

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, 2020
or

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

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

CYCLERION THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Massachusetts

(State or other jurisdiction of
incorporation or organization)

83-1895370

(I.R.S. Employer
Identification No.)

301 Binney Street, Cambridge, Massachusetts
(Address of principal executive offices)

02142

(Zip Code)

(857) 327-8778

Registrant's Telephone Number, Including Area Code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	CYCN	The Nasdaq 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 3, 2020, the registrant had 33,961,868 shares of common stock, no par value, outstanding.

CYCLERION PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2020
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report 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 IW-6463;
- the COVID-19 pandemic affecting our clinical trials and other operating activities in ways that are difficult to judge at this time;
- 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;
- our interpretation of the data from the pralicipat Phase 2 clinical trial in patients with diabetic nephropathy, including regarding the clinical site whose results appear to be inconsistent with the overall study population;
- our ability to out-license pralicipat;
- 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;
- the tax treatment of the spin-off distribution and the limitations of the tax matters agreement that we entered into with Ironwood; 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, 2019, our quarterly reports on Form 10-Q for the fiscal quarters ended March 31, 2020 and June 30, 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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 66,840	\$ 94,895
Related party accounts receivable	400	1,474
Prepaid expenses	1,218	1,966
Other current assets	1,666	2,862
Total current assets	70,124	101,197
Restricted cash, net of current portion	3,837	4,991
Property and equipment, net	10,180	11,613
Operating lease right-of-use asset	44,396	68,137
Other assets	2,865	540
Total assets	\$ 131,402	\$ 186,478
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,360	\$ 3,230
Related party accounts payable	495	81
Accrued research and development costs	2,160	2,198
Accrued expenses and other current liabilities	5,605	9,320
Short-term note payable	3,509	—
Current portion of operating lease liabilities	3,133	3,420
Total current liabilities	16,262	18,249
Operating lease liabilities, net of current portion	39,786	70,500
Commitments and contingencies	—	—
Stockholders' equity		
Common stock, no par value, 400,000,000 shares authorized and 33,961,555 issued and outstanding at September 30, 2020 and 400,000,000 shares authorized and 27,598,133 issued and outstanding at December 31, 2019	—	—
Accumulated deficit	(144,201)	(85,627)
Paid-in capital	219,582	183,376
Accumulated other comprehensive loss	(27)	(20)
Total stockholders' equity	75,354	97,729
Total liabilities and stockholders' equity	\$ 131,402	\$ 186,478

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue from related party	\$ 400	\$ 1,398	\$ 2,163	\$ 3,026
Cost and expenses:				
Research and development	13,703	22,295	44,322	74,458
General and administrative	8,033	7,119	21,551	27,019
(Gain) loss on lease modification, net	444	—	(1,669)	—
Total cost and expenses	<u>22,180</u>	<u>29,414</u>	<u>64,204</u>	<u>101,477</u>
Loss from operations	(21,780)	(28,016)	(62,041)	(98,451)
Sublease termination income, net	2,875	—	2,875	—
Interest and other income, net	93	699	592	1,498
Net loss	<u>\$ (18,812)</u>	<u>\$ (27,317)</u>	<u>\$ (58,574)</u>	<u>\$ (96,953)</u>
Net loss per share:				
Basic and diluted net loss per share	\$ (0.59)	\$ (1.00)	\$ (2.01)	\$ (3.54)
Weighted average shares used in calculating:				
Basic and diluted net loss per share	32,096	27,434	29,196	27,380
Other comprehensive loss:				
Net loss	\$ (18,812)	\$ (27,317)	\$ (58,574)	\$ (96,953)
Other comprehensive loss:				
Foreign currency translation adjustment (loss) gain	3	5	(7)	1
Total other comprehensive (loss) gain	<u>3</u>	<u>5</u>	<u>(7)</u>	<u>1</u>
Comprehensive loss	<u><u>\$ (18,809)</u></u>	<u><u>\$ (27,312)</u></u>	<u><u>\$ (58,581)</u></u>	<u><u>\$ (96,952)</u></u>

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

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

	Common Stock		Net Parent Investment		Paid-in capital		Accumulated deficit		Accumulated other comprehensive loss		Total Stockholders' equity (deficit)
	Shares	Amount									
Balance at December 31, 2018	—	\$ —	\$ (10,445)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (10,445)
Net loss	—	—	(37,381)	—	—	—	—	—	—	—	(37,381)
Net transfers from Ironwood	—	—	36,085	—	—	—	—	—	—	—	36,085
Ironwood allocation - share-based compensation	—	—	3,989	—	—	—	—	—	—	—	3,989
Balance at March 31, 2019	—	\$ —	\$ (7,752)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (7,752)
Net loss	—	—	—	—	—	(32,254)	—	—	—	—	(32,254)
Net transfers from Ironwood	—	—	2,602	—	—	—	—	—	—	—	2,602
Ironwood allocation - share-based compensation	—	—	—	—	—	—	—	—	—	—	—
Separation-related adjustments	—	—	7,752	—	—	—	—	—	—	—	7,752
Reclassification of net parent company investment	—	—	(2,602)	2,602	—	—	—	—	—	—	—
Distribution of common stock by Ironwood upon separation	15,562,555	—	—	—	—	—	—	—	—	—	—
Issuance of common stock - 2019 private placement, net of fees	11,817,165	—	—	164,622	—	—	—	—	—	—	164,622
Issuance of common stock upon exercise of options and employee stock purchase plan	9,527	—	—	—	—	—	—	—	—	—	—
Issuance of common stock awards	21,942	—	—	—	—	—	—	—	—	—	—
Share-based compensation expense related to share-based awards to employees	—	—	—	6,224	—	—	—	—	—	—	6,224
Foreign currency translation adjustment	—	—	—	—	—	(4)	—	—	—	—	(4)
Balance at June 30, 2019	27,411,189	\$ —	\$ —	\$ 173,448	\$ —	\$ (32,254)	\$ (4)	\$ —	\$ 141,190	\$ —	(27,317)
Net loss	—	—	—	—	(27,317)	—	—	—	—	—	(27,317)
Issuance of common stock upon exercise of options and employee stock purchase plan	57,256	—	—	372	—	—	—	—	—	—	372
Share-based compensation expense related to share-based awards to employees	—	—	—	4,948	—	—	—	—	—	—	4,948
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	—	5
Balance at September 30, 2019	27,468,445	\$ —	\$ —	\$ 178,768	\$ —	\$ (59,571)	\$ 1	\$ —	\$ 119,198	\$ —	—

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

	Common Stock		Net Parent Investment	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

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

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

	Nine Months Ended September 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (58,574)	\$ (96,953)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	1,827	2,047
Net loss on disposal of property and equipment	205	76
Gain on lease modification	(1,669)	—
Sublease termination income, net	(2,875)	—
Share-based compensation expense	11,785	15,161
Changes in operating assets and liabilities:		
Related party accounts receivable	1,074	(1,440)
Prepaid expenses	748	(1,297)
Other current assets	(8)	(49)
Operating lease assets	(3,592)	2,108
Other assets	(979)	25
Accounts payable	(1,094)	1,942
Related party accounts payable	414	187
Accrued research and development costs	(38)	(1,719)
Operating lease liabilities	(2,000)	3,395
Accrued expenses and other current liabilities	(3,673)	(3,535)
Net cash (used in) operating activities	(58,449)	(80,052)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,489)	(6,714)
Proceeds from sale of property and equipment	71	99
Net cash (used in) investing activities	(1,418)	(6,615)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from 2020 private placement	24,250	—
Gross proceeds from 2019 private placement	—	175,000
Costs associated with 2019 private placement	—	(10,378)
Proceeds from exercises of stock options and ESPP	172	365
Proceeds from short-term note payable	3,509	—
Transfers from Ironwood	—	46,439
Net cash provided by financing activities	27,931	211,426
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(7)	1
Net (decrease) increase in cash, cash equivalents and restricted cash	(31,943)	124,760
Cash, cash equivalents and restricted cash, beginning of period	102,620	—
Cash, cash equivalents and restricted cash, end of period	\$ 70,677	\$ 124,760
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	\$ 95
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated and balance sheets		
Cash and cash equivalents	\$ 66,840	\$ 117,034
Restricted cash	3,837	7,726
Total cash, cash equivalents and restricted cash	\$ 70,677	\$ 124,760

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

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

1. Nature of Business

Nature of Operations

Cyclerion Therapeutics, Inc. (“Cyclerion”, the “Company” or “we”) is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing innovative medicines for people with serious diseases of the central nervous system (“CNS”), including cognitive and neurodegenerative disorders. Our current lead asset, IW-6463, is a pioneering CNS-penetrant sGC stimulator in clinical development for Mitochondrial Encephalomyopathy, Lactic Acidosis and Stroke-like episodes (MELAS) and Alzheimer’s disease with vascular pathology (“ADV”). sGC stimulators are small molecules that act synergistically with nitric oxide (“NO”) 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.

