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, 2022
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	**83-1895370**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
245 First Street, 18th Floor, Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	(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 Stock Market LLC (Nasdaq Global Select Market)

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 1, 2022, the registrant had 43,494,184 shares of common stock, no par value, outstanding.

CYCLERION PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2022
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- we could be delisted from Nasdaq;
- there is substantial doubt regarding our ability to continue as a going concern;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching and commercializing our product candidates, including CY6463;
- the coronavirus (“COVID-19”) pandemic and related constraints on supply chains and human resource availability affecting our clinical trials and other operating activities;
- 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;
- whether the praliciguat out-license will result in the creation of any therapies;
- whether any development, regulatory, and commercialization milestones or royalty payments provided for in the agreement with Akebia (as defined below) will be achieved;
- the impact on our business of workforce and expense reduction initiatives;
- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;
- the safety profile and related adverse events of our product candidates;
- the efficacy and perceived therapeutic benefits of our product candidates, their potential indications and their market potential;
- U.S. and non-U.S. regulatory requirements for our product candidates, including any post-approval development and regulatory requirements, and the ability of our product candidates to meet such requirements;
- our ability to attract and retain employees needed to execute our business plans and strategies and our ability to manage the impact of any loss of key employees;

- our ability to obtain and maintain intellectual property protection for our product candidates and the strength thereof;
- our future financial performance, revenues, expense levels, payments, cash flows, profitability, tax obligations, capital raising and liquidity sources, real estate needs and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates;
- the impact of government regulation in the life sciences industry, particularly with respect to healthcare reform; and
- trends and challenges in the markets for our potential products.

See the "Risk Factors" section in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and elsewhere in this Quarterly Report on Form 10-Q for a further description of these and other factors. We caution you that the risks, uncertainties, and other factors referenced above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot assure you that we will realize the results, benefits, or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. There can be no assurance that (i) we have correctly measured or identified all of the factors affecting our business or the extent of these factors' likely impact, (ii) the available information with respect to these factors on which such analysis is based is complete or accurate, (iii) such analysis is correct or (iv) our strategy, which is based in part on this analysis, will be successful. All forward-looking statements in this report apply only as of the date of this report or as of the date they were made and, except as required by applicable law, we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise.

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,405	$ 53,961
Accounts receivable	227	100
Prepaid expenses	536	928
Other current assets	488	468
Total current assets	21,656	55,457
Property and equipment, net	—	65
Operating lease right-of-use asset	1,264	1,402
Other assets	2,133	2,407
Total assets	$ 25,053	$ 59,331
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,645	$ 1,828
Accrued research and development costs	4,316	6,353
Accrued expenses and other current liabilities	2,568	2,904
Total current liabilities	8,529	11,085
Commitments and contingencies (Note 6)	—	—
Stockholders' equity		
Common stock, no par value, 400,000,000 shares authorized and 43,494,184 issued and outstanding at September 30, 2022 and 400,000,000 shares authorized and 43,410,185 issued and outstanding at December 31, 2021	—	—
Accumulated deficit	(251,938)	(215,076)
Paid-in capital	268,490	263,345
Accumulated other comprehensive loss	(28)	(23)
Total stockholders' equity	16,524	48,246
Total liabilities and stockholders' equity	$ 25,053	$ 59,331

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,	
	2022	2021	2022	2021
Revenues:				
Revenue from license agreement	$ —	$ —	$ —	$ 3,000
Revenue from development agreement	—	77	297	138
Revenue from grants	—	271	720	271
Total revenues	—	348	1,017	3,409
Cost and expenses:				
Research and development	7,082	7,032	27,043	27,178
General and administrative	3,525	4,601	10,998	16,207
Loss on lease termination	—	—	—	881
Total cost and expenses	10,607	11,633	38,041	44,266
Loss from operations	(10,607)	(11,285)	(37,024)	(40,857)
Interest and other income (expenses), net	111	(5)	162	(15)
Net loss	$ (10,496)	$ (11,290)	$ (36,862)	$ (40,872)
Net loss per share:				
Basic and diluted net loss per share	$ (0.24)	$ (0.26)	$ (0.85)	$ (1.08)
Weighted average shares used in calculating:				
Basic and diluted net loss per share	43,488	43,291	43,457	37,730
Other comprehensive loss:				
Net loss	$ (10,496)	$ (11,290)	$ (36,862)	$ (40,872)
Other comprehensive loss:				
Foreign currency translation adjustment (loss) gain	(3)	—	(5)	1
Comprehensive loss	$ (10,499)	$ (11,290)	$ (36,867)	$ (40,871)

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, 2020	34,047,300	$ —	$ 222,949	$ (163,429)	$ (27)	$ 59,493
Net loss	—	—	—	(13,399)	—	(13,399)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	82,625	—	27	—	—	27
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,921	—	—	1,921
Share-based compensation expense related to issuance of stock options and RSUs to non-employees	—	—	391	—	—	391
Balance at March 31, 2021	34,129,925	$ —	$ 225,288	$ (176,828)	$ (27)	$ 48,433
Net loss	—	—	—	(16,182)	—	(16,182)
Issuance of common stock - 2021 equity private placement and ATM	9,087,547		30,497			30,497
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	57,777	—	133	—	—	133
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,942	—	—	1,942
Share-based compensation expense related to issuance of stock options and RSUs to non-employees	—	—	398	—	—	398
Foreign currency translation adjustment	—	—	—	—	1	1
Balance at June 30, 2021	43,275,249	$ —	$ 258,258	$ (193,010)	$ (26)	$ 65,222
Net loss	—	—	—	(11,290)	—	(11,290)
Issuance of common stock - ATM	1,500	—	6	—	—	6
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	33,340	—	37	—	—	37
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	2,018	—	—	2,018
Share-based compensation expense related to issuance of stock options and RSUs to non-employees	—	—	394	—	—	394
Balance at September 30, 2021	43,310,089	$ —	$ 260,713	$ (204,300)	$ (26)	$ 56,387

