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, 2021
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 5, 2021, the registrant had 43,315,745 shares of common stock, no par value, outstanding.

CYCLERION PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2021
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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:

- 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 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 arrangements of our product candidates;
- whether the praliciguat out-license will result in the creation of any therapies for the treatment of patients with kidney disease;
- 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;
- potential indemnification liabilities we may owe to Ironwood after the Separation (as defined below); and
- trends and challenges in the markets for our potential products.

See the “Risk Factors” section in Item 1A of our annual report on Form 10-K for the fiscal year ended December 31, 2020, 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, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,503	$ 54,395
Accounts receivable	158	—
Related party accounts receivable	—	127
Prepaid expenses	562	816
Other current assets	459	3,163
Total current assets	63,682	58,501
Restricted cash, net of current portion	—	3,837
Property and equipment, net	112	6,865
Operating lease right-of-use asset	1,449	43,402
Other assets	2,499	2,773
Total assets	$ 67,742	$ 115,378
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,174	$ 1,149
Related party accounts payable	—	286
Accrued research and development costs	3,432	1,421
Accrued expenses and other current liabilities	3,240	7,294
Short-term note payable	3,509	3,509
Current portion of operating lease liabilities	—	3,293
Total current liabilities	11,355	16,952
Operating lease liabilities, net of current portion	—	38,933
Commitments and contingencies	—	—
Stockholders' equity		
Common stock, no par value, 400,000,000 shares authorized and 43,310,089 issued and outstanding at September 30, 2021 and 400,000,000 shares authorized and 34,047,300 issued and outstanding at December 31, 2020	—	—
Accumulated deficit	(204,300)	(163,429)
Paid-in capital	260,713	222,949
Accumulated other comprehensive loss	(26)	(27)
Total stockholders' equity	56,387	59,493
Total liabilities and stockholders' equity	$ 67,742	$ 115,378

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,	
	2021	2020	2021	2020
Revenues:				
Revenue from license agreement	$ 0	$ —	$ 3,000	$ —
Revenue from development agreement	77	—	138	—
Revenue from related party	—	400	—	2,163
Revenue from grants	271	—	271	—
Total revenues	348	400	3,409	2,163
Cost and expenses:				
Research and development	7,032	13,703	27,178	44,322
General and administrative	4,601	8,033	16,207	21,551
(Gain) / loss on lease modification and termination	—	444	881	(1,669)
Total cost and expenses	11,633	22,180	44,266	64,204
Loss from operations	(11,285)	(21,780)	(40,857)	(62,041)
Sublease termination income, net	—	2,875	—	2,875
Interest and other income (expenses), net	(5)	93	(15)	592
Net loss	$ (11,290)	$ (18,812)	$ (40,872)	$ (58,574)
Net loss per share:				
Basic and diluted net loss per share	$ (0.26)	$ (0.59)	$ (1.08)	$ (2.01)
Weighted average shares used in calculating:				
Basic and diluted net loss per share	43,291	32,096	37,730	29,196
Other comprehensive loss:				
Net loss	$ (11,290)	$ (18,812)	$ (40,872)	$ (58,574)
Other comprehensive loss:				
Foreign currency translation adjustment (loss) gain	—	3	1	(7)
Comprehensive loss	$ (11,290)	$ (18,809)	$ (40,871)	$ (58,581)

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

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 (deficit)
	Shares	Amount				
Balance at December 31, 2019	27,598,133	$ —	$ 183,376	$ (85,627)	$ (20)	$ 97,729
Net loss	—	—	—	(20,228)	—	(20,228)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	156,761	—	1		—	1
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	4,036		—	4,036
Foreign currency translation adjustment					2	2
Balance at March 31, 2020	27,754,894	$ —	$ 187,413	$ (105,855)	$ (18)	$ 81,540
Net loss	—	—	—	(19,534)	—	(19,534)
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	102,816	—	155	—	—	155
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	3,952	—	—	3,952
Foreign currency translation adjustment				—	(12)	(12)
Balance at June 30, 2020	27,857,710	$ —	$ 191,520	$ (125,389)	$ (30)	$ 66,101
Net loss	—	—	—	(18,812)	—	(18,812)
Issuance of common stock - 2020 private placement	6,062,500	—	24,250	—	—	24,250
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	41,345	—	16	—	—	16
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	3,796	—	—	3,796
Foreign currency translation adjustment	—	—	—	—	3	3
Balance at September 30, 2020	33,961,555	$ —	$ 219,582	$ (144,201)	$ (27)	$ 75,354

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 (deficit)
	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 to non-employees	—	—	391	—	—	391
Foreign currency translation adjustment	—	—	—	—	—	—
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 - June 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
Foreign currency translation adjustment	—	—	—	—	—	—
Balance at September 30, 2021	43,310,089	$ —	$ 260,713	$ (204,300)	$ (26)	$ 56,387