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 Innovation 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 priorities are advancing its ongoing IW-6463 clinical programs and seeking the out-licensing of praliciguat:

IW-6463, 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 is one of several fundamental neurotransmitters, yet it has not been leveraged for its full CNS therapeutic potential. IW-6463 stimulates sGC, a signaling enzyme that responds to the presence of NO, to enhance the body’s natural ability to produce cGMP, an important signaling molecule, naturally. An impaired NO-sGC-cGMP signaling pathway is believed to play an important role in the pathogenesis of neurodegenerative diseases and is critical to basic neuronal functions. Agents that stimulate sGC to produce cGMP may compensate for deficient NO signaling.

On January 13, 2020 the Company released positive top line results from our first-in-human study of IW-6463. IW-6463 was generally well tolerated in healthy human adults. The study demonstrated IW-6463 penetration across the blood-brain-barrier at levels expected to be pharmacologically active as well as a mild reduction in blood pressure providing evidence of peripheral pharmacological activity.

On October 14, 2020, the Company announced positive topline results from its IW-6463 Phase 1 translational pharmacology study. Treatment with IW-6463 in this 15-day 24-subject crossover study confirmed and extended results seen in earlier Phase 1 studies: once daily oral treatment demonstrated desired CNS exposure, blood-brain-barrier penetration and target engagement. Subjects receiving IW-6463 showed meaningful improvements in certain neurophysiological and objective performance measures that are associated with age-related cognitive decline and neurodegenerative diseases. Effects on cerebral blood flow and markers of bioenergetics were not observed in this study. IW-6463 was shown to be safe and generally well-tolerated. These results support the ongoing development of IW-6463 in serious CNS diseases.

We will soon begin enrolling our IW-6463 Phase 2 clinical trial in Mitochondrial Encephalomyopathy, Lactic acidosis, and Stroke-like episodes (MELAS). Over the coming months, the Company will use the findings of the translational pharmacology study and from the previous Phase 1 study, to inform further clinical development activities, including the planned Phase 2 clinical trial in Alzheimer’s disease with vascular pathology in 2021.

Olinciguat, an orally-administered, once-daily, vascular sGC stimulator for the potential treatment of sickle cell disease (“SCD”). Olinciguat was evaluated in the STRONG-SCD study, a randomized, placebo-controlled, dose-ranging Phase 2 study of 70 participants with sickle cell disease designed to evaluate safety, tolerability, and pharmacokinetics of olinciguat, compared to placebo, and to explore effects on daily symptoms and biomarkers of disease activity when dosed over a 12-week treatment period. On October 14, 2020, the Company announced topline results from this study. It did not demonstrate adequate activity to support further internal clinical development. The Company intends to complete its analysis of the study results and present or publish them in a future forum.

Praliciguat, an orally administered, once-daily systemic sGC stimulator that was evaluated in two Phase 2 proof-of-concept studies: a dose-ranging study in 156 adult patients with diabetic nephropathy, and a study in 196 adult patients with heart failure with preserved ejection fraction (HFpEF), CAPACITY-HFpEF. On October 30, 2019, we released topline results from these studies. The Company’s efforts to out-license rights to praliciguat have expanded to discussions beyond treatment of cardiometabolic disorders to include additional indications where sGC stimulators have demonstrated efficacy.

The Separation

On April 1, 2019, Ironwood Pharmaceuticals, Inc. (“Ironwood”) completed the previously announced 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.

In connection with the Separation, on March 30, 2019, the Company entered into certain agreements with Ironwood to provide a framework for the Company’s relationship with Ironwood following the Separation, including, among others, the Separation Agreement, Tax Matters Agreement, and Employee Matters Agreement (“EMA”).

In addition, in connection with the Separation, on April 1, 2019, the Company entered into a Development Agreement, an Ironwood Transition Services Agreement, a Cyclerion Transition Services Agreement and an Intellectual Property License Agreement with Ironwood.

On April 2, 2019, the Company issued 11,817,165 shares in a private placement (the “2019 Equity Private Placement”) of common stock to accredited investors for gross proceeds of \$175 million (net proceeds of approximately \$165 million).

2020 Equity Private Placement

On July 29, 2020, the Company entered into a Common Stock Purchase Agreement (the “2020 Equity Private Placement”) with two investors for a private placement of 6,062,500 shares of the Company’s common stock, at a purchase price of \$4.00 per share 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 use a placement agent or broker in connection with the 2020 Equity Private Placement and incurred no commissions and no material direct transaction fees.

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. As of September 30, 2020, no shares have been issued or sold under the ATM Offering.

Basis of Presentation

The Company did not operate as a separate, stand-alone entity for the prior interim period covered by the interim condensed consolidated and combined financial statements. The Company's condensed consolidated balance sheets as of September 30, 2020 and December 31, 2019, condensed consolidated and combined statements of operations and comprehensive loss and statements of cash flows for the three and nine months ended September 30, 2020 and combined statements of operations and comprehensive loss for the three months ended September 30, 2019 consist of the condensed consolidated balances and activity of Cyclerion as prepared on a stand-alone basis. The Company's condensed consolidated and combined statements of operations and comprehensive loss and statements of cash flows for the nine months ended September 30, 2019 have been prepared on a "carve out" basis.

The unaudited condensed consolidated and combined financial statements reflect the historical results of the operations, financial position and cash flows of Cyclerion, in conformity with United States generally accepted accounting principles ("U.S. GAAP").

The accompanying unaudited condensed consolidated and combined financial statements reflect the condensed consolidated and combined financial position and condensed consolidated and combined results of operations of the Company as an independent, publicly-traded company for the period after the Separation on April 1, 2019. The unaudited condensed consolidated and combined financial statements also reflect the financial position and results of operations of the Company as a combined reporting entity of Ironwood for periods prior to the Separation.

For periods prior to the Separation, the unaudited condensed consolidated and combined financial statements of Cyclerion reflect the assets, liabilities, and expenses directly attributable to Cyclerion, as well as allocations of certain corporate level expenses, deemed necessary to fairly present the results of operations and cash flows of Cyclerion, as discussed further below. As such, these allocations may not be indicative of the actual amounts that would have been recorded had Cyclerion operated as an independent, publicly traded company for the years presented.

Prior to the Separation, Cyclerion was dependent upon Ironwood for all of its working capital and financing requirements, as Ironwood used a centralized approach to cash management and financing its operations. There were no cash amounts specifically attributable to Cyclerion for the historical periods presented; therefore, there is no cash reflected for historical periods in the condensed consolidated and combined financial statements. Accordingly, cash and cash equivalents, debt or related interest expense have not been allocated to Cyclerion in the historical financial statements. Financing transactions related to Cyclerion are accounted for as a component of net parent investment in the historical combined balance sheets and as a financing activity on the accompanying combined statements of cash flows.

Prior to the Separation, Cyclerion's combined financial statements included an allocation of expenses related to certain Ironwood corporate functions, including senior management, legal, human resources, finance, information technology and quality assurance. These expenses were allocated to Cyclerion based on direct usage or benefit where identifiable, with the remainder allocated pro-rata based on project related costs, headcount or other measures. These allocations may not be indicative of the actual expense that would have been incurred had Cyclerion operated as an independent, publicly traded company for the periods presented.

Prior to the Separation, the combined balance sheets of Cyclerion included assets and liabilities that were allocated principally on a specific identification basis and net parent investment was shown in lieu of stockholders' equity. As a result of the Separation, the Company's net parent investment balance was reclassified to paid-in capital.

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. The Company expects these losses to continue into the foreseeable future as the Company continues the development and clinical testing of its product candidate IW-6463, and its discovery research programs. On April 2, 2019, the Company received gross proceeds of \$175 million (net proceeds of approximately \$165 million) from the 2019 Equity Private Placement. On July 29, 2020, the Company received proceeds of approximately \$24.3 million from the 2020 Equity Private Placement.

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, 2020, 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 and combined financial statements contained in the Company's 2019 annual report on Form 10-K. The Company includes herein certain updates to those policies.

Leases

The Company has a property lease for its headquarters location at 301 Binney Street, Cambridge, MA (the "Head Lease"). The Company determines if an arrangement is a lease at the inception of the contract. The asset component of the Company's operating leases is recorded as operating lease right-of-use ("ROU") assets, and the liability component is recorded as current portion of operating lease liabilities and operating lease liabilities, net of current portion, in the Company's consolidated balance sheets.

