

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2019

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

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 Act). Yes  No

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, no par value	CYCN	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

As of May 8, 2019, the registrant had 27,401,660 shares of common stock, no par value, outstanding.

**CYCLERION PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2019**  
**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I — FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	
<a href="#">Financial Statements (unaudited)</a>	
<a href="#">Condensed Combined Balance Sheets as of March 31, 2019 and December 31, 2018</a>	4
<a href="#">Condensed Combined Statements of Operations for Three Months Ended March 31, 2019 and 2018</a>	5
<a href="#">Condensed Combined Statements of Net Parent Investment for Three Months Ended March 31, 2019 and 2018</a>	6
<a href="#">Condensed Combined Statements of Cash Flows for Three Months Ended March 31, 2019 and 2018</a>	7
<a href="#">Notes to Condensed Combined Financial Statements</a>	8
<u>Item 2.</u>	
<a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	18
<u>Item 3.</u>	
<a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	27
<u>Item 4.</u>	
<a href="#">Controls and Procedures</a>	27
<b><u>PART II — OTHER INFORMATION</u></b>	
<u>Item 1.</u>	
<a href="#">Legal Proceedings</a>	27
<u>Item 1A.</u>	
<a href="#">Risk Factors</a>	27
<u>Item 6.</u>	
<a href="#">Exhibits</a>	27
<a href="#">Signatures</a>	29

## SPECIAL 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,” “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:

- our business and operations following the separation and any benefits or costs of the separation, including the tax treatment;
- our post-separation relationships with Ironwood, third parties, collaborators and our employees;
- our ability to operate as a standalone company and execute our strategic priorities;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching and commercializing our product candidates, including olinciguat, praliciguat and IW-6463;
- 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 and the potential indications and market opportunities therefor;
- U.S. and foreign 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 key employees needed to execute our business plans and strategies and our expectations regarding 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 status 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 distribution and the limitations imposed on us under the tax matters agreement that we entered into with Ironwood; and
- trends and challenges in our potential markets.

See the “Risk Factors” section in the registration statement on Form S-1 filed with the SEC on April 18, 2019, 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.

## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements

## Cyclerion Therapeutics, Inc.

## Condensed Combined Balance Sheets

(In thousands)

(Unaudited)

	March 31, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Prepaid expenses	\$ 927	\$ 867
Other current assets	12	12
Total current assets	939	879
Property and equipment, net	8,815	6,497
Other assets	19	25
Total assets	<u>\$ 9,773</u>	<u>\$ 7,401</u>
<b>LIABILITIES AND NET PARENT INVESTMENT</b>		
Current liabilities:		
Accounts payable	\$ 5,671	\$ 2,781
Accrued research and development costs	6,243	5,261
Accrued expenses and other current liabilities	5,559	9,804
Total current liabilities	17,473	17,846
Other liabilities	52	—
Net parent investment:		
Net parent investment	(7,752)	(10,445)
Total liabilities and net parent investment	<u>\$ 9,773</u>	<u>\$ 7,401</u>

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

**Cyclerion Therapeutics, Inc.**  
**Condensed Combined Statements of Operations**

**(In thousands)**

**(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Cost and expenses:</b>		
Research and development	\$ 26,404	\$ 21,514
General and administrative	10,977	3,769
<b>Total cost and expenses</b>	<b>37,381</b>	<b>25,283</b>
<b>Loss from operations</b>	<b>(37,381)</b>	<b>(25,283)</b>
<b>Net loss</b>	<b>\$ (37,381)</b>	<b>\$ (25,283)</b>

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

## Cyclerion Therapeutics, Inc.

## Condensed Combined Statements of Net Parent Investment

(In thousands)

(Unaudited)

	Parent Company Net Investment
<b>Ending Parent company net investment as of December 31, 2017</b>	\$ (8,567)
Net loss	(25,283)
Net transfers from Parent	26,591
Parent allocation—Share-based compensation	2,508
<b>Ending Parent company net investment as of March 31, 2018</b>	<u>\$ (4,751)</u>
<b>Ending Parent company net investment as of December 31, 2018</b>	\$ (10,445)
Net loss	(37,381)
Net transfers from Parent	36,085
Parent allocation—Share-based compensation	3,989
<b>Ending Parent company net investment as of March 31, 2019</b>	<u>\$ (7,752)</u>

