 our Form 10-K for the fiscal year ended December 31, 2022 and the Form 10-Q for the period ended June 30, 2023, 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. 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 and has been successfully targeted with several drugs.

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.

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.

Zagociguat and CY3018 are orally administered CNS-penetrant sGC stimulators. On July 28, 2023, Tisento purchased zagociguat and CY3018 in exchange for \$8 million in cash consideration, \$2.4 million as 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 Tisento Parent's outstanding equity securities.

Cycleron continues to evaluate other activities aimed at enhancing shareholder value, which may potentially include collaborations, licenses, mergers, acquisitions, and/or other targeted investments. No such activities are currently pending.

The following table summarizes our research and development expenses of continuing operations, employee and facility related costs allocated to research and development expense, and discovery and pre-clinical

phase programs, for the three and nine months ended September 30, 2023 and 2022. The product pipeline expenses related primarily to external costs associated with nonclinical studies and clinical trial costs.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Product pipeline external costs	\$ 58	\$ 168	\$ 88	\$ 534
Personnel and related internal costs	304	858	555	2,938
Facilities and other	218	388	848	1,331
Total research and development expenses	\$ 580	\$ 1,414	\$ 1,491	\$ 4,803

Securing regulatory approvals for new drugs is a lengthy and costly process. Any failure by us or our partners 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.

The successful development of any current or future 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.
- The duration of any clinical trials we may conduct 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 any clinical trials we may conduct 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.

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 in Part II, Section 1A of our Form 10-Q for the period ended June 30, 2023, we are unable to determine the duration and costs to complete current or future nonclinical and clinical stages of any current or future product candidates, including as licensed to third parties, or when, or to what extent, we may generate revenues from the commercialization and sale of any current or future 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 September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	\$	%	2023	2022	\$	%
	(dollars in thousands)				(dollars in thousands)			
Revenues:								
Revenue from development agreement	—	—	—	0%	—	297	(297)	100%
Total revenues	—	—	—	0%	—	297	(297)	(100)%
Cost and expenses:								
Research and development	580	1,414	(834)	(59)%	1,491	4,803	(3,312)	(69)%
General and administrative	2,131	3,104	(973)	(31)%	6,361	9,579	(3,218)	(34)%
Impairment loss	3,304	—	3,304	100%	3,304	—	3,304	100%
Total cost and expenses	6,015	4,518	1,497	33%	11,156	14,382	(3,226)	(22)%
Loss from operations	(6,015)	(4,518)	(1,497)	33%	(11,156)	(14,085)	2,929	(21)%
Interest and other income, net	107	111	(4)	(4)%	257	162	95	59%
Net loss from continuing operations	(5,908)	(4,407)	(1,501)	34%	(10,899)	(13,923)	3,024	(22)%
Discontinued operations:								
Gain (loss) from discontinued operations	13,474	(6,089)	19,563	(321)%	7,330	(22,939)	30,269	(132)%
Net gain (loss)	\$ 7,566	\$ (10,496)	\$ 18,062	(172)%	\$ (3,569)	\$ (36,862)	\$ 33,293	(90)%

Revenues. There was no revenue recognized during the three months ended September 30, 2023 and 2022. The decrease in revenue of approximately \$0.3 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 can be attributed to approximately \$0.3 million of revenue generated from the Akebia Supply Agreement in the nine months ended September 30, 2022.

Research and development expense. The decrease in research and development expense of approximately \$0.8 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was driven by decreases of approximately \$0.6 million in salaries and other employee-related expenses including non-cash stock-based compensation, approximately \$0.1 million in IT services, and approximately \$0.1 million in external research costs related to discovery research.

The decrease in research and development expense of approximately \$3.3 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was driven by decreases of approximately \$2.4 million in salaries and other employee-related expenses including approximately \$1.6 million in non-cash stock-based compensation, approximately \$0.2 million in IT services, approximately \$0.3 million in professional services, and approximately \$0.4 million in external research costs related to discovery research.