ROU assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term at the commencement date. The Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments if an implicit rate of return is not provided with the lease contract. Operating lease right-of-use assets are adjusted for incentives received.

Lease cost is recognized on a straight-line basis over the lease term, and includes amounts related to short-term leases. Variable lease costs that do not depend on an index or rate are recognized as incurred.

ROU assets and operating lease liabilities are remeasured upon certain modifications to leases using the present value of remaining lease payments and estimated incremental borrowing rate upon lease modification. The difference between the remeasured ROU assets and the operating lease liabilities are recognized as a gain or loss in operating expenses. The Company reviews any changes to its lease agreements for potential modifications and/or indicators of impairment of the respective ROU asset.

On October 18, 2019, the Company entered into an agreement to sublease 15,700 rentable square feet of its Head Lease to a subtenant (the "Sublease Agreement"). Sublease income is recognized on straight-line basis over the term of the sublease agreement and is recorded net of the related rent expense from the Head Lease within interest and other income, net in the condensed consolidated and combined statements of operations and comprehensive loss. In sublease agreements that contain non-monetary consideration, the Company estimates the fair market value of the non-monetary consideration received using market data and recognizes it on a straight-line basis over the sublease term. Variable lease consideration that does not depend on an index or rate is allocated to a non-lease component and is recognized over time in accordance with the pattern of transfer. No modification or impairment was deemed to have occurred by entering into the sublease agreement because the Company was not released, either fully or in part, from its obligations under the Head Lease. See Note 8, *Leases*.

On February 28, 2020 the Company entered into an amendment to its Head Lease at 301 Binney Street in Cambridge, Massachusetts (the “Lease Amendment”). The Lease Amendment provided for the partial termination of the Company’s rights and obligations with respect to a portion of the leased premises of approximately 40,000 rentable square feet. The Company will continue to lease approximately 74,000 rentable square feet under terms of the amended lease. 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 ROU assets and operating lease liabilities were remeasured using an incremental borrowing rate at the date of modification and the Company recorded a gain of approximately \$2.1 million as a component of operating expenses for the three months ended March 31, 2020. No impairment of the ROU asset was deemed to have occurred. See Note 8, *Leases*.

On September 15, 2020, the Company entered into an amendment to its Head Lease at 301 Binney Street in Cambridge, Massachusetts (the “Second Lease Amendment”). The Second Lease Amendment provided for the partial termination of the Company’s rights and obligations with respect to a portion of the leased premises of approximately 17,000 rentable square feet (the “Surrender Space”). The Surrender Space includes the 15,700 rentable square feet being subleased by the Company to a subtenant. The Company will continue to lease approximately 57,000 rentable square feet under terms of the amended lease. 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 and the Company recorded a loss of approximately \$0.4 million as a component of operating expenses for the three months ended September 30, 2020. No impairment of the ROU asset was deemed to have occurred. See Note 8, *Leases*.

On September 15, 2020, concurrent with the execution of the Second Lease Amendment, the Company entered into an agreement with its subtenant to terminate the Sublease Agreement of approximately 15,700 rentable square feet (“the Sublease Termination Agreement”). Under the terms of the Sublease Termination Agreement, the former subtenant is obligated to provide licensed rooms and services to the Company free of charge through the original sublease term. Upon termination of the sublease, the Company recognized sublease termination income of approximately \$3.1 million related to the prepaid rooms and services, and wrote off the remaining indirect costs from the sublease of approximately \$0.2 million, in the condensed consolidated and combined statements of operations and comprehensive loss. See Note 8, *Leases*.

Paycheck Protection Program Loan

On April 21, 2020, the Company 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”). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The Promissory Note has a 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 six-month deferral period where interest accrues, but no payments are due. 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. The Company 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 PPP and is subject to review by the Small Business Association (the “SBA”) for compliance with program requirements, including the Company’s certification that the current economic uncertainty made the PPP loan request necessary to support ongoing operations. On October 2, 2020, the SBA issued procedural guidance with respect to PPP loans and changes in ownership and the Company believes that it is compliant with respect to the 2020 Equity Private Placement and the ATM Offering.

In June 2020, the Payroll Protection Program Flexibility Act (“PPPFA”) was signed into law adjusting certain key terms of loans issued under the PPP. In accordance with the PPPFA, the initial deferral period may be extended from six to up to ten months and the loan maturity may be extended from two to five years. The PPPFA also provided for certain other changes, including the extent to which the loan may be forgiven.

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 the Company maintains its payroll levels over a twenty-four-week period following the loan date. The loan forgiveness amount may be reduced if the Company terminates employees or reduces salaries during the twenty-four-week period. The Company believes that it has used the proceeds for

eligible purposes consistent with the provisions of the PPPFA. However, there can be no assurance that any portion of the loan will be forgiven and that we will not have to repay the loan in full.

As the legal form of the Promissory Note is a debt obligation, the Company is accounting for it as debt under Accounting Standards Codification (ASC) 470, *Debt* and recorded an initial short-term liability of \$3.5 million in the condensed consolidated balance sheet upon receipt of the loan proceeds. The Company is accruing interest over the term of the loan and is not imputing additional interest at a market rate because the guidance on imputing interest in ASC 835-30, *Interest* excludes transactions where interest rates are prescribed by a government agency. A de minimis amount of interest expense has been recognized within interest and other income, net in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and a de minimis amount of interest expense has been accrued within accrued expenses and other current liabilities on the condensed consolidated balance sheet as of September 30, 2020. If any amount of the loan is ultimately forgiven, income from the extinguishment of debt would be recognized as a gain on loan extinguishment in the consolidated statement of operations and comprehensive loss.

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 condensed consolidated and combined financial statements, the Company did not adopt any new accounting pronouncements during the nine months ended September 30, 2020 that had a material effect on its condensed consolidated and combined financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments* (“ASU 2019-04”), ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* (“ASU 2019-05”) to provide additional guidance on the adoption of ASU 2016-13, ASU No. 2019-10, *Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)* (“ASU 2019-10”), ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses* (“ASU 2019-11”) and ASU No. 2020-02, *Financial Instruments—Credit Losses (Topic 326) and Leases (Topic 842)* (“ASU 2020-02”). ASU 2019-04 added Topic 326, Financial Instruments—Credit Losses, and made several amendments to the codification and also modified the accounting for available-for-sale debt securities. ASU 2019-05 provides targeted transition relief by providing an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. ASU 2019-10 aligned the effective dates of certain major updates not yet effective to conform to the FASB’s new philosophy of staggering major updates between large public companies and all other entities. ASU 2019-11’s major provisions included additional clarifications and practical expedients related to expected recoveries for purchased assets with credit deterioration, troubled debt restructuring, accrued interest receivables, and other areas when adopting ASU 2016-13. ASU 2020-02 provided amendments to the Topic 326 including a new section related to credit losses measured at amortized cost and a clarification to Topic 842 and is effective when adopting other areas of *Financial Instruments—Credit Losses* Topic 326. As a public business entity that qualifies as a smaller reporting company, ASU 2016-13, ASU 2019-04 and ASU 2019-05 are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of these ASUs will have on the Company’s financial position and results of operations.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (“ASU 2018-13”): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement* (“ASU 2018-13”) which amends the disclosure requirements for fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted ASU 2018-13 in the first quarter of 2020 and the adoption of this standard did not have a material impact on the Company’s financial position or results of operations.

In August 2018, the FASB issued ASU No. 2018-15, *Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract* (“ASU 2018-15”). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC 350-40, *Intangibles—Goodwill and Other—Internal Use Software* (ASC 350-40), to determine which implementation costs to capitalize as assets or expense as incurred. The internal-use software guidance in ASC 350-40 requires that certain costs incurred during the application development stage be capitalized and other costs incurred during the preliminary project and post-implementation stages be expensed as they are incurred. A customer’s accounting for the hosting component of the arrangement is not affected by this guidance. The amendments in ASU 2018-15 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted ASU 2018-15 in the first quarter of 2020 and the adoption of this standard did not have a material impact on the Company’s financial position or results of operations.

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

3. Related Party Transactions

Relationship with Ironwood

Prior to April 1, 2019, the Company was managed and operated in the normal course of business under Ironwood. Ironwood became a related party when Mark Currie, Ironwood’s former Chief Scientific Officer and the Company’s President, joined Ironwood’s board in April 2019 following the Separation.

Certain shared costs were allocated to the Company and reflected as expenses in the Company’s stand-alone combined financial statements for periods prior to the Separation. The expenses reflected in the condensed combined financial statements for periods prior to the Separation may not be indicative of expenses that will be incurred by the Company in the future.