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

## Cyclerion Therapeutics, Inc.

## Condensed Combined Statements of Cash Flows

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
<b>Cash flows from operating activities:</b>		
Net loss	\$ (37,381)	(25,283)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	525	356
Share-based compensation expense	3,989	2,508
Changes in assets and liabilities:		
Prepaid expenses	(60)	(19)
Other current assets	—	8
Other assets	6	18
Accounts payable	2,890	1,362
Accrued research and development costs	982	(2,235)
Accrued expenses and other current liabilities	(5,274)	(3,144)
Other liabilities	52	—
Net cash used in operating activities	<u>(34,271)</u>	<u>(26,429)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,814)	(162)
Net cash used in investing activities	<u>(1,814)</u>	<u>(162)</u>
<b>Cash flows from financing activities:</b>		
Transfer from Parent Company	36,085	26,591
Net cash provided by financing activities	<u>36,085</u>	<u>26,591</u>
Net increase (decrease) in cash and cash equivalents	—	—
Cash and cash equivalents, beginning of period	\$ —	\$ —
Cash and cash equivalents, end of period	<u>\$ —</u>	<u>\$ —</u>
<b>Supplemental cash flow disclosure:</b>		
Non-cash investing activities		
Fixed asset purchases in accounts payable and accrued expenses	<u>\$ 1,029</u>	<u>\$ 680</u>

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

**Cyclerion Therapeutics, Inc.**

**Notes to the Condensed Combined Financial Statements**

**(Unaudited)**

**1. Nature of Business**

**Nature of Operations**

Cyclerion Therapeutics, Inc. (“Cyclerion” or the “Company”) is a clinical-stage biopharmaceutical company harnessing the power of soluble guanylate cyclase (“sGC”) pharmacology to discover, develop and commercialize breakthrough treatments for serious and orphan diseases. Cyclerion’s focus is enabling the full therapeutic potential of next-generation sGC stimulators. The Company’s strategy rests on a solid scientific foundation that is enabled by our people and capabilities, external collaborations, and a responsive capital allocation approach.

**The Separation**

In May 2018, Ironwood Pharmaceuticals, Inc. (“Ironwood” or the “Parent”) announced its plans to separate its sGC business from its commercial and gastrointestinal business. In furtherance of this plan, on March 6, 2019, Ironwood’s board of directors approved the distribution of all of the issued and outstanding shares of Cyclerion common stock on the basis of one share of Cyclerion common stock for every 10 shares of Ironwood common stock issued and outstanding on March 19, 2019, the record date for the distribution, which is referred to herein as the Distribution.

On January 7, 2019, in connection with the Distribution, the Company and various investors entered into a common stock purchase agreement, which was subsequently amended and restated on February 25, 2019 (the “Amended and Restated Common Stock Purchase Agreement”), pursuant to which, upon the completion of the Distribution, these investors have made an aggregate cash investment in Cyclerion of \$175 million in exchange for shares of Cyclerion common stock.

On February 25, 2019, Cyclerion and various investors entered into an amended and restated common stock purchase agreement pursuant to which these investors have made an aggregate cash investment in Cyclerion of \$175 million in exchange for shares of Cyclerion common stock.

On April 1, 2019, 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 regular way 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.

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 (“Private Placement Shares”) of its common stock to accredited investors for gross proceeds of \$175 million (net proceeds of approximately \$165 million) pursuant to the Amended and Restated Common Stock Purchase Agreement. The funds associated with the sale of Private Placement Shares were received by the Company on April 2, 2019.

**Basis of Presentation**

The accompanying unaudited condensed combined financial statements have been prepared on a stand-alone basis and are derived from Ironwood’s consolidated financial statements and accounting records. The unaudited condensed



combined financial statements reflect the historical results of the operations, financial position and cash flows of Cycleron, in conformity with United States generally accepted accounting principles (“U.S. GAAP”).

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

As part of Ironwood, Cycleron was dependent upon Ironwood for all of its working capital and financing requirements, as Ironwood uses a centralized approach to cash management and financing its operations. There were no cash amounts specifically attributable to Cycleron for the historical periods presented; therefore, there is no cash reflected in the combined financial statements. Accordingly, cash and cash equivalents, debt or related interest expense have not been allocated to Cycleron in the combined financial statements. Financing transactions related to Cycleron are accounted for as a component of Net Parent Investment in the combined balance sheets and as a financing activity on the accompanying combined statements of cash flows. Cycleron’s condensed 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 have been allocated to Cycleron 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 Cycleron operated as an independent, publicly traded company for the periods presented. See Notes 8 and 10 for further description of the accounting for the Separation. The combined balance sheets of Cycleron include assets and liabilities that were allocated principally on a specific identification basis. As Cycleron was not historically held by a single legal entity, Net Parent Investment is shown in lieu of stockholder’s equity in the combined financial statements. Net Parent Investment represents the cumulative investment by Ironwood in Cycleron through the dates presented, inclusive of operating results. Balances between Cycleron and Ironwood that were not historically settled in cash are included in Net Parent Investment. All significant transactions between the Company and Ironwood have been included in the accompanying condensed combined financial statements. Transactions with Ironwood are reflected in the accompanying condensed combined statements of Net Parent Investment as Net Transfers from Parent, and in the accompanying condensed combined balance sheets within Net Parent Investment.