Cyclerion Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(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	43,410,185	$ —	$ 263,345	$ (215,076)	$ (23)	$ 48,246
Net loss	—	—	—	(12,978)	—	(12,978)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	38,175	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	1,476	—	—	1,476
Share-based compensation expense related to issuance of stock options to non-employees	—	—	291	—	—	291
Foreign currency translation adjustment	—	—	—	—	(1)	(1)
Balance at March 31, 2022	43,448,360	$ —	$ 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	31,475	—	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 and RSUs to non-employees	—	—	289	—	—	289
Foreign currency translation adjustment	—	—	—	—	(1)	(1)
Balance at June 30, 2022	43,479,835	$ —	$ 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	14,349	—	—	—	—	—
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 and RSUs to non-employees	—	—	290	—	—	290
Foreign currency translation adjustment	—	—	—	—	(3)	(3)
Balance at September 30, 2022	43,494,184	$ —	$ 268,490	$ (251,938)	$ (28)	$ 16,524

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,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (36,862)	$ (40,872)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	65	424
Net loss on disposal of property and equipment	—	6,322
Loss on lease termination	—	881
Share-based compensation expense	5,128	7,064
Changes in operating assets and liabilities:		
Accounts receivable	(127)	(158)
Related party accounts receivable	—	127
Prepaid expenses	392	254
Other current assets	(20)	1,254
Operating lease assets	138	(105)
Other assets	274	274
Accounts payable	(183)	25
Related party accounts payable	—	(286)
Accrued research and development costs	(2,037)	2,011
Operating lease liabilities	—	(1,048)
Accrued expenses and other current liabilities	(336)	(4,054)
Net cash (used in) operating activities	(33,568)	(27,887)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	—	(7)
Proceeds from sale of property and equipment	—	1,464
Net cash provided by investing activities	—	1,457
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from equity private placement and ATM	—	30,503
Proceeds from exercises of stock options and ESPP	17	197
Net cash provided by financing activities	17	30,700
Effect of exchange rate changes on cash and cash equivalents	(5)	1
Net decrease in cash, cash equivalents and restricted cash	(33,556)	4,271
Cash, cash equivalents and restricted cash, beginning of period	53,961	58,232
Cash, cash equivalents and restricted cash, end of period	$ 20,405	$ 62,503
Supplemental cash flow disclosure:		
Cash and cash equivalents	$ 20,405	$ 62,503
Total cash, cash equivalents and restricted cash	$ 20,405	$ 62,503

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

1. Nature of Business

Nature of Operations

Cyclerion Therapeutics, Inc. (“Cyclerion”, the “Company” or “we”) is a clinical-stage biopharmaceutical company on a mission to develop treatments for mitochondrial diseases, including Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes ("MELAS"). Our lead asset, CY6463, is a pioneering, central nervous system (“CNS”)-penetrant, soluble guanylate cyclase ("sGC") stimulator that is currently in clinical development for MELAS. sGC stimulators are small molecules that act synergistically with nitric oxide ("NO") as positive allosteric modulators of sGC to boost production of cyclic guanosine monophosphate ("cGMP"). cGMP is a key second messenger that, when produced by sGC, regulates diverse and critical biological functions in the CNS including mitochondrial function, neuronal function, inflammation, and vascular dynamics.

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

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

Company Overview

The Company’s mission is to develop treatments for mitochondrial diseases, including MELAS. Its priority is advancing its ongoing CY6463 clinical program for MELAS.

CNS assets. CY6463 is an orally administered CNS-penetrant sGC stimulator that is being developed as a symptomatic and potentially disease modifying therapy for MELAS and potentially other primary mitochondrial disease. NO-sGC-cGMP is a fundamental signaling network, that is widely used in the nervous system. CY6463 enhances the brain’s natural ability to produce cGMP, an important second messenger in the CNS, by stimulating sGC, a key node in the NO-sGC-cGMP pathway. This pathway is critical to basic CNS functions and deficient NO-sGC-cGMP signaling is believed to play an important role in the pathogenesis of many CNS diseases. Agents that stimulate sGC to produce cGMP may compensate for deficient NO signaling.

On January 13, 2020, we announced positive results from our Phase 1 first-in-human study that provided the foundation for continued development of CY6463. The results from this study indicate that CY6463 was well tolerated. Pharmacokinetic data, obtained from both blood and cerebral spinal fluid ("CSF"), support once-daily dosing, with or without food, and demonstrated CY6463 penetration of the blood-brain-barrier with CSF concentrations expected to be pharmacologically active.

On October 14, 2020, we announced positive topline results from our CY6463 Phase 1 translational pharmacology study in healthy elderly participants. Treatment with CY6463 for 15-days in this 24-subject study confirmed and extended results seen in the earlier first-in-human Phase 1 study: once daily oral treatment demonstrated blood-brain-barrier penetration with expected CNS exposure and target engagement. Results also showed significant improvements in neurophysiological and objective performance measures as well as in inflammatory biomarkers associated with aging and neurodegenerative diseases. CY6463 was safe and generally well tolerated in this study. Significant effects on cerebral blood flow and markers of bioenergetics were not observed in this study of healthy elderly participants. We believe that these results, together with nonclinical data, support continued development of CY6463 as a potential new medicine for serious CNS diseases.

On June 10, 2022, we announced positive topline clinical data for CY6463 in our signal-seeking clinical study for the potential treatment of MELAS. In this open-label, single-arm study of the oral, once-daily sGC stimulator in eight adults aged 18 or older with MELAS, improvements were seen across a range of assessments, including mitochondrial disease-associated biomarker such as lactate and GDF-15, a broad panel of inflammatory

biomarkers, cerebral blood flow, and functional connectivity between neural networks. These positive effects after 29 days of dosing were supported by correlations across several endpoints. CY6463 was well tolerated with no adverse events and pharmacokinetics were consistent with the Phase 1 study in healthy volunteers. The positive data from this study further support the potential of CY6463 to provide therapeutic benefit to people living with MELAS.