(a) Corporate costs

Ironwood incurred significant corporate costs for services provided to Cycleron. These costs included expenses for information systems, accounting, other financial services (such as treasury, audit and purchasing), human resources, legal, facilities and Separation-related costs. A portion of these costs benefited Cycleron and have been allocated to Cycleron using a pro-rata method based on project related costs, headcount, or other measures that management believes are consistent and reasonable. The corporate costs allocated to Cycleron, prior to the Separation, and included in the combined statements of operations was approximately \$6.8 million for the three months ended March 31, 2019 and was included in general and administrative expenses.

(b) Cash Management and Financing

Cycleron participated in Ironwood’s centralized cash management and financing programs prior to the Separation. Disbursements were made through centralized accounts payable systems operated by Ironwood. Cash receipts were transferred to centralized accounts, also maintained by Ironwood. As cash is disbursed and received by Ironwood, it was accounted for by Cycleron through net parent investment. All obligations were financed by Ironwood and financing decisions were determined by central Ironwood treasury operations until the Separation.

Other Transactions with Ironwood

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

Under the Transition Services Agreements, the Company provides certain services to Ironwood, and Ironwood provides certain services to the Company, each related to corporate functions such as finance, procurement, facilities and development for a period of up to two years from the date of the Separation, unless earlier terminated or extended by mutual agreement. These services are charged to and from Ironwood and are recorded as part of operating expenses. All services provided to and from the Company under the Transition

Services Agreements were completed as of March 31, 2020 and the agreements were terminated. The net charge to operating expenses for the Transition Services Agreements was de minimis for the three and nine months ended September 30, 2020 and was de minimis and \$0.1 million for the three and nine months ended September 30, 2019, respectively.

Under the Development Agreement, the Company provides certain research and development services to Ironwood at mutually agreed upon rates and the amounts earned are recorded as revenue from related party. Such research and development activities are governed by a joint steering committee composed of representatives of both Ironwood and the Company. Ironwood and the Company have agreed that the Development Agreement will not be renewed beyond its initial term which ends on March 31, 2021. The Company recorded approximately \$0.4 million and \$2.2 million in revenue from related party for services provided under the Development Agreement for the three and nine months ended September 30, 2020, respectively, and recorded \$1.4 million and \$3.0 million for the three and nine months ended September 30, 2019, respectively.

In accordance with the Separation Agreement, there were certain other transactions and adjustments post-Separation between the Company and Ironwood. During the three and nine months ended September 30, 2020, the Company recorded approximately \$0.6 million and \$0.7 million in general and administrative expense for the reimbursement of certain expenses to Ironwood in accordance with the Separation Agreement. During the three months ended September 30, 2019, Cyclerion paid Ironwood approximately \$1.3 million associated with tenant improvement reimbursement provisions. The total amount due from Ironwood at September 30, 2020 and December 31, 2019 was approximately \$0.4 million and \$1.5 million, respectively, primarily from the Development Agreement, and is reflected as related party accounts receivable. There was approximately \$0.1 million due to Ironwood at September 30, 2020 and December 31, 2019, respectively.

Peter Hecht, Ironwood's former Chief Executive Officer and the Chief Executive Officer and board member of Cyclerion, donated 2.5 million of his shares of Ironwood common stock to American Endowment Foundation for the creation of a donor advised fund that divested these shares to invest \$34.0 million in Cyclerion as part of the financing transaction completed by Cyclerion on April 2, 2019. Mark Currie has invested \$4.0 million in Cyclerion as part of this financing. Dr. Currie and certain other investors have funded a portion of their investment through sales of Ironwood common stock.

Other Related Party Transactions

During the three and nine months ended September 30, 2020, the Company recorded approximately \$0.4 million and \$1.0 million, respectively, of research and development costs to a related party which it engaged to provide research and development transaction support services. The entity became a related party when Mark Currie, the Company's President, joined its board in January 2020. There was approximately \$0.4 million and a de minimis amount due to the related party at September 30, 2020 and December 31, 2019, 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 presents 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, 2020 and December 31, 2019 (in thousands):

	Fair Value Measurements as of September 30, 2020 Using:				Total
	Level 1	Level 2	Level 3		
Cash equivalents:					
Money market funds	\$ 65,827	\$ —	\$ —	\$ 65,827	
Cash equivalents	<u>\$ 65,827</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 65,827</u>	

	Fair Value Measurements as of December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 93,859	\$ —	\$ —	\$ 93,859

5. Property and Equipment

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

	September 30, 2020	December 31, 2019
Laboratory equipment	\$ 12,288	\$ 14,505
Software	2,261	2,232
Construction in progress	5	915
Computer and office equipment	1,547	1,890
Leasehold improvements	14,859	13,673
Property and equipment, gross	30,960	33,215
Less: accumulated depreciation and amortization	(20,780)	(21,602)
Property and equipment, net	<u>\$ 10,180</u>	<u>\$ 11,613</u>

As of September 30, 2020, and December 31, 2019, the Company's property and equipment was primarily located in Cambridge, Massachusetts.

Depreciation and amortization expense of the Company's property and equipment was approximately \$0.6 million and \$0.7 million for the three months ended September 30, 2020 and 2019, respectively, and approximately \$1.8 million and \$2.0 million for the nine months ended September 30, 2020 and 2019, respectively. The Company recorded a net loss on disposal of property and equipment of a de minimis amount and \$0.2 million for the three and nine months ended September 30, 2020, respectively, recognized within operating expenses in the condensed consolidated and combined statements of operations and comprehensive loss. Leasehold improvements of \$1.5 million were put into service in the nine months ended September 30, 2020, of which \$0.9 million was included in construction in progress as of December 31, 2019.

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2020	December 31, 2019
Accrued incentive compensation	\$ 2,598	\$ 3,767
Salaries	1,024	1,730
Accrued vacation	768	969
Professional fees	872	441
Accrued severance and benefit costs	—	2,009
Other	343	404
Accrued expenses and other current liabilities	<u>\$ 5,605</u>	<u>\$ 9,320</u>

7. Commitments and Contingencies

Other Funding Commitments

As of September 30, 2020 and December 31, 2019, the Company had several ongoing studies in various clinical trial stages. The Company's most significant clinical trial expenditures are related to contract research organizations. These contracts are generally cancellable, with notice, at the Company's option and do not have any significant cancellation penalties.

Guarantees

On September 6, 2018, Cycleron was incorporated in Massachusetts and its officers and directors are indemnified for certain events or occurrences while they are serving in such capacity. Prior to the Separation, the Company's officers and directors were similarly indemnified under Delaware law.

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, 2020 and December 31, 2019.

8. Leases

The FASB issued ASU 2016-02, or the leasing standard or ASC 842, in February 2016. ASU 2016-02 requires lessees to recognize assets and liabilities on the balance sheet for the rights and obligations created by all leases with terms of more than 12 months. ASU 2016-02 also requires certain qualitative and quantitative disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases.

On April 1, 2019, the Company entered into the Head Lease, a direct operating lease for its existing premises located at 301 Binney Street, Cambridge, MA consisting of approximately 114,000 rentable square feet of office and lab space on the first and second floors. The Head Lease is for a term of 123 months with two five-year extension options and certain expansion rights. The Head Lease includes a letter of credit, initially in the amount of \$7.7 million, posted with the landlord as a security deposit, which is collateralized by a money market account recorded as restricted cash on the Company's condensed consolidated balance sheets. Cycleron has also entered into customary non-disturbance arrangements with the building landlord's mortgagee and with the property ground lessor recognizing Cycleron's leasehold interest in this property.

The Head Lease provides for annual base rent of approximately \$11.0 million in the first year, which increases on a yearly basis by 3.0% (subject to an abatement of base rent of approximately \$2.7 million in the first year of the lease). The Company is obligated to pay the landlord for certain costs, taxes and operating expenses related to the premises, subject to certain exclusions; however, the Company has concluded that these payments are not in-substance fixed payments and therefore are not included in the calculation of the related lease liability and asset under ASC 842. Additionally, the Company has made the policy election to adopt the practical expedient to not separate lease components from non-lease components for the right-to-use asset class of office and laboratory space. This policy election results in the Company accounting for the lease component, the use of the premises, and the non-lease components, which include a property management fee, as a single lease component.

The Company recorded the liability associated with the Head Lease at the present value of the lease payments not yet paid, discounted using the discount rate for the Head Lease established at the commencement date. As the Head Lease does not provide an implicit rate, the Company had to estimate the incremental borrowing rate, or IBR, as of the commencement date. The IBR is defined under ASC 842 as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments in a similar economic environment. The Company determined its IBR to be 10.9% at the time of the agreement, which was used to discount the remaining lease payments over the remaining lease term and recorded a lease liability of \$71.3 million on April 1, 2019. This lease liability will be amortized over the remaining lease term in an amount equal to the difference between the cash rent paid and the monthly interest calculated on the remaining lease liability.