### **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 the product candidates, olinciguat, praliciguat and IW-6463, and its discovery research programs. The Company completed a private placement financing that would fund operations through at least the next 12 months (see Note 10), but as of March 31, 2019, had not received the cash associated with the financing. Accordingly, the Company’s continued operations are dependent on its ability to raise additional capital through the sale of equity or debt securities. In the event that the Company is unable to raise sufficient funds, it would have to substantially alter, or possibly even discontinue or curtail operations, or sell assets at distressed prices. This uncertainty raises substantial doubt about the Company’s ability to continue as a going concern as of March 31, 2019. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On April 2, 2019, the Company issued 11,817,165 shares of its common stock to accredited investors for gross proceeds of \$175 million (net proceeds of approximately \$165 million) pursuant to the Amended and Restated Common Stock Purchase Agreement, dated February 25, 2019. The funds associated with the sale of Private Placement Shares were received by the Company on April 2, 2019, and as a result, the substantial doubt surrounding the Company’s ability to continue as a going concern has been alleviated. As of April 2, 2019, the Company, though it expects negative cash flows to continue through 2019 as it continues the development and clinical stage testing of its product candidates and its discovery research programs, expects to be able to fund operating expenses and capital expenditure requirements through the first quarter of 2021 (see Note 10).

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

### **Principles of Combination**

The accompanying condensed combined financial statements include the accounts of Cycleron. All significant intercompany transactions with Ironwood are deemed to have been paid in the period the costs were incurred. Expenses

related to corporate allocations from Ironwood to the Company are considered to be effectively settled for cash in the condensed combined financial statements at the time the transaction was recorded.

## Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision-maker in deciding how to allocate resources and in assessing performance. The Company currently operates in one reportable business segment—human therapeutics.

## Use of Estimates

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

## Cash and Cash Equivalents

The Company considers all highly liquid investment instruments with a remaining maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents may consist of money market funds, U.S. government-sponsored securities and repurchase agreements. The carrying amount of cash equivalents approximates fair value. There were no cash amounts specifically attributable to Cycleron for the historical periods presented; therefore, there is no cash reflected in the condensed combined financial statements.

## Property and Equipment

Property and equipment are recorded at cost, and are depreciated when placed into service using the straight-line method based on their estimated useful lives as follows:

<b>Asset Description</b>	<b>Estimated Useful Life (In Years)</b>
Laboratory equipment	5
Computer and office equipment	3
Furniture and fixtures	7
Software	3

Included in property and equipment are certain costs of software obtained for internal use. Costs incurred during the preliminary project stage are expensed as incurred, while costs incurred during the application development stage are capitalized and amortized over the estimated useful life of the software. The Company also capitalizes costs related to specific upgrades and enhancements when it is probable the expenditures will result in additional functionality. Maintenance and training costs related to software obtained for internal use are expensed as incurred. Costs for capital assets not yet placed into service have been capitalized as construction in progress, and are depreciated in accordance with the above guidelines once placed into service. Maintenance and repair costs are expensed as incurred.

## Impairment of Long-Lived Assets

The Company regularly reviews the carrying amount of its long-lived assets to determine whether indicators of impairment may exist, which warrant adjustments to carrying values or estimated useful lives. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. If the carrying value of the asset exceeds such projected undiscounted cash flows,

the asset will be written down to its estimated fair value. There were no significant impairments of long-lived assets for the three months ended March 31, 2019.

### **Research and Development Costs**

The Company expenses research and development costs to operations as incurred. The Company defers and capitalizes nonrefundable advance payments made by the Company for research and development activities until the related goods are received or the related services are performed.

Research and development expenses are comprised of costs incurred in performing research and development activities, which may include salary, benefits and other employee-related expenses; share-based compensation expense; laboratory supplies and other direct expenses; facilities expenses; overhead expenses; third-party contractual costs relating to nonclinical studies and clinical trial activities and related contract manufacturing expenses, development of manufacturing processes and regulatory registration of third-party manufacturing facilities; licensing fees for the Company's product candidates; and other outside expenses.

### **General and Administrative Expenses**

The Company expenses general and administrative costs to operations as incurred. General and administrative expense consists of compensation, share-based compensation, benefits and other employee-related expenses for personnel in the Company's administrative, finance, legal, information technology, business development and human resource functions. Other costs include the legal costs of pursuing patent protection of the Company's intellectual property, general and administrative related facility costs, insurance costs and professional fees for accounting and legal services.