On July 28, 2022, we announced positive topline data from our signal-seeking clinical study of CY6463 for the potential treatment of cognitive impairment associated with schizophrenia ("CIAS") in individuals with stable schizophrenia on a stable, single, atypical antipsychotic regimen. Data from the 14-day, double blind, randomized, placebo-controlled, multiple-ascending-dose study in 48 adults aged 18-50 demonstrate that once-daily CY6463 was safe and well tolerated, with no reports of serious adverse events ("SAEs"), severe adverse events ("AEs"), or treatment discontinuation due to AEs. Study data demonstrate a strong effect on cognitive performance after two weeks of 15mg once-daily dosing. Positive movement on inflammatory biomarkers was also observed. These signals on exploratory endpoints provide further evidence of the pro-cognitive and anti-inflammatory effects of CY6463 observed in preclinical studies and prior clinical trials. Study data demonstrate the translation of sGC multi-dimensional pharmacology and the therapeutic potential of amplifying sGC signaling in the CNS and support the further development of oral, once-daily CY6463.

On October 6, 2022, we announced our mitochondrial disease-focused corporate strategic plan. Based on the positive data from the recently completed CY6463 MELAS clinical study, we will focus future development of CY6463 on genetic mitochondrial diseases, concentrating first on development in MELAS, a rare disease where the company believes it has the capabilities to advance the program independently. We are currently preparing to meet with the FDA in the fourth quarter of 2022 to discuss the CY6463 development program, including the next study and paths to registration in MELAS.

We recently capped enrollment in our signal-seeking clinical study of CY6463 for the potential treatment of Alzheimer's disease with vascular pathology ("ADv"), which will enable the Company to channel its resources to its most urgent priorities in MELAS. Data from the ADv study is expected in the first half of 2023. Learnings from this and previous CY6463 studies can be leveraged to optimize future potential Alzheimer's Disease/Vascular Dementia studies. The ADv study is supported in part by a $2 million grant from the Alzheimer’s Association’s Part the Cloud-Gates Partnership Grant Program (the "PTC Grant").

Our next generation CNS asset, CY3018, is a differentiated CNS-penetrant sGC stimulator with greater CSF-to-plasma exposure relative to CY6463. CY3018 is intended to expand the potential of sGC stimulation for the treatment of disorders of the CNS. We are completing IND-enabling activities for CY3018 and are looking to secure a partnership or other funding mechanism to develop the program in the future.

Non-CNS assets. We have other assets that are outside of our current strategic focus. These non-core assets are not being internally developed at this time. *Praliciguat* is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into the License Agreement (as defined below) with Akebia Therapeutics, Inc. (“Akebia”) relating to the exclusive worldwide license to Akebia of our rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing praliciguat and other related products and forms thereof enumerated in such agreement. *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. Olinciguat is available for licensing to a third-party partner.

2021 Equity Private Placement

On June 3, 2021, the Company entered into a Common Stock Purchase Agreement (the “2021 Equity Private Placement”) for the private placement of 5,735,988 shares of the Company’s common stock, for total gross proceeds of approximately $18 million. The closing of the 2021 Equity Private Placement occurred on June 7, 2021. The Company did not utilize the services of a placement agent or broker and accordingly incurred no material related transaction fees or commissions.

At-the-Market Offering

On July 24, 2020, the Company filed a Registration Statement on Form S-3 (the “Shelf”) with the Securities and Exchange Commission (the “SEC”) in relation to the registration of common stock, preferred stock, debt securities, warrants and units of any combination thereof for an aggregate initial offering price not to exceed

$150.0 million. The Shelf was declared effective as of July 31, 2020. On September 3, 2020, the Company entered into a Sales Agreement (the “Sales Agreement”) with Jefferies LLC (“Jefferies”) with respect to an at-the-market offering (the “ATM Offering”) under the Shelf. Under the ATM Offering, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Jefferies as its sales agent. The Company will pay to Jefferies cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. The Company has sold 3,353,059 shares of its common stock for net proceeds of $12.5 million under the ATM Offering, since entering into the Sales Agreement. No shares of common stock have been issued or sold under the ATM Offering during the nine months ended September 30, 2022.

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 condensed consolidated financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which was filed with the Securities and Exchange Commission on February 24, 2022.

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, 2022 and 2021 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, 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.

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

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

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

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

On June 1, 2022, the Company received a notice from the Nasdaq Stock Market ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common stock listed on Nasdaq has been below the minimum $1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement"). The Nasdaq deficiency letter has no immediate effect on the listing of the Company's common stock, and its common stock will continue to trade on The Nasdaq Global Select Market under the symbol "CYCN" at this time.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided a period of 180 calendar days, or until November 28, 2022, to regain compliance with the Bid Price Requirement. If at any time before November 28, 2022, the bid price of the Company's common stock closes at a $1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will provide written notification to the Company that it has regained compliance with the Bid Price Requirement. In the event the Company does not regain compliance with the Bid Price Requirement by November 28, 2022, the Company may be afforded an additional 180-day compliance period, provided it demonstrates that it meets all other applicable standards for initial listing on the Nasdaq Capital Market, except the Bid Price Requirement. If the Company does not regain compliance with the Bid Price Requirement by the end of the second compliance period, the Company's stock will be subject to delisting.

The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement, including initiating a reverse stock split. However, there can be no assurance that the Company will be able to regain compliance with the Bid Price Requirement or will otherwise be in compliance with other Nasdaq Listing Rules.

2. Summary of Significant Accounting Policies

The accounting policies of the Company are set forth in Note 2. *Summary of Significant Accounting Policies* to the consolidated financial statements contained in the Company's 2021 Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Use of Estimates

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

assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that are adopted by the Company as of the specified effective date. Except as discussed elsewhere in the notes to the consolidated financial statements, the Company did not adopt any new accounting pronouncements during the nine months ended September 30, 2022 that had a material effect on its condensed consolidated financial statements.