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (40,872)	$ (58,574)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	424	1,827
Net loss on disposal of property and equipment	6,322	205
(Gain) / loss on lease modification and termination	881	(1,669)
Sublease termination income, net	—	(2,875)
Share-based compensation expense	7,064	11,785
Changes in operating assets and liabilities:		
Accounts receivable	(158)	—
Related party accounts receivable	127	1,074
Prepaid expenses	254	748
Other current assets	1,254	(8)
Operating lease assets	(105)	(3,592)
Other assets	274	(979)
Accounts payable	25	(1,094)
Related party accounts payable	(286)	414
Accrued research and development costs	2,011	(38)
Operating lease liabilities	(1,048)	(2,000)
Accrued expenses and other current liabilities	(4,054)	(3,673)
Net cash (used in) operating activities	(27,887)	(58,449)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(7)	(1,489)
Proceeds from sale of property and equipment	1,464	71
Net cash provided by (used in) investing activities	1,457	(1,418)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from equity private placement and ATM	30,503	24,250
Proceeds from exercises of stock options and ESPP	197	172
Proceeds from short-term note payable	—	3,509
Net cash provided by financing activities	30,700	27,931
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1	(7)
Net increase (decrease) in cash, cash equivalents and restricted cash	4,271	(31,943)
Cash, cash equivalents and restricted cash, beginning of period	58,232	102,620
Cash, cash equivalents and restricted cash, end of period	$ 62,503	$ 70,677
Supplemental cash flow disclosure:		
Cash paid for initial direct costs of lease modification	$ —	$ 6,507
Non-cash investing activities		
Fixed asset purchases in accounts payable and accrued expenses	$ —	$ 4
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 62,503	$ 66,840
Restricted cash	—	3,837
Total cash, cash equivalents and restricted cash	$ 62,503	$ 70,677

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 that restore cognitive function. Our lead asset, CY6463 (previously known as, IW-6463), is a pioneering, central nervous system ("CNS")-penetrant, soluble guanylate cyclase (sGC) stimulator that is currently in clinical development for Alzheimer's disease with vascular pathology (ADv), and Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes (MELAS), and cognitive impairment associated with schizophrenia (CIAS). 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 neuronal function, neuroinflammation, cellular bioenergetics, and vascular function.

Cyclerion GmbH, a wholly owned subsidiary, was incorporated in Zug, Switzerland on May 3, 2019. Cyclerion GmbH is an operational entity with one employee who is the Company's Chief Scientific Officer. 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 that restore cognitive function. Its priorities are advancing its ongoing CY6463 clinical programs and next generation compound, CY3018.

CNS assets. CY6463 is an orally administered CNS-penetrant sGC stimulator that is being developed as a symptomatic and potentially disease modifying therapy for serious CNS diseases. Nitric oxide sGC-cGMP is a fundamental CNS signaling network, but it has not yet been leveraged for its full therapeutic potential. 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 neurodegenerative 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 Phase 1 healthy participant study results indicate that CY6463 was well tolerated. Pharmacokinetic (PK) 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 shown to be safe and generally well tolerated. 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.

We have initiated our CY6463 Phase 2a clinical trial in adult participants with MELAS. Startup activities are ongoing for our Phase 2a clinical trial in ADv, with enrollment expected to begin in 2021.The ADv study will be

supported in part by a grant from the Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program ("PTC Grant"), which provides Cyclerion with $2 million of funding over two years. Our phase 1b clinical study in CIAS has been activated and enrollment has begun.

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.

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 and with the exception of praliciguat, are available for licensing to a third-party partner. *Praliciguat* is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into a License Agreement 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 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.

The Separation

On April 1, 2019, Ironwood Pharmaceuticals, Inc. ("Ironwood") completed the separation of its sGC business, and certain other assets and liabilities, into a separate, independent publicly traded company by way of a pro-rata distribution of all of the outstanding shares of common stock of Cyclerion Therapeutics, Inc. through a dividend distribution of one share of the Company's common stock, with no par value per share, for every 10 shares of Ironwood common stock held by Ironwood stockholders as of the close of business on March 19, 2019, the record date for the Distribution (the entire transaction being the "Separation"). As a result of the Separation, the Company became an independent public company and commenced trading under the symbol "CYCN" on the Nasdaq Global Select Market on April 2, 2019.

2020 Equity Private Placement

On July 29, 2020, the Company entered into a Common Stock Purchase Agreement (the "2020 Equity Private Placement") for the private placement of 6,062,500 shares of the Company's common stock, for total gross proceeds of approximately $24.3 million. The closing of the 2020 Equity Private Placement occurred on July 29, 2020. The Company did not utilize the services of a placement agent or broker and accordingly incurred no material related transaction fees or commissions.

June 2021 Equity Private Placement

On June 3, 2021, the Company entered into a Common Stock Purchase Agreement (the "June 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 June 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. During the nine months ended September 30, 2021, the Company sold 3,353,059 shares of its common stock for net proceeds of $12.5 million under the ATM Offering, after deducting commissions paid to Jefferies of approximately $0.4 million.

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 year ended December 31, 2020, which was filed with the Securities and Exchange Commission on February 25, 2021.

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, 2021 and 2020 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.

The Company has experienced negative operating cash flows for all historical periods presented and the Company expects these losses to continue into the foreseeable future as the Company continues the development and clinical testing of its product candidate CY6463, CY3018 and its discovery research programs. Through September 30, 2021, the Company had raised an aggregate of $219.8 million in net proceeds from equity private placements and the ATM Offering.

After considering the Company's current research and development plans and the timing expectations related to the progress of its programs, and after considering its existing cash and cash equivalents as of September 30, 2021, the Company did not identify conditions or events that would raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these financial statements were issued.