### **Patent Costs**

The Company incurred and recorded as operating expense legal and other fees related to patents of approximately \$0.4 million and \$0.1 million for three months ended March 31, 2019 and 2018, respectively. These costs were charged to general and administrative expenses as incurred.

### **Subsequent Events**

The Company considers events or transactions that have occurred after the balance sheet date of March 31, 2019, but prior to the filing of the financial statements with the Securities and Exchange Commission to provide additional evidence relative to certain estimates or to identify matters that require additional recognition or disclosure. Subsequent events have been evaluated through the filing of the financial statements accompanying this Quarterly Report on Form 10-Q (see Note 10).

### **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 combined financial statements, the Company did not adopt any new accounting pronouncements during the three months ended March 31, 2019 and 2018, that had a material effect on its combined financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"), which supersedes the lease accounting requirements in ASC Topic 840, *Leases*, and most industry-specific guidance with ASC Topic 842, *Leases*. ASU 2016-02 requires the identification of arrangements that should be accounted for as leases by lessees. In general, for lease arrangements exceeding a 12-month term, these arrangements must now be recognized as assets and liabilities on the balance sheet of the lessee. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization and interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. In July 2018, the FASB issued ASU No. 2018-10, *Leases (Topic 842)* ("ASU 2018-10"), *Codification Improvements* and ASU No. 2018-11, *Leases (Topic 842)* ("ASU 2018-11"), to provide additional guidance for the adoption of Topic 842. ASU 2018-10 clarifies certain provisions, and corrects unintended applications of the guidance, such as the rate

implicit in a lease, impairment of the net investment in a lease, lessee reassessment of lease classifications, lessor reassessment of lease term and purchase options, variable payments that depend on an index or rate and certain transition adjustments. The amendments in ASU 2018-11 will allow for an additional transition method, whereby at the adoption date the entity recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption, while the comparative period disclosures continue recognition under ASC Topic 840. Additionally, ASU 2018-11 includes a practical expedient for separating contract components for lessors. In December 2018, the FASB issued ASU No. 2018-20, *Leases (Topic 842)* (“ASU 2018-20”), *Narrow-Scope Improvements for Lessors*, which provided clarification for lessors on how to apply the new leases standard when accounting for sales taxes, certain lessor costs, and certain requirements related to variable payments in contracts. In March 2019, the FASB issued ASU No. 2019-01, *Leases (Topic 842)* (“ASU 2019-01”), *Codification Improvements*, which aligned the new leases guidance with existing guidance for fair value of the underlying asset by lessors that are not manufacturers or dealers. It also clarified an exemption for lessors and lessees from a certain interim disclosure requirement associated with adopting the board’s new lease accounting standard. The Company’s analysis includes, but is not limited to, reviewing existing leases, reviewing other service agreements for embedded leases, establishing policies and procedures, assessing potential disclosures and evaluating the impact of adoption on the Company’s combined financial statements. The Company adopted ASU 2016-02, ASU 2018-10, ASU 2018-11, ASU 2018-20, and ASU 2019-01 in the first quarter of 2019. The adoption of these standards did not have a material impact on the Company’s financial position and the related footnote disclosures as of and for the three months ended March 31, 2019 under the current basis of presentation. The Company expects the adoption of these standards to have a material impact on the Company’s financial position and related footnote disclosures in the second quarter of 2019, related to the commencement of its premises lease (see Note 10).

In October 2016, the FASB issued ASU No. 2016-16, *Accounting for Income Taxes: Intra-Entity Asset Transfers of Assets Other than Inventory* (“ASU 2016-16”). ASU 2016-16 eliminates the ability to defer the tax expense related to intra-entity asset transfers other than inventory. Under the new standard, entities should recognize the income tax consequences on an intra-entity transfer of an asset other than inventory when the transfer occurs. ASU 2016-16 is effective for fiscal periods beginning after December 15, 2018. The Company adopted this standard during the three months ended March 31, 2019. Adoption of this standard did not have a material impact on the Company’s financial position or results of operations.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-based Payments* (“ASU 2018-07”). ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning with the accounting for share-based payments to employees, with certain exceptions. Measurement of equity-classified nonemployee awards issued in exchange for goods or services used or consumed in an entity’s own operations will be fixed at the grant date, which may lower the cost and reduce volatility in the income statement. Entities also may use the expected term to measure nonemployee options or elect to use the contractual term as the expected term, on an award-by-award basis. ASU 2018-07 is effective for the fiscal periods beginning after December 15, 2018. The Company adopted this standard during the three months ended March 31, 2019. 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 is currently evaluating the potential impact that the adoption of ASU 2018-15 may have on the Company’s financial position and 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 combined financial statements upon adoption.