The Company had a tenant improvement allowance from the landlord of approximately \$2.3 million for certain permitted costs related to the buildup of the premises. The Company is deemed to be the owner of these

tenant improvements during the lease term. These \$2.3 million of improvements are included in the Company's property, plant and equipment balances in its consolidated balance sheets as of September 30, 2020 and December 31, 2019 and are depreciated over the shorter of their useful life or the related lease term. The Company received the payment for the tenant allowance in the third quarter of 2019.

On April 1, 2019, the Company recorded a right-of-use asset in the amount \$71.3 million. The right-of-use asset is being amortized over the remaining lease term in an amount equal to the difference between the calculated straight-line expense of the total lease payments less the monthly interest calculated on the remaining lease liability.

On February 28, 2020 the Company entered into an amendment to our Head Lease at 301 Binney Street in Cambridge, Massachusetts. The Lease Amendment provides for the partial termination of the Company's rights and obligations with respect to a portion of the leased premises of approximately 40,000 rentable square feet. The Company will continue to lease approximately 74,000 square feet including the area covered by the subleased premise, discussed below. The Company reduced its remaining lease payments through June 2029 by approximately \$41.9 million. In connection with the Lease Amendment, the Company paid \$6.3 million for a termination fee and \$0.2 million for other initial direct costs, which will be deferred and recognized over the remaining lease term. The Company's security deposit was 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 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 nine months ended September 30, 2020.

On September 15, 2020 the Company entered into the Second Lease Amendment to our Head Lease at 301 Binney Street in Cambridge, Massachusetts. The Second Lease Amendment provides for the partial termination of the Company's rights and obligations with respect to a portion of the leased premises of approximately 17,000 rentable square feet. The Surrender Space includes 15,700 rentable square feet being subleased by the Company to a subtenant. The Company will continue to lease approximately 57,000 square feet of space. 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, which is classified as restricted cash on the Company's condensed consolidated balance sheet as of September 30, 2020.

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.

The Company has an operating lease right-of-use asset of approximately \$44.4 million and \$68.1 million related to the amended Head Lease recorded in its condensed consolidated balance sheets as of September 30, 2020 and December 31, 2019, respectively. The Company has current operating lease liabilities of approximately \$3.1 million and \$3.4 million, and noncurrent operating lease liabilities of approximately \$39.8 million and \$70.5 million, related to the amended Head Lease recorded in its condensed consolidated balance sheets as of September 30, 2020 and December 31, 2019, respectively.

Lease cost is recognized on a straight-line basis over the lease term. 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. Variable lease costs not subject to an index or rate are recognized as incurred. For the three and nine months ended September 30, 2020, the Company recognized a total of approximately \$0.4 million and \$1.9 million, respectively, of variable lease costs related to the Head Lease, as amended.

Supplemental cash flow information related to leases for the nine months ended September 30, 2020 is as follows:

	Nine Months Ended September 30, 2020
Decrease in right-of-use assets related to lease modifications	\$ 27,333
Decrease in operating lease liabilities due to lease modifications	\$ 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 March 31, 2019, the Company entered into a short-term sublease of approximately 24,000 rentable square feet with Ironwood to provide temporary working space for a portion of its workforce while the buildout of the Company's new premises was being completed. The sublease was for an initial one-month term with several one-month extension options. The Company subleased the space for approximately 1.5 months, vacating the space and terminating the sublease in mid-May 2019. The Company incurred \$0.2 million in rent expense related to the sub-lease for the nine months ended September 30, 2019.

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 has no extension options. The sublease provides for annual base rent of approximately \$1.5 million in the first year, which increases 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 is 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 relates exclusively to non-lease components and will 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.

On September 15, 2020, concurrent with execution of the Second Lease Amendment, the Company entered into the Sublease Termination Agreement to terminate its sublease of 15,700 rentable square feet. Under the terms of the Sublease Termination Agreement, the subtenant is 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 expects to receive the benefit of 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, of which \$1.5 million is recorded in other current assets and \$2.9 million is recorded in other assets in the condensed consolidated balance sheets as of September 30, 2020. 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. The effects of the Sublease Termination Agreement are recorded within sublease termination income, net in the condensed consolidated and combined statements of operations and comprehensive loss.

The Company determined that the licensed rooms represent a lease under ASC 842. Once the Company obtains control of the rooms, the prepaid rooms balance will be reclassified from other assets to a ROU asset, and

the related lease expense will be recorded on a straight-line basis over the lease term. The Company determined that the licensed services represent a non-lease component, which will be recognized separately from the lease component for this asset class. The expense related to the licensed services will be recognized on a straight-line basis over the period the services are received. Both the lease expense and services expense will be recognized as a component of research and development costs in the condensed consolidated and combined statements of operations and comprehensive loss.

For the three and nine months ended September 30, 2020, gross sublease income of \$0.4 million and \$1.5 million, respectively, and net sublease income of approximately \$0.1 million and \$0.3 million, respectively, was recorded in interest and other income, net in the condensed consolidated and combined statements of operations and comprehensive loss.

Future minimum lease payments under non-cancelable operating leases under ASC 842 as of September 30, 2020 are as follows:

	Operating Lease Payments
2020 (remaining three months)	\$ 1,335
2021	5,742
2022	5,908
2023	6,080
2024	6,256
2025 and thereafter	30,486
Total future minimum lease payments (receipts)	<u>55,807</u>
Less: present value adjustment	12,888
Operating lease liabilities at September 30, 2020	<u>42,919</u>
Less: current portion of operating lease liabilities	3,133
Operating lease liabilities, net of current portion	<u>\$ 39,786</u>

9. Share-based Compensation Plans

Prior to the Separation, share-based compensation expense was allocated to Cycleron using a combined specific identification and pro-rata method based on internal project related costs and headcount that management believed were consistent and reasonable.

In connection with the Separation, Cycleron adopted its own share-based compensation plans. Specifically, Cycleron adopted the 2019 Employee Stock Purchase Plan (“2019 ESPP”) and the 2019 Equity Incentive Plan (“2019 Equity Plan”). Under the 2019 ESPP, eligible employees may use payroll deductions to purchase shares of stock in offerings under the plan, and thereby acquire an interest in the future of the Company. Under the 2019 Equity Plan, new post-Separation awards, including stock options and restricted stock units (“RSUs”), may be granted to employees of the Company.

Cycleron 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 Cycleron 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 Cycleron options, regardless of which company employed them post-Separation. For employees that were ultimately employed by Cycleron, unvested Ironwood options and RSUs were converted to unvested Cycleron options and RSUs.

The conversion of equity awards resulting from the Separation impacted approximately 143 employees and was treated as a Type 1 modification under ASC Topic 718, *Share Based Payments*, as the awards are expected to vest under the original terms. Incremental compensation expense was measured as the excess, if any, of the fair

value of the modified award over the fair value of the original award immediately before its terms were modified. The fair value of RSUs and restricted stock awards was measured using the fair value stock price immediately before and immediately after the modification date which resulted in no incremental compensation expense. The fair value of stock options was measured using the Black-Scholes option pricing method using the appropriate valuation assumptions immediately before and immediately after the modification date. As a result of the modification, Cyclerion recognized a one-time incremental expense of approximately \$0.3 million for the vested stock options and will recognize an incremental expense of approximately \$7.5 million for the unvested stock options over their remaining vesting period.

The following table provides share-based compensation reflected in the Company's condensed consolidated and combined statements of operations and comprehensive loss for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020		2019	
	\$ 1,784	\$ 2,192	\$ 5,584	\$ 6,774
Research and development				
General and administrative	2,012	2,756	6,200	8,386
	<u>\$ 3,796</u>	<u>\$ 4,948</u>	<u>\$ 11,784</u>	<u>\$ 15,160</u>

There were no stock options granted for the three months ended September 30, 2020. For the nine months ended September 30, 2020, the Company granted stock options to purchase an aggregate 270,846 shares at a weighted average grant date fair value of \$2.15 per share.

As of September 30, 2020, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested time-based stock options held by Cyclerion's employees is \$16.5 million and the weighted average period over which that expense is expected to be recognized is 2.39 years.

As of September 30, 2020, the unrecognized share-based compensation expense related to stock options containing market conditions held by Cyclerion's employees is \$0.3 million, which is expected to be recognized over a weighted-average period of 3.6 years.