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 2020 annual report on Form 10-K. The Company includes herein certain updates to those policies.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. 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 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.

Revenue

The Company generates revenue from research and development grants under contracts with third parties that do not create customer-vendor relationships. The Company's research and development grants are non-exchange transactions and are not within the scope of ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Contribution revenue earned from activities performed pursuant to research and development grants is reported as grant revenue in the Company's condensed consolidated statements of operations. Revenue from these grants is recognized as the Company incurs qualifying expenses as stipulated by the terms of the respective grant. Cash received from grants in advance of incurring qualifying expenses is recorded as deferred revenue. The Company records revenue and a corresponding receivable when qualifying costs are incurred before receiving payment from the grants.

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, 2021 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 becomes mandatorily effective for all entities 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 is currently evaluating the impact that ASU 2021-04 will have on its financial statements and related disclosures.

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. Related Party Transactions

Development Agreement with Ironwood

As part of the Separation from Ironwood, the Company entered into a Development Agreement with Ironwood.

Under the Development Agreement, the Company provided certain research and development services to Ironwood at mutually agreed upon rates and the amounts earned are recorded as revenue from related party for the three and nine months ended September 30, 2020. Such research and development activities were governed by a joint steering committee composed of representatives of both Ironwood and the Company. Ironwood and the Company have agreed not to renew the Development Agreement beyond the end of its initial term on March 31, 2021. These transactions under the Development Agreement were considered related party transactions due to Mark Currie's role as President of the Company through December 31, 2020, and board member of Ironwood. In January 2021, Mark Currie's role transitioned from President of the Company to a senior advisor on a consulting basis. Therefore, effective January 2021, transactions under the Development Agreement are no longer accounted for as related party transactions. The Company recorded approximately $0.4 million and $2.2 million as related party revenue for the three and nine months ended September 30, 2020, respectively.

4. 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, 2021 and December 31, 2020 (in thousands):

	Fair Value Measurements as of September 30, 2021:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 61,451	$ —	$ —	$ 61,451
Cash equivalents	$ 61,451	$ —	$ —	$ 61,451

	Fair Value Measurements as of December 31, 2020:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 53,240	$ —	$ —	$ 53,240
Cash equivalents	$ 53,240	$ —	$ —	$ 53,240

During the nine months ended September 30, 2021 and 2020, 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.

5. Property and Equipment

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

	September 30, 2021	December 31, 2020
Software	$ 2,214	$ 2,214
Computer and office equipment	51	44
Leasehold improvements	—	14,894
Property and equipment, gross	2,265	17,152
Less: accumulated depreciation and amortization	(2,153)	(10,287)
Property and equipment, net	$ 112	$ 6,865

As of September 30, 2021, and December 31, 2020, the Company's property and equipment was primarily located in Cambridge, Massachusetts.

Depreciation and amortization expense of the Company's property and equipment was a de minimis amount and approximately $0.6 million for the three months ended September 30, 2021 and 2020, respectively, and approximately $0.4 million and $1.8 million for the nine months ended September 30, 2021 and 2020, respectively.

During the nine months ended September 30, 2021, the Company recorded a non-cash loss of $6.3 million, on the disposal of leasehold improvements as a result of its Head Lease (as defined below) termination (see Note 8 to the Condensed Consolidated Financial Statements). The non-cash loss on the disposal of leasehold improvements was recognized as a component of operating expenses in the condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2021. The Company did not record any disposal of property and equipment during the three months ended September 30, 2021.

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Accrued incentive compensation	$ 957	$ 1,720
Salaries	450	514
Accrued vacation	338	555
Professional fees	503	689
Accrued severance and benefit costs	159	3,640
Other	833	176
Accrued expenses and other current liabilities	$ 3,240	$ 7,294

7. 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, 2021 and December 31, 2020.

8. Leases

On April 1, 2019, the Company entered into the Head Lease (the "Head Lease"), a direct operating lease for its former headquarters located at 301 Binney Street, Cambridge, MA originally consisting of approximately 114,000 rentable square feet of office and laboratory space on the first and second floors. The Head Lease had a term of 123 months with two five-year extension options and certain expansion rights. The Head Lease also included a letter of credit of $7.7 million, posted with the landlord as a security deposit, which was collateralized by

a money market account recorded as restricted cash on the Company's condensed consolidated balance sheets. The Company had also entered into customary non-disturbance arrangements with the building landlord's mortgagee and with the property ground lessor recognizing Company's leasehold interest in this property.

On February 28, 2020, the Company amended the Head Lease (the "Lease Amendment"). The Lease Amendment partially terminated the Company's rights and obligations with respect to an approximately 40,000 rentable square feet. The Company continued to lease the remaining space of approximately 74,000 square feet including the area covered by the subleased premise, discussed below. In connection with this Lease Amendment, the Company reduced its remaining lease payments through June 2029 by approximately $41.9 million and paid a $6.3 million termination fee and $0.2 million related to other initial direct costs, which were deferred and recognized over the remaining lease term. The Company's security deposit was also reduced by approximately $2.7 million to approximately $5.0 million.