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

In May 2021 the FASB issued Accounting Standards Update No. 2021-04, Earnings Per Share ("Topic 260"), Debt-Modifications and Extinguishments ("Subtopic 470-50"), Compensation-Stock Compensation ("Topic 718"), and Derivatives and Hedging-Contracts in Entity’s Own Equity ("Subtopic 815-40"): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, a consensus of the Emerging Issues Task Force ("EITF") , which amends the FASB Accounting Standards Codification ("ASC" or the “Codification”) to provide explicit guidance, and, thus, reduce diversity in practice, on accounting by issuers for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after the modification or exchange. This amendment provides that for an entity that presents earnings per share ("EPS") in accordance with Topic 260, the effects of a modification or an exchange of a freestanding equity-classified written call option that is recognized as a dividend should be an adjustment to net income (or net loss) in the basic EPS calculation. The amended guidance is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, and should be applied prospectively to modifications or exchanges occurring on or after the effective date. The Company adopted ASU 2021-04 in the first quarter of 2022, 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, 2022, and December 31, 2021 (in thousands):

	Fair Value Measurements as of September 30, 2022:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 19,331	$ —	$ —	$ 19,331
Cash equivalents	$ 19,331	$ —	$ —	$ 19,331

	Fair Value Measurements as of December 31, 2021:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 52,917	$ —	$ —	$ 52,917
Cash equivalents	$ 52,917	$ —	$ —	$ 52,917

During the nine months ended September 30, 2022 and 2021, there were no transfers between levels. The fair value of the Company's cash equivalents, consisting of money market funds, is based on quoted market prices in active markets with no valuation adjustment.

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

4. Property and Equipment

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

	September 30, 2022	December 31, 2021
Software	$ 2,214	$ 2,214
Computer equipment	51	51
Property and equipment, gross	2,265	2,265
Less: accumulated depreciation and amortization	(2,265)	(2,200)
Property and equipment, net	$ —	$ 65

As of September 30, 2022, and December 31, 2021, the Company's property and equipment was primarily located in Boston, Massachusetts.

Depreciation and amortization expense of the Company's property and equipment was $0.1 million and $0.4 million for the nine months ended September 30, 2022 and 2021, respectively.

5. Accrued Expenses and Other Current Liabilities

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

	September 30, 2022	December 31, 2021
Accrued incentive compensation	$ 1,017	$ 1,369
Salaries	383	266
Accrued vacation	330	345
Professional fees	679	398
Other	159	526
Accrued expenses and other current liabilities	$ 2,568	$ 2,904

6. Commitments and Contingencies

Other Funding Commitments

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

Guarantees

On September 6, 2018, Cyclerion 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, 2022 and December 31, 2021.

7. Leases

On April 30, 2021, the Company entered into a Termination Agreement (the "Termination Agreement") for its Head Lease (the "Head Lease") for the Company's former headquarters located at 301 Binney Street, Cambridge, MA, as initially amended on February 28, 2020, and further amended on September 15, 2020. Pursuant to the Termination Agreement, the Company surrendered the leased space of approximately 57,000 square feet to the building’s landlord. The Company did not pay any termination fees in connection with the Termination Agreement. As a result of the termination of the Head Lease, the related right-of-use asset was written off, the lease liability was derecognized, and the $3.8 million security deposit was returned to the Company and recorded as part of our cash balance.

Lease cost was recognized on a straight-line basis over the lease term. For the three and nine months ended September 30, 2021, the Company recognized approximately $0.6 million and $2.2 million, respectively, of total lease costs and $0.2 million and $0.7 million, respectively, of variable lease costs, related to the Head Lease. The Company did not record any lease costs related to the Head Lease during the nine months ended September 30, 2022. For the three and nine months ended September 30, 2021, the Company paid $0.5 million and $1.9 million, respectively, related to its lease liability.

In May 2021 the Company signed a 12-month membership agreement to lease space with WeWork at 501 Boylston Street, Boston, Massachusetts, commencing on August 1, 2021. The agreement was extended for six months on August 1, 2022. The 12-month agreement and 6-month extension are accounted for as short-term leases. The Company recorded $0.1 million and $0.2 million of lease expense associated with the membership agreement during the three and nine months ended September 30, 2022, respectively.

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

The Company determined that the Sublease Termination Agreement constituted a non-monetary exchange under ASC 845 Nonmonetary Transactions (“ASC 845”) where, in return for the free rooms and the services, the Company agreed to terminate its rights and obligations under the sublease agreement. In accordance with ASC 845, the Company determined that the accounting for the transaction should be based on the fair value of assets or services involved. The Company estimated the fair value of the rooms and services to be approximately $1.5 million and $2.9 million, respectively.

The Company determined that the licensed rooms represent a lease under ASC Topic 842 Leases. The Company obtained control of the rooms in the third quarter of 2021 and the prepaid rooms balance of approximately $1.4 million was reclassified from other assets to a ROU asset. The related lease expense is recognized on a straight-line basis over the lease term of 8.88 years. The Company recorded a de minimis amount, and $0.1 million of lease expense during the three and nine months ended September 30, 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 $0.3 million for the three and nine months ended September 30, 2022, respectively. Both the lease expense and services expense are recognized as a component of research and development costs in the condensed consolidated statements of operations and comprehensive loss.

8. Share-based Compensation Plans

In 2019, Cyclerion adopted share-based compensation plans. Specifically, Cyclerion 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”).

Cyclerion also mirrored two of Ironwood Pharmaceuticals, Inc. ("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 Cyclerion equity awards upon the Separation as part of the equity conversion. As a result of the Separation and in accordance with the EMA, employees of both companies retained their existing Ironwood vested options and received a pro-rata share of Cyclerion options, regardless of which company employed them post-Separation. For employees that were ultimately employed by Cyclerion, unvested Ironwood options and RSUs were converted to unvested Cyclerion 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, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 773	$ 957	$ 2,396	$ 2,874
General and administrative	889	1,455	2,732	4,190
	$ 1,662	$ 2,412	$ 5,128	$ 7,064

A summary of stock option activity for the nine months ended September 30, 2022, 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, 2021	7,080,426	$ 10.73	6.9	—
Granted	1,695,303	1.16		
Exercised	—	—		
Cancelled or forfeited	(609,302)	7.88		
Outstanding as of September 30, 2022	8,166,427	$ 8.96	6.6	$ 64
Exercisable at September 30, 2022	5,361,333	$ 12.16	5.5	$ —

As of September 30, 2022, 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 $4.1 million and the weighted average period over which that expense is expected to be recognized is 3.2 years.