As of September 30, 2020, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested RSUs held by the Company's employees is 3.8 million and the weighted-average period over which that expense is expected to be recognized is 2.01 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,	
	2020	2019	2020	2019
Numerator:				
Net loss (in thousands)	\$ (18,812)	\$ (27,317)	\$ (58,574)	\$ (96,953)
Denominator:				
Weighted average shares used in calculating net loss per share — basic and diluted (in thousands)	32,096	27,434	29,196	27,380
Net loss per share — basic and diluted	<u>\$ (0.59)</u>	<u>\$ (1.00)</u>	<u>\$ (2.01)</u>	<u>\$ (3.54)</u>

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

Prior to April 1, 2019, there were no Cycleron shares outstanding, as such, the shares outstanding immediately after the distribution and the 2019 Equity Private Placement were used to calculate the basic and diluted net loss per share for the nine months ended September 30, 2019.

11. Defined Contribution Plan

Prior to the Separation, Ironwood maintained a defined contribution 401(k) Savings Plan in the form of a qualified 401(k) plan for the benefit of substantially all of its employees, which included Ironwood employees who became Cycleron employees. Compensation expense related to the 401(k) match was allocated to Cycleron using a pro-rata method based on project-related costs and headcount that management believes are consistent and reasonable.

Subsequent to the Separation, Cycleron 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 Cycleron plan. Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. Cycleron contributions to the plan are at the sole discretion of the board of directors. Currently, Cycleron 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 \$0.4 million related to the defined contribution 401(k) Savings Plan for the three and nine months ended September 30, 2020, respectively. Included in compensation expense for employees that are directly attributable to Cycleron is approximately \$0.1 million and \$0.5 million for the three and nine months ended September 30, 2019, respectively.

12. 2019 Workforce Reduction

On October 30, 2019, the Company began a reduction of its current workforce by approximately thirty (30) full-time employees in order to align its resources with its ongoing clinical and preclinical programs, innovation strategy and partnering work. The total one-time costs related to the 2019 workforce reduction were approximately \$3.0 million. The workforce reduction was substantially completed during the year ended December 31, 2019, in which the Company recorded approximately \$2.8 million of severance and benefits costs. The workforce reduction was finalized during the three months ended March 31, 2020, in which the Company recorded approximately \$0.2 million in additional severance and benefits costs.

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	<u>\$ 2,009</u>	<u>\$ 158</u>	<u>\$ 2,137</u>	<u>\$ (30)</u>	<u>\$ 0</u>

13. Subsequent Events

The Company intends to focus on developing treatments for serious CNS diseases and will direct its investments to its current priorities, including the ongoing MELAS study, the planned ADv study and further characterization of IW-6463 novel pharmacology. On November 5, 2020, the Company began a reduction of its current workforce by approximately 48 full-time employees to align its resources with these priorities. The reduction will take place primarily during the fourth quarter of 2020 and is expected to be completed by the end of the first quarter of 2021. The Company estimates that it will incur aggregate charges in connection with the workforce reduction of approximately \$5.0 million for employee severance and benefit costs, nearly all of which are expected to result in cash expenditures. The Company also intends to exit its current laboratory and office facilities in early 2021.

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 and combined financial statements and the corresponding notes included in this Quarterly Report on Form 10-Q, as well as the audited consolidated and combined 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, IW-6463, is a pioneering CNS-penetrant sGC stimulator in clinical development for MELAS and ADv. 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.

Separation from Ironwood Pharmaceuticals

On April 1, 2019, Ironwood Pharmaceuticals Inc., or Ironwood, completed the separation of its sGC business, and certain other assets and liabilities, into us as a separate, independent publicly traded company by way of a pro-rata distribution of our common stock through a dividend distribution of one share of our 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, which we refer to herein as the Separation. As a result of the Separation, we became an independent public company and commenced trading under the symbol “CYCN” on the Nasdaq Global Select Market on April 2, 2019.

In connection with the Separation, on March 30, 2019, we entered into certain agreements with Ironwood to provide a framework for our relationship with Ironwood following the Separation, including, among others, a Separation Agreement, a Tax Matters Agreement, and an Employee Matters Agreement.

In addition, in connection with the Separation, on April 1, 2019, we entered into a Development Agreement, an Ironwood Transition Services Agreement, a Cycleron Transition Services Agreement and an Intellectual Property License Agreement with Ironwood. All services provided to and from the Company under the Transition Services Agreements were completed as of March 31, 2020 and the agreements were terminated. Ironwood and the Company have agreed that the Development Agreement will not be renewed beyond its initial term which ends on March 31, 2021.

On April 2, 2019, we issued 11,817,165 shares of our common stock, in the 2019 Equity Private Placement to accredited investors for gross proceeds of \$175 million (net proceeds of approximately \$165 million).

Our historical condensed consolidated and combined financial statements for the periods prior to the Separation have been derived from Ironwood’s combined financial statements and accounting records and are presented in conformity with United States Generally Accepted Accounting Principles, or U.S. GAAP.

Our historical financial statements may not be indicative of our future performance and do not necessarily reflect what our results of operations, financial condition and cash flows would have been had we operated as a separate, publicly traded company for the periods presented prior to the Separation. The condensed consolidated and

combined financial statements prior to the Separation included herein do not reflect any changes that occurred in our financing or operations as a result of the Separation from Ironwood.

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.

The core of our portfolio is *IW-6463*, 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 is one of several fundamental neurotransmitters, but it has not yet been leveraged for its full CNS therapeutic potential. IW-6463 stimulates sGC, a signaling enzyme that responds to the presence of NO, to enhance the body's natural ability to produce cyclic guanosine monophosphate (cGMP), an important signaling molecule. An impaired NO-sGC-cGMP signaling pathway is believed to play an important role in the pathogenesis of neurodegenerative diseases and is critical to basic neuronal functions. 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 IW-6463. The Phase 1 healthy participant study results indicate that IW-6463 was well tolerated. Pharmacokinetic (PK) data, obtained from both blood and cerebral spinal fluid, support once-daily dosing with or without food and demonstrated IW-6463 penetration of the blood-brain-barrier at levels expected to be pharmacologically active.

In October 2020, we announced positive topline results from our IW-6463 Phase 1 translational pharmacology study. Treatment with IW-6463 in this 15-day 24-subject crossover study confirmed and extended results seen in earlier Phase 1 studies: once daily oral treatment demonstrated desired CNS exposure, blood-brain-barrier penetration and target engagement. Results also showed statistically significant improvements in neurophysiological and objective performance measures associated with age-related cognitive decline and neurodegenerative diseases. IW-6463 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 preclinical data, support continued development of IW-6463 as a potential new medicine for serious CNS diseases.

We will soon begin enrolling our IW-6463 Phase 2 clinical trial in Mitochondrial Encephalomyopathy, Lactic acidosis, and Stroke-like episodes (MELAS). In the coming months, we will use the findings of the translational pharmacology study, in addition to observations from the previous Phase 1 study, to inform further clinical development activities, including the initiation of a planned Phase 2 clinical trial in Alzheimer's disease with vascular pathology (ADv) in H1 2021, as well as explore other potential indications.

Non-core assets in our portfolio are:

Olinciguat, an orally administered, once-daily, vascular sGC stimulator. Olinciguat was evaluated in the STRONG-SCD study, a randomized, placebo-controlled, dose-ranging Phase 2 study of 70 participants with sickle cell disease designed to evaluate safety, tolerability, and pharmacokinetics of olinciguat, compared to placebo, as well as to explore effects on daily symptoms and biomarkers of disease activity when dosed over a 12-week treatment period. On October 14, 2020, we announced topline results from this study, which did not demonstrate adequate activity to support further internal clinical development. We intend to complete analysis of the study results and present them or publish them in a future forum.

Praliciguat, an orally administered, once-daily systemic sGC stimulator that was evaluated in two Phase 2 proof-of-concept studies: a dose-ranging study in 156 adult patients with diabetic nephropathy, and a study in 196 adult patients with heart failure with preserved ejection fraction (HFpEF), CAPACITY-HFpEF. On October 30, 2019, we released topline results from these studies. The Company's efforts to out-license rights to praliciguat have expanded to discussions beyond treatment of cardiometabolic disorders to include additional indications where sGC stimulators have demonstrated efficacy.

Discovery Research. We have ongoing discovery research work, focused primarily on further expanding the potential of sGC stimulation in CNS disorders.