The Lease Amendment was determined to be a lease modification that qualified as a change of accounting on the existing lease and not a separate contract. As such, the Right-of-Use ("ROU") assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification of 9.7%, which resulted in a reduction of the ROU asset of $21.4 million and a reduction in the operating lease liabilities of $23.5 million. The Company recorded the resulting gain of approximately $2.1 million as a component of operating expenses in the condensed consolidated statement of operations and comprehensive loss for the year ended December 31, 2020.

On September 15, 2020, the Company entered into the Second Lease Amendment (the "Second Lease Amendment") to its Head Lease. The Second Lease Amendment partially terminated the Company's rights and obligations with respect to approximately 17,000 rentable square feet (the "Surrender Space"), including 15,700 rentable square feet subleased by the Company to a subtenant. The Company continues to lease approximately 57,000 square feet of space under the terms of the Second Lease Amendment. The Company reduced its remaining lease payments through June 2029 by approximately $16.9 million. The Company paid no termination or other initial direct costs related to the execution of the Second Lease Amendment. The Company's security deposit was reduced by approximately $1.2 million to approximately $3.8 million.

The Second Lease Amendment was determined to be a lease modification that qualified as a change of accounting on the existing lease and not a separate contract. As such, the ROU assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification of 6.1%, which resulted in a reduction of the ROU asset of $5.9 million and a reduction in the operating lease liabilities of $5.5 million. The Company recorded the resulting loss of approximately $0.4 million as a component of operating expenses in the condensed consolidated statement of operations and comprehensive loss for the year ended December 31, 2020.

On April 30, 2021, the Company entered into a Termination Agreement (the "Termination Agreement") for its Head Lease 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. In total, the Company recognized a loss on the termination of the Head Lease of $0.9 million during the nine months ended September 30, 2021. The loss is included in "General and administrative" expenses on our condensed consolidated statement of operations and comprehensive loss.

The Company had an operating lease ROU asset of approximately $43.4 million related to the amended Head Lease recorded in its condensed consolidated balance sheets as of December 31, 2020. The Company had current and non-current operating lease liabilities of approximately $3.3 million and $38.9 million, respectively, related to the amended Head Lease recorded in its consolidated balance sheets as of December 31, 2020.

Lease cost is recognized on a straight-line basis over the lease term. For the three and nine months ended September 30, 2021, the Company recognized a de minimis amount and a total of approximately $2.3 million of total lease costs related to the Head Lease, respectively, as amended. Variable lease costs not subject to an index or rate are recognized as incurred. For the nine months ended September 30, 2021, the Company recognized a total of approximately $0.7 million of variable lease costs related to the Head Lease, as amended. The Company did not record any lease costs related to the Head Lease, as amended, during the three months ended September 30, 2021.

For the three and nine months ended September 30, 2020, the Company recognized a total of approximately $2.0 million and $6.9 million, respectively, of total lease costs and $0.4 million and $1.9 million, respectively, of variable lease costs, related to the Head Lease, as amended.

In May 2021 the Company signed a membership agreement to lease space with WeWork at 501 Boylston Street. The lease commenced on August 1, 2021 and was accounted for as a short term lease. The Company recorded a de minimis lease expense associated with the membership agreement during the three months ended September 30, 2021.

Supplemental cash flow information related to leases for the nine months ended September 30, 2021 is as follows:

	Nine Months Ended September 30,	
	2021	2020
Decrease in right-of-use assets related to lease modifications and termination	$ 42,058	$ 27,333
Decrease in operating lease liabilities due to lease modifications and termination	$ 41,177	$ 29,002
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	$ —	$ 6,076
Weighted-average remaining lease term of operating leases (in years)	—	8.8
Weighted-average discount rate of operating leases	—	6.1%

On October 18, 2019, the Company entered into an agreement with a third party to sublease 15,700 rentable square feet of its lease premises under the Head Lease. The sublease was scheduled to expire on June 30, 2029, unless earlier terminated in accordance with the sublease agreement, and had no extension options. The sublease provided for annual base rent of approximately $1.5 million in the first year, which increased on a yearly basis by 3.0% (subject to an abatement of base rent of approximately $0.7 million for the first six months of the sublease). As part of the consideration for the sublease, the sublessee agreed to provide licensed rooms and services within the sublease premises to the Company over the sublease term free of charge. In addition, the sublessee was responsible for its pro rata share of certain costs, taxes and operating expenses related to the subleased space, the consideration for which is variable and is based on the actual operating costs of the lessor. The Company allocated the total consideration in the sublease agreement between the lease and non-lease components in the contract based on their relative standalone prices. The Company determined that the variable consideration related exclusively to non-lease components and would be recognized as incurred. The sublease included an initial security deposit of $0.5 million, which was provided by the sublessee in the form of a letter of credit, and an additional security deposit of $0.4 million within nine months of the sublease commencement.

For the nine months ended September 30, 2020, gross sublease income of $1.5 million was recorded related to the sublease. Net sublease income of approximately $0.3 million was recorded in interest and other income in the condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2020.