### **3. Property and Equipment**

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

	March 31, 2019	December 31, 2018
Laboratory equipment	\$ 18,477	\$ 17,753
Software	2,609	2,593
Construction in progress	2,785	741
Computer and office equipment	961	901
Gross property and equipment	<u>24,832</u>	<u>21,988</u>
Less: accumulated depreciation and amortization	<u>(16,017)</u>	<u>(15,491)</u>
Property and equipment, net	<u>\$ 8,815</u>	<u>\$ 6,497</u>

As of March 31, 2019 and December 31, 2018, all of the Company's property and equipment was located in Cambridge, Massachusetts.

Depreciation and amortization expense of the Company's property and equipment was approximately \$0.5 million and \$0.4 million for the three months ended March 31, 2019 and 2018, respectively.

#### 4. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued incentive compensation	\$ 1,250	\$ 4,889
Salaries	547	1,513
Accrued vacation	1,258	1,048
Professional fees	1,157	1,019
Workforce reduction charges	787	565
Other	560	770
	<u>\$ 5,559</u>	<u>\$ 9,804</u>

#### 5. Commitments and Contingencies

##### *Other Funding Commitments*

As of March 31, 2019, the Company has several on-going 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*

As permitted under Delaware law, Ironwood indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at Ironwood's request in such capacity, including any such officers who served as an officer or director of Cycleron prior to the Separation. The maximum potential amount of future payments Ironwood could be required to make is unlimited; however, Ironwood has directors' and officers' insurance coverage that is intended to limit its exposure and enable it to recover a portion of any future amounts paid. On September 6, 2018, Cycleron was incorporated in Massachusetts, and is subject to Massachusetts 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 March 31, 2019 or December 31, 2018.

## 6. Share-based Compensation Plans

Ironwood maintains certain share-based compensation programs for the benefit of its officers, directors and employees, including employees of Ironwood who became employees of Cycleron in connection with the Separation. Specifically, during the three months ended March 31, 2019 and 2018, Ironwood had two share-based compensation plans pursuant to which awards were made to employees of the Company: the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan ("2010 Equity Plan") and the Amended and Restated 2010 Employee Stock Purchase Plan ("2010 Purchase Plan"). Ironwood also had one share-based compensation plan under which there are outstanding awards available to employees of the Company, but from which no further awards will be made: the Amended and Restated 2005 Stock Incentive Plan ("2005 Equity Plan"). All awards granted under the programs consist of shares of Ironwood common stock. Accordingly, the amounts presented are not necessarily indicative of future share-based compensation and do not necessarily reflect the amount that Cycleron would have issued as an independent, publicly traded company for the periods presented.

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 believes are consistent and reasonable. Share-based compensation under Ironwood's incentive stock programs allocated to Cycleron is reflected in the Company's condensed combined statements of operations as follows for the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended	
	March 31,	
	2019	2018
Research and development	\$ 1,796	\$ 1,665
General and administrative	2,193	843
	<u>\$ 3,989</u>	<u>\$ 2,508</u>

Included in share-based compensation expense of approximately \$4.0 million and \$2.5 million, is approximately \$0.9 million and \$0.7 million of share-based compensation expense for employees that are directly attributable to Cycleron for the three months ended March 31, 2019 and 2018, respectively.

## 7. Defined Contribution Plan

Ironwood maintains 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 includes Ironwood employees who became Cycleron employees. Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. Ironwood contributions to the plan are at the sole discretion of Ironwood's board of directors. Currently, Ironwood provides a matching contribution of 75% of the employee's contributions, up to \$6,000 annually. 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. Included in compensation expense is approximately \$0.3 million and \$0.2 million of expenses for employees that are directly attributable to Cycleron for the three months ended March 31, 2019 and 2018, respectively.

## 8. Related Party Transactions

### *Relationship with Ironwood*

Historically, prior to April 1, 2019, the Company was managed and operated in the normal course of business under Ironwood. Accordingly, certain shared costs were allocated to the Company and reflected as expenses in the Company's stand-alone combined financial statements. The expenses reflected in the combined financial statements 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, and facilities.

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. This methodology is applied consistently between periods however the magnitude of the allocation will vary based on the relationship of Cycleron costs compared to those of Ironwood's other operations.

The allocated corporate costs included in the combined statements of operations were approximately \$6.8 million and \$3.6 million for the three months ended March 31, 2019 and 2018, respectively, and were included in general and administrative expenses for both periods.