A summary of RSU activity for the nine months ended September 30, 2022 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2021	92,804	$ 13.70
Granted	—	—
Vested	(53,999)	14.06
Forfeited	(1,119)	14.20
Unvested as of September 30, 2022	37,686	$ 13.16

As of September 30, 2022, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested restricted stock units by the Company's employees is $0.3 million and the weighted-average period over which that expense is expected to be recognized is 0.6 years.

The Company has granted to certain employees performance-based options to purchase shares of common stock. These options are subject to performance-based milestone vesting. During the three and nine months ended September 30, 2022 and 2021 there were no shares that vested as a result of performance milestone achievements. The Company recorded no share-based compensation expense related to these performance-based options for the three and nine months ended September 30, 2022 and 2021.

The Company also has granted to certain employees stock options containing market conditions that vest upon the achievement of specified price targets of the Company's share price for a period through December 31, 2024. Vesting is measured based upon the average closing price of the Company's share price for any thirty consecutive trading days, subject to certain service requirements. Stock compensation cost is expensed on a straight-line basis over the derived service period for each stock price target within the award, ranging from approximately 4.0 to 4.6 years. The Company accelerates expense when a stock price target is achieved prior to the derived service period. As of September 30, 2022, there were 375,000 outstanding stock options containing market conditions with a weighted average exercise price of $2.01. As of September 30, 2022, there was $0.1 million of unrecognized compensation costs related to stock options containing market conditions, which is expected to be recognized over a weighted-average period of 1.44 years.

9. Loss per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss (in thousands)	$ (10,496)	$ (11,290)	$ (36,862)	$ (40,872)
Denominator:				
Weighted average shares used in calculating net loss per share — basic and diluted (in thousands)	43,488	43,291	43,457	37,730
Net loss per share — basic and diluted	$ (0.24)	$ (0.26)	$ (0.85)	$ (1.08)

We exclude shares of common stock related to stock options and RSUs from the calculation of diluted net loss per share since the inclusion of such shares would be anti-dilutive. The following table sets forth potential shares that were considered anti-dilutive for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock Options	8,166,427	6,965,428	8,166,427	6,965,428
RSUs	37,686	148,361	37,686	148,361
	8,204,113	7,113,789	8,204,113	7,113,789

10. Defined Contribution Plan

The Company has established a defined contribution 401(k) Savings Plan which allows eligible employees to contribute from 1% to 100% of their compensation, subject to certain IRS limits. 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 $0.2 million related to the defined contribution 401(k) Savings Plan for the three and nine months ended September 30, 2022, respectively, and a de minimis amount, and approximately $0.5 million for the three and nine months ended September 30, 2021, respectively.

11. License Agreement

Akebia License Agreement

On June 3, 2021, the Company and Akebia entered into a License Agreement (the “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 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 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 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 License Agreement, the Company determined the License Agreement represents a service arrangement under the scope of ASC 606. Given the reversion of the rights under the License Agreement represents a penalty in substance for a termination by Akebia, the contract term would be the stated term of the 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 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 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, 2022, and recorded $0.3 million, as revenue from the Supply Agreement in the nine months ended September 30, 2022.

12. Grant Revenue

In August 2021, the Company was approved to receive funding from the PTC Grant for the Phase 2 study of CNS sGC stimulation in AD with vascular features. The granting period is July 1, 2021, to December 31, 2022, and the Company will receive an award of up to $2 million. The Company determined that this transaction is non-reciprocal as there is not considered to be a commensurate value exchanged with the Alzheimer's Association as the funding provider. Where commensurate value is not exchanged for goods and services provided, a recipient assesses whether the grant is conditional or unconditional. The Company considered all conditions and barriers associated with this grant and determined the grant is conditional and revenue will be recognized upon achieving certain milestones and incurring internal costs specifically covered by this grant. Under ASC 958-605, revenues will be recognized as the Company incurs expenses related to the PTC Grant. The Company did not record any allowable expense for the three months ended September 30, 2022, and recorded approximately $0.7 million of allowable expenses as grant revenue for the nine months ended September 30, 2022.

13. Employee Retention Credit

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was enacted into law providing an employee retention credit (“ERC”), which is a refundable tax credit against certain employment taxes. The Taxpayer Certainty and Disaster Tax Relief Act of 2020 and the American Rescue Plan Act of 2021 extended and expanded the availability of the ERC. The ERC was available through December 31, 2021 and is equal to 70% of qualified wages paid to employees. During each quarter in 2021, a maximum of $10,000 in qualified wages for each employee is eligible for the ERC. Therefore, the maximum tax credit that can be claimed by an eligible employer in 2021 is $7,000 per employee per calendar quarter. The Company qualified for the ERC for the first three quarters of 2021 because it averaged less than 500 full-time employees in 2019 and had a gross receipts decrease of more than 20% from respective or alternative (comparing gross receipts for the immediately preceding calendar quarter with those for the corresponding calendar quarter in 2019) quarters of 2019, the relevant criteria for the ERC.

During the nine months ended September 30, 2022, the Company recorded $0.2 million in the consolidated statement of operations and comprehensive loss as an offset to payroll costs in their respective expense lines.

14. Subsequent Events

On October 6, 2022, the Board of Directors of the Company implemented a reduction of approximately 45% of the Company's workforce, or 13 full-time employees to align its resources with its mitochondrial disease-focused strategy. The Company expects that this workforce reduction will take place during the fourth quarter of 2022. The Company estimates that it will incur aggregate charges in connection with the workforce reduction of approximately $1.9 million for one-time employee severance and benefit costs primarily in the fourth quarter of 2022, nearly all of which are expected to result in cash expenditures. As a result of the workforce reduction, the Company expects to realize annual cash savings of approximately $4.1 million. The Company may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction.