General and administrative expense. The decrease in general and administrative expenses of approximately \$1.0 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was primarily driven by decreases of approximately \$0.6 million in stock-based compensation, approximately \$0.2 million in amortization of insurance policies and approximately \$0.2 million in salary expense.

The decrease in general and administrative expenses of approximately \$3.2 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was primarily driven by decreases of approximately \$2.1 million in non-cash stock-based compensation, approximately \$0.8 million in salaries and other employee-related costs, approximately \$0.3 million in amortization of insurance policies, approximately \$0.2 million in board member fees, approximately \$0.2 million in rent expenses, partially offset by an increase of \$0.5 million in legal fees associated with corporate strategic initiatives.

Impairment loss. The impairment loss consists of an impairment loss of operating lease of approximately \$3.3 million during the three and nine months ended September 30, 2023. There was no impairment loss recognized during the three and nine months ended September 30, 2022.

Gain (loss) from discontinued operations. The gain from discontinued operations increased by \$19.6 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022. The gain was primarily driven by the one-time gain of sale of approximately \$15.8 million, and approximately \$5.0 million decrease of research and development expense, offset by \$1.2 million increase in general and administrative expenses due to the closing costs related to the disposal incurred during the three months ended September 30, 2023. The decrease in research and development expense included approximately \$3.6 million decrease in external research costs related to zagociguat clinical trials and CY3018 costs and approximately \$1.2 million decrease in salaries and other employee-related expenses.

The increase in gain from discontinued operations of approximately \$30.3 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was driven by the one-time gain of sale of approximately \$15.8 million, and approximately \$17.8 million decrease of research and development expense, offset by \$2.6 million increase in general and administrative expenses due to closing and transaction costs related to the disposal incurred during the nine months ended September 30, 2023. The decrease in research and development expense included approximately \$13.3 million decreased in external research costs in related to zagociguat clinical trials and CY3018 costs, approximately \$3.5 million decrease in salaries and other employee-related expenses and approximately \$1.0 million decrease in consulting expense.

Interest and other income increased by approximately \$0.1 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 due to an increase of approximately \$0.1 million in interest income driven by higher interest rates.

Liquidity and Capital Resources

On September 3, 2020, we entered into the Sales Agreement with Jefferies with respect to the ATM Offering under the Shelf. The Shelf expired in July 2023. We did not sell any shares of our common stock under the Shelf in 2022 or 2023.

On May 19, 2023, we sold 225,000 shares of our common stock, pursuant to a Common Stock Purchase Agreement, and 351,037 shares of Series A Preferred Stock, to our CEO, for total gross proceeds of approximately \$5 million. There were no material fees or commissions related to the transaction.

On July 28, 2023, we closed the transactions contemplated by the Asset Purchase Agreement receiving proceeds of \$8.0 million as cash consideration, approximately \$2.4 million as reimbursement for certain operating expenses related to zagociguat and CY3018 programs for the period between signing and closing of the transaction, and 10% of all of Tisento Parent's outstanding equity securities.

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 September 30, 2023, we had approximately \$9.1 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

We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our 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 our plans sufficiently alleviates substantial doubt about our 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 our analysis, management excluded certain elements of our 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 our control and/or have not been approved by the Board of Directors as of the date of these consolidated financial statements.

We have incurred recurring losses since our inception, including a net loss of \$3.6 million for the nine months ended September 30, 2023. In addition, as of September 30, 2023, we had an accumulated deficit of \$259.2 million. We expect that our cash, cash equivalents and marketable securities as of September 30, 2023, will be sufficient to fund operations into 2025, however we will need to obtain additional funding to sustain operations as we expect to continue to generate operating losses for the foreseeable future. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern.

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.

Reverse Stock Split

On May 15, 2023, we filed Articles of Amendment to our Restated Articles of Organization with the Secretary of Commonwealth of Massachusetts to effect a 1-for-20 reverse stock split of our issued and outstanding shares of common stock. The reverse stock split was reflected on the Nasdaq Capital Market beginning with the opening of trading on May 16, 2023. No fractional shares were issued in connection with the reverse stock split. All share amounts and per share amounts disclosed in this Quarterly Report on Form 10-Q have been adjusted retroactively to reflect the reverse stock split for all periods presented.