#### *(b) Cash Management and Financing*

Cycleron participated in Ironwood's centralized cash management and financing programs. Disbursements were made through centralized accounts payable systems which are 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 Related Party Transactions*

Ironwood has and currently obtains health insurance services for its employees, including employees of Ironwood who became employees of Cycleron, from an insurance provider whose President and Chief Executive Officer became a member of Ironwood's Board of Directors in April 2016. Expenses related to insurance premiums were allocated to Cycleron using a pro-rata method based on internal project assignments and headcount, that management believes are consistent and reasonable. Insurance premiums allocated to Cycleron amounted to approximately \$0.5 million and approximately \$0.6 million for the three months ended March 31, 2019 and 2018, respectively, and is reflected in the Company's condensed combined statements of operations. Accordingly, the amounts presented are not necessarily indicative of future expense and do not necessarily reflect the results that Cycleron would have experienced as an independent company for the periods presented. At March 31, 2019 and December 31, 2018, the Company had no outstanding payable balance due to this related party.

Peter Hecht, Ironwood's former Chief Executive Officer and the Chief Executive Officer and board member of Cycleron, 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 Cycleron as part of the financing transaction completed by Cycleron on April 2, 2019. Mark Currie, Ironwood's former Chief Scientific Officer and President of Cycleron and board member of Ironwood, has invested \$4.0 million in Cycleron as part of this financing. Dr. Currie and certain other investors have funded a portion of their investment through sales of Ironwood common stock. Given the aforementioned director and officer affiliations with both Ironwood and Cycleron, these investments are considered to be related party transactions.

## 9. Workforce Reduction

On June 27, 2018, Ironwood, as part of its plans to separate its sGC business from its commercial and gastrointestinal business determined the initial organizational designs for the continuing Ironwood business and Cycleron,

including employees' roles and responsibilities. As part of this process Ironwood initiated, a reduction in its headquarter-based workforce by approximately 40 employees and substantially completed the reduction in its workforce during the year ending December 31, 2018. During the three months ended March 31, 2019, Ironwood did not record any costs related to this reduction in workforce.

On February 7, 2019, following further analysis of Ironwood's strategy and core business needs, and in an effort to further strengthen the operational efficiency of its organization, Ironwood commenced a reduction in its workforce by 35 employees, primarily based in the home office. Ironwood completed the reduction in its workforce during the first quarter of 2019. Employees expected to go to Cycleron were excluded from the workforce reduction; however certain charges associated with the reduction were allocated to Cycleron. During the three months ended March 31, 2019, Ironwood recorded approximately \$3.3 million in total costs related to this reduction in workforce for one-time employee severance and benefit costs. Expenses related to workforce reduction were allocated to Cycleron using a pro rata method based on internal project assignments and headcount, that management believes are consistent and reasonable. Workforce reduction charges allocated to Cycleron amounted to approximately \$0.5 million recorded in research and development expense and approximately \$0.1 million recorded in general and administrative expense for the three months ended March 31, 2019.

The following table summarizes the accrued liabilities activity allocated to Cycleron in connection with the reduction in workforce for the three months ended March 31, 2019 (in thousands):

	Amounts Accrued at December 31, 2018	Charges	Amount Paid	Amounts Accrued at March 31, 2019
June 2018 Reduction	565	—	268	297
February 2019 Reduction	—	580	90	490
<b>Total</b>	<b>\$ 565</b>	<b>\$ 580</b>	<b>\$ 358</b>	<b>\$ 787</b>

## 10. Subsequent Events

The Company has assessed subsequent events from the balance sheet date through May 13, 2019, the date at which the financial statements were available to be issued.

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, the Tax Matters Agreement, and the Employee Matters Agreement.

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

On April 1, 2019, 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 Cycleron 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. As a result of the Separation, the Company became an independent public company and commenced regular way trading under the symbol "CYCN" on the Nasdaq Global Select Market on April 2, 2019.

On April 2, 2019, the Company issued 11,817,165 shares of its common stock to accredited investors for gross proceeds of \$175 million (net proceeds of approximately \$165 million) pursuant to the Amended and Restated Common Stock Purchase Agreement. The Company received the funds associated with the sale of Private Placement Shares on April 2, 2019, and as a result, the substantial doubt surrounding the Company's ability to continue as a going concern (as discussed in Note 1) has been alleviated. As of April 2, 2019, the Company, though it expects negative cash flows to continue through 2019 as it continues the development and clinical stage testing of its product candidates and its discovery research programs, expects to be able to fund operating expenses and capital expenditure requirements through the first quarter of 2021.