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, 2021. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those referenced or set forth under "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company on a mission to develop treatments for mitochondrial diseases, including MELAS. Our lead asset, CY6463, is a pioneering CNS-penetrant sGC stimulator that modulates a key node in a fundamental signaling network. The multidimensional pharmacology elicited by the stimulation of sGC has the potential to impact a broad range of diseases that involve the CNS. CY6463 is currently in clinical development for MELAS. sGC stimulators are small molecules that act synergistically with NO as positive allosteric modulators of sGC to boost production of cGMP. cGMP is a key second messenger that, when produced by sGC, regulates diverse and critical biological functions in the CNS including mitochondrial function, neuronal function, inflammation and vascular dynamics.

We operate in one reportable business segment—human therapeutics.

Financial Overview

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

CNS assets. CY6463 is an orally administered CNS-penetrant sGC stimulator that is being developed as a symptomatic and potentially disease-modifying therapy for MELAS and potentially other primary mitochondrial diseases. NO-sGC-cGMP is a fundamental signaling network, that is widely used in the nervous system. CY6463 enhances the brain's natural ability to produce cGMP, an important second messenger in the CNS, by stimulating sGC, a key node in the NO-sGC-cGMP pathway. This pathway is critical to basic CNS functions, and deficient NO-sGC-cGMP signaling is believed to play an important role in the pathogenesis of many CNS diseases. Agents that stimulate sGC to produce cGMP may compensate for deficient NO signaling.

In January 2020, we announced positive results from our Phase 1 first-in-human study that provided the foundation for continued development of CY6463. The results from this study indicate that CY6463 was well tolerated. Pharmacokinetic data, obtained from both blood and cerebral spinal fluid, support once-daily dosing with or without food and demonstrated CY6463 penetration of the blood-brain-barrier with CSF concentrations expected to be pharmacologically active.

In October 2020, we announced positive topline results from our CY6463 Phase 1 translational pharmacology study in healthy elderly participants. Treatment with CY6463 for 15 days in this 24-subject study confirmed and extended results seen in the earlier first-in-human Phase 1 study: once-daily oral treatment demonstrated blood-brain-barrier penetration with expected CNS exposure and target engagement. Results also showed significant improvements in neurophysiological and objective performance measures as well as in inflammatory biomarkers associated with aging and neurodegenerative diseases. CY6463 was safe and generally well tolerated in this study. Significant effects on cerebral blood flow and markers of bioenergetics were not observed in this study of healthy elderly participants. We believe that these results, together with nonclinical data, support continued development of CY6463 as a potential new medicine for serious CNS diseases.

In June 2022, we announced positive topline clinical data for CY6463 in our signal-seeking clinical study for the potential treatment of MELAS. In this open-label, single-arm study of the oral, once-daily sGC stimulator in eight adults aged 18 or older with MELAS, improvements were seen across a range of assessments, including mitochondrial disease-associated biomarker such as lactate and GDF-15, a broad panel of inflammatory biomarkers, cerebral blood flow, and functional connectivity between neural networks. These positive effects after 29 days of dosing were supported by correlations across several endpoints. CY6463 was well tolerated with no adverse events and pharmacokinetics were consistent with the Phase 1 study in healthy volunteers. The positive data from this study further support the potential of CY6463 to provide therapeutic benefit to people living with MELAS.

In July 2022, we announced positive topline data from our signal-seeking clinical study of CY6463 for the potential treatment of CIAS in individuals with stable schizophrenia on a stable, single, atypical antipsychotic regimen. Data from the 14-day, double blind, randomized, placebo-controlled, multiple-ascending-dose study in 48 adults aged 18-50 demonstrate that once-daily CY6463 was safe and well tolerated, with no reports of serious adverse events ("SAEs"), severe adverse events ("AEs"), or treatment discontinuation due to AEs. Study data demonstrate a strong effect on cognitive performance after two weeks of 15mg once-daily dosing. Positive movement on inflammatory biomarkers was also observed. These signals on exploratory endpoints provide further evidence of the pro-cognitive and anti-inflammatory effects of CY6463 observed in preclinical studies and prior clinical trials. Study data demonstrate the translation of sGC multi-dimensional pharmacology and the therapeutic potential of amplifying sGC signaling in the CNS and support the further development of oral, once-daily CY6463.

On October 6, 2022, we announced our mitochondrial disease-focused corporate strategic plan. Based on the positive data from the recently completed CY6463 MELAS clinical study, we will focus future development of CY6463 on genetic mitochondrial diseases, concentrating first on development in MELAS, a rare disease where the company believes it has the capabilities to advance the program independently. We are currently preparing to meet with the FDA in the fourth quarter of 2022 to discuss the CY6463 development program, including the next study and paths to registration in MELAS.

We recently capped enrollment in our signal-seeking clinical study of CY6463 for the potential treatment of ADv, which will enable the Company to channel its resources to its most urgent priorities in MELAS. Data from the ADv study is expected in the first half of 2023. Learnings from this and previous CY6463 studies can be leveraged to optimize future potential Alzheimer's Disease/Vascular Dementia studies. The ADv study is supported in part by a $2 million grant from the Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program (the "PTC Grant").

Our next-generation CNS asset, CY3018, is a differentiated CNS-penetrant sGC stimulator with greater CSF-to-plasma exposure relative to CY6463 based on nonclinical studies. CY3018 is intended to expand the potential of sGC stimulation for the treatment of disorders of the CNS. We are completing IND-enabling activities for CY3018 and are looking to secure a partnership or other funding mechanism to develop the program in the future.

Non-CNS assets. We have other assets that are outside of our current strategic focus. These non-core assets are not being internally developed at this time. *Praliciguat* is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into the 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 the pharmaceutical compound praliciguat and other related products and forms thereof enumerated in such agreement. *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. Olinciguat is available for licensing to a third-party partner.