Cash Flows

The following is a summary of cash flows for the years ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Change	
	2023	2022	\$	%
	(dollars in thousands)			
Net cash used in operating activities	\$ (19,704)	\$ (33,568)	\$ 13,864	(41)%
Net cash provided by investing activities	\$ 10,402	\$ —	\$ 10,402	—
Net cash provided by financing activities	\$ 5,024	\$ 17	\$ 5,007	100%

Cash Flows from Operating Activities

Net cash used in operating activities was \$19.7 million for the nine months ended September 30, 2023 compared to \$33.6 million for the nine months ended September 30, 2022. The decrease in net cash used in operations of \$13.9 million primarily relates to a decrease of approximately \$33.3 million in our net loss and adjusted by an increase of approximately \$3.3 million in impairment loss, offset by an increase of approximately \$15.8 million in gain on disposal of discontinued operations, a decrease of approximately \$4.2 million in stock-based compensation, and a decrease of approximately \$2.8 million in working capital accounts.

Cash Flows from Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2023 of \$10.4 million was due to cash proceeds received from the disposal of discontinued operations of approximately \$10.4 million. There was no investing activity incurred in the nine months ended September 30, 2022.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 of \$5.0 million was due to cash received from the May 2023 stock purchase agreement of \$5 million. There was a de minimis amount of financing activity in the nine months ended September 30, 2022.

Funding Requirements

We expect our expenses to fluctuate as we continue to maintain out-license opportunities and seek to broaden our portfolio through in-licensing of complementary CNS assets. We expect that our cash, cash equivalents and marketable securities as of September 30, 2023, will be sufficient to fund operations into 2025, however we will need to obtain additional funding to sustain operations as we expect to continue to generate operating losses for the foreseeable future. Failure to obtain necessary capital when needed may delay development of any future product candidates, 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 current and any future product candidates, and any preclinical studies and clinical trials we may conduct;
- costs, timing and outcome of regulatory review of any future product candidates;
- costs of future activities, including medical affairs, manufacturing and distribution, for any of any future 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 current or future 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, of which there can be no assurance. 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, as to which raise there can be no assurances, we may have to relinquish 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 funds, we may need to cease operations.

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 September 30, 2023, we had no uncertain tax positions.

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 and in Part II, Item 1A of our Quarterly Report on Form 10-Q for the period ended June 30, 2023.

Item 5. Other Information

On July 28, 2023, the transactions contemplated by the Asset Purchase Agreement were consummated. Upon the closing, the Company sold to Tisento specified assets relating to the Company’s zagociguat and CY3018 programs and Tisento assumed certain liabilities relating thereto, including, but not limited to (i) liabilities, costs and expenses arising after the date of the Asset Purchase Agreement relating to the employment of certain Cycleron employees and the conduct of certain preclinical and clinical trial activities prior to the closing of the transactions contemplated by the Asset Purchase Agreement, and (ii) liabilities relating to such assets to the extent relating to the period after the closing of the transaction. In consideration for such sale and assumption, at such closing the Company received proceeds of \$8 million as cash consideration, reimbursement for certain operating expenses related to such assets for the period between signing and closing of the Asset Purchase Agreement, and 10% of the issued and outstanding equity securities of Tisento Parent immediately following such closing, subject to certain protections against dilution.

The foregoing summary is qualified entirely by reference to the Asset Purchase Agreement, a copy of which is incorporated by reference herein as Exhibit 10.3, which is filed as Exhibit 2.1 to the Current Report on Form 8-K filed on May 11, 2023 (File No. 001-38787).

Item 6. Exhibits

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

EXHIBIT INDEX

Exhibit No.	Description
31.1	Certificate of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certificate of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	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
32.2	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
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: November 13, 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: November 13, 2023

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

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: November 13, 2023

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

**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 September 30, 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: November 13, 2023

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

**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 September 30, 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: November 13, 2023

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