Peter Hecht, Ironwood's former Chief Executive Officer and the Chief Executive Officer and board member of Cycleron, 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 Cycleron as part of this financing. Mark Currie, Ironwood's former Chief Scientific Officer and President of Cycleron and board member of Ironwood, has invested \$4.0 million in Cycleron as part of this financing. Dr. Currie and certain other investors have funded a portion of their investment through sales of Ironwood common stock. Given the aforementioned director and officer affiliations with both Ironwood and Cycleron, these investments are considered to be related party transactions.

On April 1, 2019, the Company entered into a direct lease (the "Lease") for its existing operating premises consisting of approximately 114,000 rentable square feet of office and lab space on the first and second floors. The Lease is for a term of 123 months with two five-year extension options and certain expansion rights. The Lease includes a letter of credit of \$7.7 million posted with the landlord as a security deposit. 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. As part of the Separation, certain improvements are being completed in the Company's leased premises. To accommodate the post-Separation completion of such improvements, on March 31, 2019, the Company entered into a short-term swing space sublease of approximately 24,000 rentable square feet in Ironwood's remaining premises to allow a portion of the Company's workforce to continue to operate while such improvements are completed. The sublease is for an initial one-month term with several one-month extension options. The Company is responsible for completing all work to separate the premises and to improve its directly leased premises.

On April 29, 2019, Andreas Busch, Ph.D. joined the Company as Chief Innovation Officer. Dr. Busch leads the Company's Innovation Center.

On May 3, 2019, the Company's 100% wholly owned Swiss entity, Cycleron GmbH was incorporated. The subsidiary is located in Zug, Switzerland and will support the Company's Innovation Center.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the unaudited condensed combined financial statements and the corresponding notes included in this Quarterly Report on Form 10-Q, as well as the audited combined financial statements as of December 31, 2017 and 2018 and corresponding notes included in the registration statement on Form S-1, filed with the Securities and Exchange Commission, or the SEC, on April 18, 2019. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions which reflect our current views with respect to, among other things, our business, operations and financial performance. See "Special Note Regarding Forward-Looking Statements." You should review the "Risk Factors" section in the registration statement on Form S-1 filed with the SEC on April 18, 2019, and elsewhere in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

### **Overview**

We are a clinical-stage biopharmaceutical company harnessing the power of soluble guanylate cyclase, or sGC, pharmacology to discover, develop and commercialize breakthrough treatments for serious and orphan diseases. Our focus is enabling the full therapeutic potential of next-generation sGC stimulators. Our strategy rests on a solid scientific foundation that is enabled by our people and capabilities, external collaborations and a responsive capital allocation approach.

We operate in one reportable business segment—human therapeutics.

### **Separation from Ironwood Pharmaceuticals**

In May 2018, Ironwood Pharmaceuticals, Inc., referred to herein as Ironwood or the Parent, announced its plans to separate its sGC business from its commercial and gastrointestinal business. In furtherance of this plan, on March 6, 2019, Ironwood's board of directors approved the distribution of all of the issued and outstanding shares of our common stock on the basis of one share of our common stock for every 10 shares of Ironwood common stock issued and outstanding on March 19, 2019, the record date for the distribution, which is referred to herein as the Distribution.

On January 7, 2019, in connection with the Distribution, we entered into a common stock purchase agreement with various investors, which agreement was subsequently amended and restated on February 25, 2019, which we refer to as the Amended and Restated Common Stock Purchase Agreement, pursuant to which, upon the completion of the Distribution, these investors have made an aggregate cash investment in us of \$175 million in exchange for shares of our common stock.

On April 1, 2019, 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 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 regular way 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.

On April 2, 2019, we issued 11,817,165 shares of our common stock, or the Private Placement Shares, to accredited investors for gross proceeds of \$175 million (net proceeds of approximately \$165 million) pursuant to the Amended and Restated Common Stock Purchase Agreement. We received the funds associated with the sale of the Private Placement Shares on April 2, 2019.

Cycleron's historical combined financial statements have been prepared on a stand-alone basis and are derived from Ironwood's combined financial statements and accounting records and are presented in conformity with U.S. GAAP.

Cyclerion's financial position, results of operations and cash flows historically operated, as part of Ironwood's financial position, results of operations and cash flows prior to and until the distribution of Cyclerion's common stock to Ironwood's stockholders. These historical combined financial statements may not be indicative of Cyclerion's future performance and do not necessarily reflect what Cyclerion's combined results of operations, financial condition and cash flows would have been had Cyclerion operated as a separate, publicly traded company during the periods presented. Cyclerion expects that changes will occur in its operating structure and its capitalization as a result of the Separation. See "The Separation and Distribution" included in the information statement attached as an exhibit to the registration statement on Form 10, as amended, filed with the SEC on March 11, 2019 for additional detail.

## Financial Overview

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

The core of our research and development strategy is to harness the power of sGC pharmacology to develop therapies for serious and orphan diseases.