The following table summarizes our research and development expenses, employee and facility related costs allocated to research and development expense, and discovery and pre-clinical phase programs, for the three

and nine months ended September 30, 2022 and 2021. The product pipeline expenses relate primarily to external costs associated with nonclinical studies and clinical trial costs, which are presented by development candidates.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(in thousands)		(in thousands)	
Product pipeline external costs:				
CY6463	$ 3,076	$ 3,064	$ 12,608	$ 7,114
CY3018	864	977	3,260	1,581
Discovery research	168	76	534	603
Total product pipeline external costs	4,108	4,117	16,402	9,298
Personnel and related internal costs	2,225	2,320	8,212	8,633
Facilities and other	749	595	2,429	9,247
Total research and development expenses	$ 7,082	$ 7,032	$ 27,043	$ 27,178

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

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

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

- The full impact of COVID-19 pandemic continues to develop and could continue to adversely affect our programs and operations, including our clinical trials, corporate development, and other activities. Cyclerion works closely with its clinical trial sites and investigators to deliver trials in a manner consistent with the safety of study participants and healthcare professionals.
- The duration of clinical trials may vary substantially according to the type and complexity of the product candidate and may take longer than expected.
- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional financing in upcoming periods, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our development efforts or other operations.
- The United States FDA and comparable agencies outside the United States. impose substantial and varying requirements on the introduction of therapeutic pharmaceutical products, which typically require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures.
- Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.
- The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a product candidate and are difficult to predict.
- The costs, timing and outcome of regulatory review of a product candidate may not be favorable, and, even if approved, a product may face post-approval development and regulatory requirements.
- The emergence of competing technologies and products and other adverse market developments may reduce or eliminate the potential value of our pipeline.

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, 2021, and elsewhere in this Quarterly Report on Form 10-Q, we are unable to determine the duration and costs to complete current or future nonclinical and clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of our product candidates. Development timelines, probability of success and development costs vary widely. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the data from the studies of each product candidate, the competitive landscape and ongoing assessments of such product candidate’s commercial potential.

General and Administrative Expense. General and administrative expense 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, 2021, 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	
	2022	2021	$	%	2022	2021	$	%
	(dollars in thousands)				(dollars in thousands)			
Revenues:								
Revenue from license agreement	$ —	$ —	$ —	0 %	$ —	$ 3,000	$ (3,000)	(100)%
Revenue from development agreement	—	77	(77)	100 %	297	138	159	115 %
Revenue from grants	—	271	(271)	100 %	720	271	449	100 %
Total revenues	—	348	(348)	(100)%	1,017	3,409	(2,392)	(70)%
Cost and expenses:								
Research and development	7,082	7,032	50	1 %	27,043	27,178	(135)	(0)%
General and administrative	3,525	4,601	(1,076)	(23)%	10,998	16,207	(5,209)	(32)%
Loss on lease termination	—	—	—	0 %	—	881	(881)	(100)%
Total cost and expenses	10,607	11,633	(1,026)	(9)%	38,041	44,266	(6,225)	(14)%
Loss from operations	(10,607)	(11,285)	678	(6)%	(37,024)	(40,857)	3,833	(9)%
Interest and other income (expenses), net	111	(5)	116	(2320)%	162	(15)	177	(1180)%
Net loss	$ (10,496)	$ (11,290)	$ 794	(7)%	$ (36,862)	$ (40,872)	$ 4,010	(10)%

Revenues. No revenue was recorded for the three months ended September 30, 2022, compared to $0.3 million associated with the PTC Grant and approximately $0.1 million associated with the Supply Agreement that were recorded in the three months ended September 30, 2021.

The decrease in revenue of approximately $2.4 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 can be attributed to $3.0 million up-front payment from the License Agreement received in the nine months ended September 30, 2021, partially offset by an increase of $0.4 million of revenue generated from the PTC Grant and approximately $0.2 million of revenue generated from the Supply Agreement.

Research and development expense. The increase in research and development expense of approximately $0.1 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was driven by an increase of $0.2 million in professional services expenses, partially offset by a decrease of $0.1 million in employee-related costs.

The decrease in research and development expense of approximately $0.1 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 was driven by decreases of approximately $4.2 million of non-cash write-off of leasehold improvements related to the Termination Agreement, approximately $2.6 million reduction in the Company's total leased premises cost, and approximately $0.4 million in employee-related expenses, offset by a net increase of approximately $7.1 million in external research costs. The increase in external research costs was primarily due to approximately $5.5 million associated with the CIAS and ADv clinical trials, and approximately $2.3 million associated with CY3018 IND-enabling activities, partially offset by a decrease of approximately $0.7 million in discovery research costs.

General and administrative expense. The decrease in general and administrative expense of approximately $1.1 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 was primarily driven by decreases of approximately $0.6 million in stock-based compensation, and approximately $0.5 million in professional services expenses.

The decrease in general and administrative expense of approximately $5.2 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 was primarily driven by approximately $2.1 million of non-cash write off of leasehold improvements in 2021 related to the Termination Agreement, and decreases of approximately $1.5 million in stock-based compensation, approximately $0.7 million in employee-related costs, and approximately $0.9 million in professional services expenses.

Loss on lease termination. No loss was recorded in the nine months ended September 30, 2022, compared to a loss on lease modification of $0.9 million recorded in the nine months ended September 30, 2021 related to the Termination Agreement to the Head Lease of 301 Binney Street in Cambridge, Massachusetts that was executed on April 30, 2021.

Interest and other income (expenses), net. Interest and other income increased by approximately $0.1 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 due to an increase in interest rates.

Interest and other income increased by approximately $0.2 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 due to an increase in interest rates.

Liquidity and Capital Resources

On September 3, 2020, the Company entered into the Sales Agreement with Jefferies with respect to the ATM Offering under the Shelf. Under the ATM Offering, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $50.0 million through Jefferies as its sales agent. The Company will pay to Jefferies cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. The Company has sold 3,353,059 shares of its common stock for net proceeds of $12.5 million under the ATM Offering since entering into the Sales Agreement, with no shares of common stock issued or sold under the ATM Offering during the nine months ended September 30, 2022.

On June 7, 2021, we closed on a private placement of 5,735,988 shares of our common stock, pursuant to a Common Stock Purchase Agreement, for total gross proceeds of approximately $18 million. There were no material fees or commissions related to the transaction. The Company intends to use the proceeds to fund working capital and other general corporate purposes.