On September 15, 2020, concurrent with execution of the Second Lease Amendment, the Company entered into the Sublease Termination Agreement (the "Sublease Termination Agreement") to terminate its sublease of 15,700 rentable square feet. 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 constitutes 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. Accordingly, prepaid rooms and services of $4.4 million were recorded upon the

sublease termination. Termination fee income of $3.1 million was recognized related to the rooms and services, after considering the rent receivable balance of $1.3 million outstanding from the subtenant. The remaining unamortized direct costs of $0.2 million were written off. As of September 30, 2021, the Company had approximately $0.4 million and $2.5 million recorded in other current assets and other assets, respectively in the condensed consolidated balance sheets as of September 30, 2021 related to the services.

The Company determined that the licensed rooms represent a lease under ASC 842. 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 of lease expense during the three months ended September 30, 2021. 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 de minimis amount for the three months ended September 30, 2021. 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.

9. 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’s 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, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 957	$ 1,784	$ 2,874	$ 5,584
General and administrative	1,455	2,012	4,190	6,200
	$ 2,412	$ 3,796	$ 7,064	$ 11,784

A summary of stock option activity for the nine months ended September 30, 2021, 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, 2020	7,426,356	$ 11.87	7.0	1,178
Granted	834,250	3.40		
Exercised	(58,055)	2.21		
Cancelled or forfeited	(1,237,123)	10.24		
Outstanding as of September 30, 2021	6,965,428	$ 11.22	6.7	$ 873
Exercisable at September 30, 2021	4,373,344	$ 13.72	5.7	$ 301

As of September 30, 2021, 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 $9.6 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, 2021 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2020	294,913	$ 14.52
Granted	39,369	3.17
Vested	(88,217)	15.06
Forfeited	(97,704)	14.41
Unvested as of September 30, 2021	148,361	$ 11.25

As of September 30, 2021, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested restricted stock units by the Company's employees is $1 million and the weighted-average period over which that expense is expected to be recognized is 0.94 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, 2021 and 2020 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, 2021 and 2020.

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. The Company does not reverse expense recognized if the share price target(s) are ultimately not achieved but expense is reversed when a stock award recipient has a break in service prior to the completion of the derived service period. For each of the three months ended September 30, 2021 and 2020, the Company recorded a de minimis amount of share-based compensation expense, respectively related to these stock options containing market conditions. During the nine months ended September 30, 2021, 150,000 stock options containing market conditions were forfeited with a weighted average exercise price of $2.01. As of September 30, 2021, there were 450,000 outstanding stock options containing market conditions with a weighted average exercise price of $2.01. As of September 30, 2021, there was $0.2 million of unrecognized compensation costs related to stock options containing market conditions, which is expected to be recognized over a weighted-average period of 2.42 years.

10. 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,	
	2021	2020	2021	2020
Numerator:				
Net loss (in thousands)	$ (11,290)	$ (18,812)	$ (40,872)	$ (58,574)
Denominator:				
Weighted average shares used in calculating net loss per share — basic and diluted (in thousands)	43,291	32,096	37,730	29,196
Net loss per share — basic and diluted	$ (0.26)	$ (0.59)	$ (1.08)	$ (2.01)

For both the three and nine months ended September 30, 2021 there were 6,965,428 shares of common stock related to stock options and 148,361 shares of common stock related to RSUs excluded from the calculation of diluted net loss per share since the inclusion of such shares would be anti-dilutive.

For the three months ended September 30, 2020, 7,439,901 shares of common stock related to stock options and 428,077 shares of common stock related to RSU's were excluded from the calculation of diluted net loss per share since the inclusion of such shares would be anti-dilutive.

11. Defined Contribution Plan

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

Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. Cyclerion contributions to the plan are at the sole discretion of the board of directors. Currently, Cyclerion 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 $0.5 million related to the defined contribution 401(k) Savings Plan for the three and nine months ended September 30, 2021, respectively, and a de minimis amount, and approximately $0.4 million for the three and nine months ended September 30, 2020, respectively.

12. Workforce Reduction

2019 Workforce Reduction

On October 30, 2019, the Company began a reduction of its current workforce by approximately thirty (30) full-time employees to align its resources with its ongoing clinical and preclinical programs, innovation strategy and partnering efforts. The total one-time costs related to the workforce reduction were approximately $3.0 million of

which approximately $2.8 million were recorded during the year ended December 31, 2019 and the remaining $0.2 million were recorded during the three months ended March 31, 2020.

The following table summarizes the accrued liabilities activity recorded in connection with the reduction in workforce for the nine months ended September 30, 2020 (in thousands):

	Amounts accrued at December 31, 2019	Charges	Amount paid	Adjustments	Amounts accrued at September 30, 2020
October 2019 workforce reduction	$ 2,009	$ 158	$ 2,137	$ (30)	$ 0
Total	$ 2,009	$ 158	$ 2,137	$ (30)	$ 0

2020 Workforce Reduction

On November 5, 2020, the Company began a reduction of its current workforce by approximately forty-eight (48) full-time employees to align its resources with its current priorities of focusing on the MELAS study, the planned ADv study and further characterization of CY6463 novel pharmacology.

The total one-time costs related to the 2020 Workforce Reduction were approximately $5.0 million, including approximately $0.1 million in stock-based compensation from the modification of certain share-based equity awards.

The Company reduced its workforce by approximately thirty-one (31) employees in the fourth quarter of 2020 and recorded approximately $4.1 million of severance and benefits costs in accordance with ASC Topic 420, *Exit or Disposal Cost Obligations*, or ASC 420, including a de minimis amount of stock-based compensation expense, for the year ended December 31, 2020. The workforce reduction was completed by the end of the first quarter of 2021.