The following table summarizes our research and development expenses and employee and facility related costs allocated to research and development expense, for the three and nine months ended September 30, 2020 and 2019. 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,	
	2020 (in thousands)	2019 (in thousands)	2020 (in thousands)	2019 (in thousands)
Product pipeline external costs:				
IW-6463	\$ 1,502	\$ 1,559	\$ 4,339	\$ 3,797
Olineciguat	2,012	2,891	6,273	10,794
Praliciguat	53	2,575	269	12,102
Discovery research	541	364	743	999
Total product pipeline external costs	4,108	7,389	11,624	27,692
Personnel and related internal costs	6,214	9,517	20,688	29,540
Facilities and other	3,381	5,389	12,010	17,226
Total research and development expenses	\$ 13,703	\$ 22,295	\$ 44,322	\$ 74,458

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 COVID-19 pandemic could affect our programs and operations in ways that are difficult to judge at this time, including our operations, clinical trials, corporate development activities and other activities. Cycleron is working closely with its clinical trial sites and investigators to deliver its ongoing and planned 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 U.S. FDA and comparable agencies outside the U.S. 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, 2019, our quarterly reports on Form 10-Q for the fiscal quarters ended March 31, 2020 and June 30, 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 condensed consolidated and combined 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 condensed consolidated and combined financial statements, and the amounts of expenses during the reported periods. Significant estimates and assumptions in our condensed consolidated and combined financial statements include those related to allocation of expenses, assets and liabilities from Ironwood’s historical financial statements for the periods prior to the Separation, impairment of long-lived assets; income taxes, including the valuation allowance for deferred tax assets; research and development expenses; contingencies and share-based compensation. 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 condensed consolidated and combined 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 condensed consolidated and combined financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

For the period prior to the Separation, our condensed consolidated and combined financial statements include an allocation of expenses related to certain Ironwood corporate functions, including senior management, legal, human resources, finance, information technology and quality assurance. These expenses were allocated to Cyclerion based on direct usage or benefit where identifiable, with the remainder allocated pro-rata based on project related costs, headcount or other measures. We considered the allocation methodologies used to be a reasonable and appropriate reflection of the historical Ironwood expenses attributable to us. The expenses reflected in the condensed consolidated and combined financial statements may not be indicative of expenses that will be incurred by us in the future. After the Separation, we began performing these corporate functions using internal resources or purchased services, certain of which were provided by Ironwood under the Transition Services Agreement. The following discussion summarizes the key factors we believed are necessary for an understanding of our consolidated financial statements.

Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2020	2019	\$	%	2020	2019	\$	%
	(dollars in thousands)				(dollars in thousands)			
Revenue from related party	\$ 400	\$ 1,398	\$ (998)	(71)%	\$ 2,163	\$ 3,026	\$ (863)	(29)%
Cost and expenses:								
Research and development	13,703	22,295	(8,592)	(39)%	44,322	74,458	(30,136)	(40)%
General and administrative	8,033	7,119	914	13%	21,551	27,019	(5,468)	(20)%
(Gain) loss on lease modification	444	—	444	100%	(1,669)	—	(1,669)	100%
Total cost and expenses	22,180	29,414	(7,234)	(25)%	64,204	101,477	(37,273)	(37)%
Loss from operations	(21,780)	(28,016)	6,236	(22)%	(62,041)	(98,451)	36,410	(37)%
Sublease termination income, net	2,875	—	2,875	100%	2,875	—	2,875	100%
Interest and other income, net	93	699	(606)	(87)%	592	1,498	(906)	(60)%
Net loss	<u>\$ (18,812)</u>	<u>\$ (27,317)</u>	<u>\$ 8,505</u>	<u>(31)%</u>	<u>\$ (58,574)</u>	<u>\$ (96,953)</u>	<u>\$ 38,379</u>	<u>(40)%</u>

Revenue from related party. The decrease in revenue from related party of approximately \$1.0 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 is the result of a decrease in services performed under the Development Agreement for Ironwood, which was entered into in connection with the Separation. The decrease in revenue from related party of approximately \$0.9 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 is due to a decrease in services provided in the current year as compared to the prior year, partially offset by the Company providing services to Ironwood for three quarters in 2020 compared to only two quarters post-Separation in 2019. Ironwood and the Company have agreed that the Development Agreement will not be renewed beyond its initial term which ends on March 31, 2021.

Research and development expense. The decrease in research and development expense of approximately \$8.6 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 was driven by a decrease of approximately \$3.3 million in salaries, stock-based compensation and other employee-related expenses primarily due to lower average headcount, a decrease of approximately \$2.0 million of facilities and operating costs allocated to research and development primarily due to reductions in the Company's total leased premises, and a net decrease of approximately \$3.3 million in external research costs. The net decrease in external research costs was primarily due to decreases of approximately \$2.5 million associated with the completion of two praliglutide phase 2 proof of concept studies, both of which reported top-line data on October 30, 2019, approximately \$0.9 million associated with olinciguat primarily due to the STRONG-SCD study and approximately \$0.1 million in IW-6463 studies, partially offset by an increase of approximately \$0.2 million discovery research.

The decrease in research and development expense of approximately \$30.1 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was primarily due to decreases of approximately \$8.8 million in salaries, stock-based compensation and other employee-related expenses primarily

due to lower average headcount, approximately \$5.2 million in facilities and operating costs allocated to research and development primarily due to reductions in the Company's total leased premises, and approximately \$16.1 million in net external research costs. The net decrease in external research costs was primarily due to decreases over the periods of approximately \$11.8 million in pralicipat studies, approximately \$4.5 million in olinciguat studies and approximately \$0.3 million in discovery research, partially offset by an increase of approximately \$0.5 million in IW-6463 studies.

General and administrative expense. The increase in general and administrative expenses of approximately \$0.9 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 was primarily due to an increase of approximately \$1.5 million in professional fees supporting the Company's financing activities, including the Shelf, the 2020 Equity Private Placement and the ATM Offering in the current year, a net increase of approximately \$0.5 million for other operating and administrative expenses and approximately \$0.4 million for patent filings, partially offset by a decrease of approximately \$1.5 million in salaries, stock-based compensation and other employee-related expenses, due to lower average headcount.

The decrease in general and administrative expenses of approximately \$5.5 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was primarily driven by approximately \$3.5 million of non-recurring outsourced professional services and other costs associated with the Separation recorded in the prior period and a decrease of approximately \$3.5 million in salaries, stock-based compensation and other employee-related costs, primarily due to lower average headcount and the pre-Separation allocation from Ironwood recorded in the prior period, partially offset by an increase of approximately \$1.5 million in professional fees supporting the Company's financing activities in the current year, including the Shelf, the 2020 Equity Private Placement and the ATM Offering.

(Gain) loss on lease modification. The loss on lease modification of \$0.4 million recorded in the three months ended September 30, 2020 is related to the Second Lease Amendment to the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on September 15, 2020.

The gain on lease modification of \$1.7 million recorded in the nine months ended September 30, 2020 is driven by a \$2.1 million gain related to the Lease Amendment to the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on February 28, 2020, partially offset by a \$0.4 million loss related to the Second Lease Amendment to the Head Lease at 301 Binney Street in Cambridge, Massachusetts that was executed on September 15, 2020.

Sublease termination income, net. The sublease termination income, net of \$2.9 million recorded in 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, net. Interest and other income, net decreased by approximately 0.6 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 due to a decrease of approximately \$0.7 million in interest income driven by lower cash balances and lower interest rates, partially offset by an increase of approximately \$0.1 million in net sublease income.

Interest and other income, net decreased by approximately 0.9 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 due to a decrease of approximately \$1.2 million in interest income driven by a lower cash balances and lower interest rates, partially offset by an increase 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 Cycleron 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 condensed consolidated and combined 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 registration statement. 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. As of September 30, 2020, no shares have been issued or sold under the ATM Offering.

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, 2020, we had approximately \$66.8 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 our development plans and clinical stage patient testing and our timing expectations related to the progress of our discovery research programs, we expect that our existing cash and cash equivalents as of September 30, 2020 will be sufficient to fund our planned operating expenses and capital expenditure requirements at least into the fourth quarter of 2021, excluding net cash flows from potential business development activities. 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, 2020 and 2019:

	Nine Months Ended September 30,		Change	
	2020	2019	\$	%
Net cash used in operating activities	\$ (58,449)	\$ (80,052)	\$ 21,603	(27)%
Net cash used in investing activities	\$ (1,418)	\$ (6,615)	\$ 5,197	(79)%
Net cash provided by financing activities	\$ 27,931	\$ 211,426	\$ (183,495)	(87)%

Cash Flows from Operating Activities

Net cash used in operating activities was \$58.4 million for the nine months ended September 30, 2020 compared to \$80.1 million for the nine months ended September 30, 2019. The decrease in net cash used in operations of \$21.6 million primarily relates to a decrease in our net loss of \$38.4 million, partially offset by the payment of a \$6.3 million termination fee related to the Head Lease modification in the current year, a decrease of stock-based compensation and other non-cash items of \$3.4 million, the recording of non-cash sublease termination income, net of \$2.9 million in the current year, an increase in the cash used by our working capital accounts of \$2.5 million, and the recording of a non-cash gain on lease modification of \$1.7 million in the current year.