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

On September 30, 2022, we had approximately $20.4 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.

Continued Nasdaq Listing

On June 1, 2022, the Company received a notice from the Nasdaq Stock Market ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common stock listed on Nasdaq has been below the minimum $1.00 per share required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the “Bid Price Requirement”). The Nasdaq deficiency letter has no immediate effect on the listing of the Company’s common stock, and its common stock will continue to trade on The Nasdaq Global Select Market under the symbol “CYCN” at this time.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided a period of 180 calendar days, or until November 28, 2022, to regain compliance with the Bid Price Requirement. If at any time before November 28, 2022, the bid price of the Company’s common stock closes at a $1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will provide written notification to the Company that it has regained compliance with the Bid Price Requirement. In the event the Company does not regain compliance with the Bid Price Requirement by November 28, 2022, the Company may be afforded an additional 180-day compliance period, provided it demonstrates that it meets all other applicable standards for initial listing on the Nasdaq Capital

Market, except the Bid Price Requirement. If the Company does not regain compliance with the Bid Price Requirement by the end of the second compliance period, the Company's stock will be subject to delisting.

The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement, including initiating a reverse stock split. However, there can be no assurance that the Company will be able to regain compliance with the Bid Price Requirement or will otherwise be in compliance with other Nasdaq Listing Rules.

Going Concern

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

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

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

Cash Flows

The following is a summary of cash flows for the years ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change	
	2022	2021	$	%
	(dollars in thousands)			
Net cash used in operating activities	$ (33,568)	$ (27,887)	$ (5,681)	20%
Net cash provided by investing activities	$ —	$ 1,457	$ (1,457)	(100)%
Net cash provided by financing activities	$ 17	$ 30,700	$ (30,683)	(100)%

Cash Flows from Operating Activities

Net cash used in operating activities was $33.6 million for the nine months ended September 30, 2022 compared to $27.9 million for the nine months ended September 30, 2021. The increase in net cash used in operations of $5.7 million primarily relates to the non-cash leasehold improvement write off of $6.3 million in the

prior year, the recording of non-cash loss on lease termination of $0.9 million in the prior year, and a decrease of stock-based compensation and other non-cash items of $2.3 million, offset by a decrease in our net loss of $4.0 million and an increase in working capital accounts of $0.2 million.

Cash Flows from Investing Activities

Net cash provided by investing activities was $1.5 million for the nine months ended September 30, 2021 was primarily related to the cash received from sale of lab equipment in 2021. There was no investing activity 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, 2021 of $30.7 million was due to cash received from the 2021 Equity Private Placement of $18 million, net proceeds from the ATM Offering of $12.5 million, and $0.2 million of proceeds from the purchases of shares under the 2019 ESPP. There was no financing activity in the nine months ended September 30, 2022.

Debt – Paycheck Protection Program

On April 21, 2020, we received loan proceeds in the amount of approximately $3.5 million pursuant to a promissory note agreement (the "Promissory Note") with a bank under the Paycheck Protection Program ("PPP"), of which certain key terms were adjusted by the Paycheck Protection Program Flexibility Act ("PPPFA"). The Promissory Note had an initial loan maturity of April 20, 2022, a stated interest rate of 1.0% per annum, and had payments of principal and interest that were due monthly after an initial deferral period where interest accrued, but no payments were due. Under the PPPFA, the initial deferral may be extended from six up to ten months and the loan maturity may be extended from two to five years. The Promissory Note provided for customary events of default, including, among others, those relating to failure to make payment when due and breaches of representations. The loan is subject to all the terms and conditions applicable under the PPPFA and is subject to review by the Small Business Association ("SBA") for compliance with program requirements.

In August 2021, the Company applied with the SBA for forgiveness of the PPP loan and was notified on November 4, 2021, that the SBA has approved our application to forgive the entire amount of the loan and accrued interest. In November 2021, the Company recorded a gain on extinguishment of debt of $3.6 million representing the principal and accrued interest for the PPP Loan.

Funding Requirements

We expect our expenses to fluctuate as we advance the preclinical activities and clinical trials of our product candidates. Based on our cash and cash equivalents position as of September 30, 2022 and our planned operating expenses and capital expenditure requirements there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date of this Quarterly Report on Form 10-Q. We will need to raise additional capital in upcoming periods, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may delay current development of our product candidates, halt new development phases, or other operations.

Because of the many risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our expenses will fluctuate, and our future funding requirements will depend on, and could increase or decrease significantly as a result of many factors, including the:

- scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- costs, timing and outcome of regulatory review of our product candidates;
- costs of future activities, including medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- cost and timing of necessary actions to support our strategic objectives;

- costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

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

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

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

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

Contractual Commitments and Obligations

Tax-related Obligations

We exclude assets, liabilities or obligations pertaining to uncertain tax positions from our summary of contractual commitments and obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of September 30, 2022, we had no uncertain tax positions.

Other Funding Commitments

As of September 30, 2022, we had, and continue to have, several ongoing studies in various clinical trial stages. Our most significant clinical trial spending is with clinical research organizations, or CROs. The contracts with CROs generally are cancellable, with notice, at our option and do not have any significant cancellation penalties.

Off-Balance Sheet Arrangements

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

New Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

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

PART II

Item 1. ***Legal Proceedings***

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

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

You should carefully review and consider the information regarding certain factors which could materially affect our business, financial condition or future results set forth under the heading "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as updated by those certain factors set forth under the heading "Risk Factors" in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. There have been no material changes from the risk factors previously disclosed therein.

Item 5. ***Other Information***

Not applicable.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

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 3, 2022

Exhibit 31.1

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 Cyclerion 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 3, 2022

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

Exhibit 31.2

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 Cyclerion 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 3, 2022

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

Exhibit 32.1

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 Cyclerion Therapeutics, Inc. for the period ended September 30, 2022 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 Cyclerion Therapeutics, Inc.

Date: November 3, 2022

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

Exhibit 32.2

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, 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 Cyclerion Therapeutics, Inc. for the period ended September 30, 2022 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 Cyclerion Therapeutics, Inc.

Date: November 3, 2022

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