The following table summarizes the accrued liabilities activity recorded in connection with the reduction in workforce for the nine months ended September 30, 2021 (in thousands):

	Amounts accrued at December 31, 2020	Charges	Amount paid	Adjustments	Amounts accrued at September 30, 2021
2020 workforce reduction	$ (3,640)	$ (858)	$ 4,339	$ —	$ (159)
Total	$ (3,640)	$ (858)	$ 4,339	$ —	$ (159)

13. 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 in the next 18 months. 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 recorded a de minimis amount as revenue from the Supply Agreement in the three and nine months ended September 30, 2021.

14. 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 incurred approximately $0.3 million of allowable expenses and recognized a corresponding amount of grant revenue for the three and nine months ended September 30, 2021. The Company had a deferred revenue balance of approximately $0.4 million related to advance billings as of September 30, 2021.

15. Subsequent Events

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 will record a gain on extinguishment of debt of $3.5 million representing the principal and a deminimis amount of accrued interest for the PPP Loan.

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. 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 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 focused on discovering, developing and commercializing innovative medicines for people with serious diseases of the CNS, including cognitive and neurodegenerative disorders. Our current lead asset, CY6463, is a pioneering CNS-penetrant sGC stimulator in clinical development for MELAS, ADv, and CIAS. sGC stimulators are small molecules that act synergistically with nitric oxide on sGC to boost production of cyclic guanosine monophosphate, or cGMP. cGMP is a key second messenger that, when produced by sGC, regulates diverse and critical biological functions in the CNS including blood flow and vascular dynamics, inflammatory and fibrotic processes, bioenergetics, metabolism and neuronal function.

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. The core of our portfolio is CY6463, an orally administered CNS-penetrant sGC stimulator that is being developed as a symptomatic and potentially disease-modifying therapy for CNS diseases associated with cognitive impairment. Nitric oxide-sGC-cGMP is a fundamental CNS signaling network, but it has not yet been leveraged for its full therapeutic potential. 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 Phase 1 study results that provided the foundation for continued development of CY6463. The Phase 1 healthy participant study results indicate that CY6463 was well tolerated. Pharmacokinetic (PK) 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.

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.

We have initiated our CY6463 Phase 2a clinical trial in adult participants with MELAS. Study start-up activities are ongoing for our Phase 2a clinical trial in ADv, with enrollment expected to begin in 2021. The ADv study will be supported in part by a grant from the Alzheimer's Association's Part the Cloud-Gates Partnership Grant Program, which provides Cyclerion with $2 million of funding over two years. Our phase 1b clinical study in CIAS has been activated and enrollment has begun.

Our next-generation CNS asset, CY3018, is a differentiated CNS-penetrant sGC 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.

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 and, with the exception of praliciguat are available for licensing to a third-party partner. *Praliciguat* is an orally administered, once-daily systemic sGC stimulator. On June 3, 2021, we entered into a License Agreement with Akebia relating to the exclusive worldwide license to Akebia of our rights to the development, manufacture, medical affairs and commercialization of pharmaceutical products containing 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.

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, 2021 and 2020. The product pipeline expenses relate primarily to external costs associated with nonclinical studies and clinical trial costs, which are presented by development candidate.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Product pipeline external costs:				
CY6463	3,064	1,502	7,114	4,339
CY3018	977	—	1,581	—
Olinciguat	63	2,012	304	6,273
Praliciguat	13	53	(401)	269
Discovery research	—	541	700	743
Total product pipeline external costs	4,117	4,108	9,298	11,624
Personnel and related internal costs	2,320	6,214	8,633	20,688
Facilities and other	595	3,381	9,247	12,010
Total research and development expenses	$ 7,032	$ 13,703	$ 27,178	$ 44,322

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, and 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.
- 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 Item 1A of our annual report on Form 10-K for the fiscal year ended December 31, 2020, 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. Certain costs associated with our separation from Ironwood are included in these expenses. 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 U.S. 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. See Note 2, *Summary of Significant Accounting Policies*, of the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

The 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.

Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)				(dollars in thousands)			
Revenues:								
Revenue from license agreement	$ —	$ —	$ —	100 %	$ 3,000	$ —	$ 3,000	100 %
Revenue from development agreement	77	—	77	100 %	138	—	138	100 %
Revenue from related party	—	400	(400)	(100)%	—	2,163	(2,163)	(100)%
Revenue from grants	271	—	271	100 %	271	—	271	100 %
Total revenues	348	400	(52)	(13)%	3,409	2,163	1,246	58 %
Cost and expenses:								
Research and development	7,032	13,703	(6,671)	(49)%	27,178	44,322	(17,144)	(39)%
General and administrative	4,601	8,033	(3,432)	(43)%	16,207	21,551	(5,344)	(25)%
(Gain) / loss on lease modification and termination	—	444	(444)	100 %	881	(1,669)	2,550	(153)%
Total cost and expenses	11,633	22,180	(10,547)	(48)%	44,266	64,204	(19,938)	(31)%
Loss from operations	(11,285)	(21,780)	10,495	(48)%	(40,857)	(62,041)	21,184	(34)%
Sublease termination income, net	—	2,875	(2,875)	(100)%	—	2,875	(2,875)	(100)%
Interest and other income (expenses), net	(5)	93	(98)	(105)%	(15)	592	(607)	(103)%
Net loss	$ (11,290)	$ (18,812)	$ 7,522	(40)%	$ (40,872)	$ (58,574)	$ 17,702	(30)%