Cash Flows from Investing Activities

Net cash used in investing activities was \$1.4 million for the nine months ended September 30, 2020 compared to \$6.6 million for the nine months ended September 30, 2019. The decrease in net cash used in investing activities of \$5.2 million was primarily from a decrease in purchases of property and equipment, primarily leasehold improvements.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2020 was \$27.9 million, resulting from the cash received from the 2020 Equity Private Placement of \$24.3 million, proceeds from the short-term note payable of \$3.5 million and proceeds from the purchases of shares under the ESPP and other stock plans. Cash provided by financing activities for the nine months ended September 30, 2019 was \$211.4 million, resulting from the net cash proceeds received from the 2019 Equity Private Placement of \$164.6 million, the cash transferred to us from Ironwood based on changes in our cash used for operations prior to the Separation of \$46.4 million and proceeds from the purchases of shares under the ESPP and other stock plans of \$0.4 million.

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 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.

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, 2020 will enable us to fund our planned operating expenses and capital expenditure requirements at least into the fourth quarter of 2021 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. As discussed under the “Risk Factors” in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, to preserve the tax-free treatment of the Separation, we may be barred, in certain circumstances, for a two year period following the Separation, from engaging in certain capital raising transactions. 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, 2020, we had no uncertain tax positions.

Other Funding Commitments

As of September 30, 2020, 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.

Transition from Ironwood and Costs to Operate as an Independent Company

Our condensed consolidated and combined financial statements for the period prior to the Separation reflect our operating results and financial position as it was operated by Ironwood, rather than as an independent company. As a result of the Separation, we have incurred additional ongoing operating expenses to operate as an independent, publicly traded, company. These costs include the cost of various corporate headquarters functions, incremental information technology-related costs and incremental costs to operate stand-alone accounting, legal, human

resources and other administrative functions. We also incur non-recurring expenses and non-recurring capital expenditures.

We entered into the Ironwood Transition Services Agreement that provided us with certain services and resources related to corporate functions for an initial term of up to two years from the date of the Separation (as applicable). All services provided by Ironwood to the Company under the Ironwood Transition Services Agreement were completed as of March 31, 2020, and it has been terminated.

It is not practicable to estimate the costs that would have been incurred in each of the periods presented in the historical financial statements for the functions described above. Actual costs that would have been incurred if we operated as a stand-alone company for the periods prior to the Separation would have depended on various factors, including organizational design, outsourcing and other strategic decisions related to corporate functions, information technology and back office infrastructure.

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 condensed consolidated and combined 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.

Item 1. Legal Proceedings

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently subject to any pending or threatened litigation that we believe, if determined adversely to us, would individually, or taken together, reasonably be expected to have a material adverse effect on our business or financial results.

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, 2019, as updated in our Quarterly Report on Form 10-Q for the fiscal quarters ended March 31, 2020 and June 30, 2020.

There have been no material changes to the risk factors described therein, except as set forth below.

We are currently pursuing clinical development activities for IW-6463. Research and development of biopharmaceutical products is inherently risky. We may encounter substantial delays in our clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities in the development of IW-6463 to treat patients with serious diseases of the central nervous system.

Our business depends heavily on the successful development, clinical testing, regulatory approvals and commercialization of our lead product candidates. On October 14, 2020, we announced topline results from our Phase 1 translational pharmacology study of IW-6463, the first sGC stimulator in clinical development for CNS disorders, which supported the ongoing development of IW-6463 in serious CNS diseases. The Company also announced its focus on discovering, developing and commercializing innovative medicines for people with serious diseases of the CNS. Although we have several product candidates, IW-6463 is the only product candidate we are now developing internally. IW-6463, and any of our other current or potential product candidates, will require regulatory approvals based on substantial additional development and testing prior to commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical and clinical studies that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate benefit-risk profile for its intended use in its intended patient population. In some instances, significant variability in safety or efficacy appear in different clinical studies of the same product candidate due to numerous factors, including changes in study protocols, differences in the number and characteristics of the enrolled study participants, variations in the dosing regimen and other clinical study parameters or the dropout rate among study participants. Product candidates in later stages of clinical studies often fail to demonstrate adequate safety and efficacy despite promising preclinical testing and early clinical studies. Companies in the biopharmaceutical industry often suffer significant setbacks in later-stage clinical studies; most product candidates that begin clinical studies are never approved for commercialization by regulatory authorities. Favorable results in earlier stage trials, such as the topline results from IW-6463's Phase 1 translational pharmacology study may not be replicated in later stage trials. If we fail to produce positive results in our clinical trials of IW-6463, the development timeline, regulatory approval and commercialization prospects of IW-6463 and, correspondingly, our business and financial prospects, would be materially adversely affected.

A pandemic, epidemic or outbreak of infectious disease, such as COVID-19, has the potential to disrupt our business, including our clinical development activities, and its effect on our business is difficult to judge at this time.

A novel strain of coronavirus (COVID-19) reached pandemic levels and has seen resurgences. Many nations, including the United States, continue to implement stay-at-home orders and travel restrictions to contain the coronavirus outbreak which, along with other related mitigation measures, may limit our ability to access patients.

and physicians at certain local clinical centers that are participating in these development activities. To a limited extent, the pandemic delayed and disrupted our recently completed studies.

We may face difficulties enrolling patients in our planned and future clinical trials if the patient populations that are eligible for our clinical trials are affected by the coronavirus. COVID-19 restrictions at trial sites could delay our clinical studies. In addition, if the patients enrolled in our clinical trials become infected with COVID-19, we may have more adverse events and deaths in our clinical trials as a result. Vulnerable patients, including patients with serious diseases of the CNS, such as the patients enrolling in our clinical trials, may be at a higher risk of contracting COVID-19 and may experience more severe symptoms from the disease, adversely affecting our chances for regulatory approval or requiring further clinical studies. Furthermore, the extent to which the pandemic hinders access to facilities, procurement of resources, raw materials or components necessary for research studies or preclinical or clinical development is not fully predictable. Delays and disruptions from the pandemic may increase our capital needs while potentially interfering with our access to capital.

Item 5. Other Information

The Company intends to focus on developing treatments for serious CNS diseases and will direct its investments to its current priorities, including the ongoing MELAS study, the planned ADv study and further characterization of IW-6463 novel pharmacology. On November 5, 2020, the Company began a reduction of its current workforce by approximately 48 full-time employees to align its resources with these priorities. The reduction will take place primarily during the fourth quarter of 2020 and is expected to be completed by the end of the first quarter of 2021. The Company estimates that it will incur aggregate charges in connection with the workforce reduction of approximately \$5.0 million for employee severance and benefit costs, nearly all of which are expected to result in cash expenditures. The Company expects to realize annual cash savings of approximately \$10.0 million from the reduction in workforce.

The Company also announced that it intends to exit its current laboratory and office facilities in early 2021, from which it expects annual cash savings of approximately \$10.0 million.

Dr. Mark Currie, the Company's President and Chief Scientific Officer ("CSO"), will transition at year end to become a senior advisor. On November 2, 2020, the Company received notice of Dr. Currie's interest in that transition. Dr. Currie will continue to assist the Company on scientific and strategic matters related to the development of the CNS portfolio. Dr. Andreas Busch, Chief Innovation Officer, will effective immediately assume Dr. Currie's CSO responsibilities while Dr. Currie continues as President through year end.

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	Open Market Sale AgreementSM, dated September 3, 2020, by and between Cycleron Therapeutics, Inc. and Jefferies LLC (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on September 3, 2020).
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 Executive Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CYCLERION THERAPEUTICS, INC.

By: /s/ Peter M. Hecht

Name: Peter M. Hecht

Title: *Chief Executive Officer (Principal Executive Officer)*

By: /s/ William I. Huyett

Name: William I. Huyett

Title: *Chief Financial Officer (Principal Financial and Accounting Officer)*

Date: November 5, 2020

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

I, Peter M. Hecht, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cycleron Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

(c) 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 5, 2020

By: /s/ Peter M. Hecht

Name: Peter M. Hecht

Title: Chief Executive Officer (Principal Executive Officer)

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

I, William I. Huyett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cycleron Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

(c) 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 5, 2020

By: /s/ William I. Huyett

Name: William I. Huyett

Title: Chief Financial Officer (Principal Financial and Accounting Officer)

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

I, Peter M. Hecht, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Cyclerion Therapeutics, Inc. for the period ended September 30, 2020 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 5, 2020

By: /s/ Peter M. Hecht

Name: Peter M. Hecht

Title: Chief Executive Officer (Principal Executive Officer)

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

I, William I. Huyett, 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, 2020 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 5, 2020

By: /s/ William I. Huyett

Name: William I. Huyett

Title: Chief Financial Officer (Principal Financial and Accounting Officer)