Revenues. As of January 2021, revenues earned from the services performed under the Development Agreement for Ironwood, are not considered to be related party revenues (See Note 3). The increase in revenue of approximately $0.1 million for the three months ended September 30, 2021, compared to the three months ended September 30, 2020, can be attributed primarily to the revenue from the PTC Grant, which was approved in August 2021, offset by a decrease in revenue generated from services performed under the Development Agreement, which ended on March 31, 2021.

The increase in revenue of approximately $1.2 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 can be attributed to $3.0 million in revenue from the License Agreement and approximately $0.3 million in revenue associated with the PTC Grant, offset by a decrease in revenue generated from services performed under the Development Agreement.

Research and development expense. The decrease in research and development expense of approximately $6.7 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 was driven by a decrease of approximately $3.9 million in salaries, stock-based compensation and other employee-related expenses primarily due to lower average headcount, and a decrease of approximately $2.8 million in facilities and operating costs allocated to research and development primarily due to the reduction in the Company's total leased premises. Comparing the three months ended September 30, 2021 to the three months ended September 30, 2020, external research costs increased by approximately $1.5 million associated with CY6463 clinical trials, MELAS, CIAS and ADv, and approximately $1.0 million for CY3018 costs, offset by a decrease of $2.0 million related to olinciguat due to the completion of the STRONG-SCD study, with topline data read out on October 14, 2020, and a decrease of approximately $0.5 million in discovery research.

The decrease in research and development expense of approximately $17.1 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was driven by a decrease of

approximately $12.1 million in salaries, stock-based compensation, and other employee-related expenses primarily due to lower average headcount, a decrease of approximately $6.9 million in facilities and operating costs allocated to research and development primarily due to the reduction in the Company's total leased premises, and a decrease of approximately $2.3 million in external research costs, partially offset by an increase of approximately $4.2 million related to a non-cash write-off of leasehold improvements related to the Termination Agreement in 2021. The decrease in external research costs was primarily due to a decrease period over period of approximately $6.0 million related to olinciguat and $0.7 million related to praliciguat studies, due to the completion of both studies, partially offset by an increase of approximately $2.8 million in clinical trial costs for CY6463 in MELAS, CIAS and ADv, and an increase of approximately $1.6 million associated with CY3018.

General and administrative expense. The decrease in general and administrative expenses of approximately $3.4 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 was primarily driven by a decrease of approximately $1.4 million in salaries, stock-based compensation and other employee-related expenses due to lower average headcount, a decrease of approximately $1.5 million in fees associated with 2020 company financing, and a decrease of approximately $0.5 million in facilities and operating costs.

The decrease in general and administrative expenses of approximately $5.3 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was primarily driven by a decrease of approximately $3.9 million in salaries, stock-based compensation and other employee-related costs due to lower average headcount, a decrease of approximately $2.0 million in facilities and operating costs, primarily due to the reduction in the Company's total leased premises, and approximately $1.5 million in fees associated with 2020 company financing, partially offset by $2.1 million of non-cash write off of leasehold improvements related to the Termination Agreement in 2021.

(Gain) loss on lease modification and termination. No gain or loss was recorded in the three months ended September 30, 2021, compared to a loss on lease modification of $0.4 million recorded in the three months ended September 30, 2020 related to the Second Lease Amendment to the Head Lease of 301 Binney Street in Cambridge, Massachusetts that was executed on September 15, 2020.

The loss on lease modification and termination of approximately $0.9 million for the nine months ended September 30, 2021 is related to the lease termination of the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on April 30, 2021, compared to a gain on lease modification and termination of approximately $1.7 million in the nine months ended September 30, 2020 related to the Lease Amendment of the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on February 28, 2020 (see Note 8 to the Condensed Consolidated Financial Statements).

Sublease termination income, net. The sublease termination income, net of $2.9 million recorded in the three and nine months ended September 30, 2020 represents the difference between the consideration received and the consideration given up related to the Sublease Termination Agreement that was executed on September 15, 2020.

Interest and other income (expenses), net. Interest and other income decreased by approximately $0.1 million for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 due to a decrease of approximately $0.1 million in net sublease income.

Interest and other income decreased by approximately $0.6 million for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 due to a decrease of approximately $0.3 million in interest income driven by a lower cash balances and lower interest rates and a decrease of approximately $0.3 million in net sublease income.

Liquidity and Capital Resources

Prior to the Separation, the primary source of liquidity for our business was cash flow allocated to Cyclerion from Ironwood. Post Separation, transfers of cash to and from Ironwood related to the Transition Service Agreements, Development Agreement, and provisions of the Separation Agreement, have been reflected in the consolidated statement of cash flows.

After the Separation on April 1, 2019, we raised approximately $165 million net of direct financing expenses with the closing of the 2019 Equity Private Placement on April 2, 2019.

On July 29, 2020, we closed on a private placement of 6,062,500 shares of our common stock, pursuant to a Common Stock Purchase Agreement, for total gross proceeds of approximately $24.3 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.

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. During the nine months ended September 30, 2021, the Company sold 3,353,059 shares of common stock for net proceeds of $12.5 million under the ATM Offering.

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, 2021, we had approximately $62.5 million of unrestricted cash and cash equivalents. Our cash equivalents include amounts held in U.S. government money market funds. We invest cash in excess of immediate requirements in accordance with our investment policy, which requires all investments held by us to be at least “AAA” rated or equivalent, with a remaining final maturity when purchased of less than twelve months, so as to primarily achieve liquidity and capital preservation.

Going Concern

Based on the timing expectations of our research and development plans, including our clinical trials, we expect that our existing cash and cash equivalents as of September 30, 2021 will be sufficient to fund our planned operating expenses and capital expenditure requirements at least through the next 12 months following the date of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, particularly as the process of testing drug candidates in clinical trials is costly and the timing of progress in these trials is uncertain.

Cash Flows

The following is a summary of cash flows for the years ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Change	
	2021	2020	$	%
	(dollars in thousands)			
Net cash used in operating activities	$ (27,887)	$ (58,449)	$ 30,562	(52)%
Net cash provided by (used in) investing activities	$ 1,457	$ (1,418)	$ 2,875	(203)%
Net cash provided by financing activities	$ 30,700	$ 27,931	$ 2,769	10%

Cash Flows from Operating Activities

Net cash used in operating activities was $27.9 million for the nine months ended September 30, 2021 compared to $58.4 million for the nine months ended September 30, 2020. The decrease in net cash used in operations of $30.6 million primarily relates to a decrease in our net loss of $17.7 million, non-cash leasehold improvement write off of $6.3 million in the current year, the recording of non-cash loss on lease termination of

$0.9 million in the current year and non-cash gain on lease modification of $1.7 million in prior year, non-cash gain on lease termination of sublease for $2.9 million in prior year, and a decrease in working capital accounts of $7.6 million, partially offset by a decrease of stock-based compensation and other non-cash items of $6.3 million.

Cash Flows from Investing Activities

Net cash provided by investing activities was $1.5 million for the nine months ended September 30, 2021 compared to net cash used in investing activities of $1.4 million for the nine months ended September 30, 2020. The increase in net cash provided by investing activities of 2.9 million was primarily from an increase in cash received from sale of lab equipment in 2021 compared to purchases of leasehold improvements and other property and equipment in 2020.

Cash Flows from Financing Activities

Net cash provided by financing activities was $30.7 million for the nine months ended September 30, 2021 compared to $27.9 million for the nine months ended September 30, 2020. The increase of 2.8 million was the result of cash received from the June 2021 Equity Private Placement of $18 million, net proceeds from the ATM Offering of $12.5 million, and proceeds from the purchases of shares under the 2019 ESPP and other stock plans, partially offset by the cash received from the 2020 Equity Private Placement of $24.3 million, the cash received from the short-term note payable of $3.5 million in 2020 and proceeds from the purchases of shares under the 2019 ESPP and other stock plans.

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 has an initial loan maturity of April 20, 2022, a stated interest rate of 1.0% per annum, and has payments of principal and interest that are due monthly after an initial deferral period where interest accrues, but no payments are 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 provides for customary events of default, including, among others, those relating to failure to make payment when due and breaches of representations. We may prepay the principal of the Promissory Note at any time without incurring any prepayment charges. 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.

The loan’s principal and accrued interest are forgivable to the extent that the proceeds are used for eligible purposes, subject to certain limitations, and that we maintain our payroll levels over a twenty-four-week period following the loan date. The loan forgiveness amount may be reduced if we terminate employees or reduce salaries during the twenty-four-week period. We believe that we have used the proceeds for eligible purposes consistent with the provisions of the PPPFA. However, the Company cannot assure at this time that the loan under the Promissory Note will be forgiven partially, or in full. In August 2021, the Company applied with the SBA for forgiveness of the loan. The SBA has 90 days to review the application prior to issuing its conclusion.

Funding Requirements

We expect our expenses to fluctuate as we advance the preclinical activities and clinical trials of our product candidates.

We believe that our existing cash and cash equivalents as of September 30, 2021 will enable us to fund our planned operating expenses and capital expenditure requirements at least through the next 12 months following the date of this Quarterly Report on Form 10-Q, excluding net cash flows from potential business development activities. We based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

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. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

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, 2021, we had no uncertain tax positions.

Other Funding Commitments

As of September 30, 2021, 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

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
10.1	Cyclerion Therapeutics, Inc. Executive Severance Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on September 25, 2019 (File No. 001-38787))
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 and Interim Chief Financial Officer (Principal Executive Officer and Principal Financial and Accounting Officer)*

Date: November 9, 2021

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 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 9, 2021

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL 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 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 9, 2021

By: /s/ Peter M. Hecht
Name: Peter M. Hecht
Title: Chief Executive Officer and Interim Chief Financial Officer (Principal Executive 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, 2021 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 9, 2021

By: /s/ Peter M. Hecht
Name: Peter M. Hecht
Title: Chief Executive Officer and Interim Chief Financial 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, 2021 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 9, 2021

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