*Olinciguat* is a once-daily, orally available vascular sGC stimulator that is well suited for the potential treatment of sickle cell disease, or SCD. We are conducting a Phase 2 study, STRONG-SCD, that is expected to enroll up to 88 patients. Based on a recently completed ascending dose clinical pharmacology study conducted in healthy volunteers, as well as blinded safety data from the ongoing STRONG SCD study, we plan to amend the STRONG-SCD study protocol to incorporate a fourth, higher dose level into the ongoing Phase 2 study, and add additional sites, including sites outside the U.S., to support enrollment into the newly added higher dose level. We believe that these intended changes will provide us with the opportunity to explore a broad range of tolerated doses and optimize our understanding of the therapeutic potential of olinciguat in sickle cell disease. With the addition of a higher dose level, we expect topline data from this study in mid-2020.

In June 2018, the U.S. Food and Drug Administration, or the FDA, granted Orphan Drug Designation to olinciguat for the treatment of patients with SCD. Orphan Drug Designation provides marketing exclusivity for seven years from the date of the product's approval for marketing and contributes to a significant reduction in development costs.

During the three months ended March 31, 2018, costs associated with olinciguat include clinical studies regarding achalasia, although we are not presently conducting further development activities for that indication.

*Praliciguat* is an orally administered, once-daily systemic sGC stimulator that is well suited for the potential treatment of serious cardiometabolic diseases given its very extensive distribution into tissues, particularly adipose, kidney, heart and liver. Praliciguat is currently in a dose-ranging Phase 2 study in adult patients with diabetic nephropathy for which enrollment recently completed with 156 patients. Additionally, Praliciguat is currently in a Phase 2 proof-of-concept trial in adult patients with heart failure with preserved ejection fraction (HFpEF), CAPACITY-HFpEF, for which enrollment recently completed with 196 patients. We expect topline data from each of these studies in the fourth quarter of 2019.

In September 2018, the U.S. FDA granted Fast Track Designation for praliciguat for the treatment of patients with HFpEF. A drug granted Fast Track Designation is eligible for several benefits, such as more frequent meetings with and communications from the FDA.

*IW-6463* is an orally administered central nervous system-penetrant sGC stimulator that, because it readily crosses the blood-brain barrier, affords an unprecedented opportunity to expand the utility of sGC pharmacology to serious neurodegenerative diseases. In January 2019, we initiated our first-in-human study of IW-6463. We expect topline data from this study in the fourth quarter of 2019.

*Liver, Lung and other Discovery Research.* Our discovery efforts are primarily focused on identifying, designing and developing sGC stimulators in serious and orphan diseases. sGC stimulation is a powerful mechanism that can broadly regulate blood flow, inflammation, fibrosis and metabolism. In diseases that are localized to specific organs or tissues, we believe that our organ-targeting strategy will maximize the efficacy of sGC pharmacology in key organs while reducing the

potential for dose-limiting hemodynamic effects sometimes observed with sGC stimulation. Our initial focus is on the liver and the lung due to the clear role of nitric oxide signaling in diseases with high unmet need that affect these organs.

The following table sets forth our research and development expenses related to our product pipeline, as well as employee and facility related costs allocated to research and development expense, for the three months ended March 31, 2019 and 2018. These product pipeline expenses relate primarily to external costs associated with nonclinical studies and clinical trial costs, which are presented by development candidates.

	Three Months Ended	
	March 31,	
	2019	2018
Development candidates (external costs):		
Praliciguat	\$ 5,855	\$ 3,460
Olinciguat	4,086	1,724
IW-6463	495	827
Discovery research	1,126	436
Total development candidates (external costs)	11,562	6,447
Personnel and related costs	8,998	9,423
Facilities and others	5,844	5,644
Total research and development expenses	\$ 26,404	\$ 21,514

The lengthy process of securing regulatory approvals for new drugs requires the expenditure of substantial resources. 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 that come with the development of pharmaceutical products, 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 duration of clinical trials may vary substantially according to the type and complexity of the product candidate and may take longer than expected.
- The FDA and comparable agencies in foreign countries 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 negatively impact us.

As a result of the factors discussed above, including the factors discussed under the “Risk Factors” section of the registration statement on Form S-1, filed with the SEC on April 18, 2019, 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, communications 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 the separation of the Company 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 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 combined financial statements, and the amounts of expenses during the reported periods. Significant estimates and assumptions in our combined financial statements include those related to allocations of expenses, assets and liabilities from Ironwood’s historical financials; 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 the accounting policy noted below 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 combined financial statements elsewhere in this Quarterly Report.

### ***Research and Development Expense***

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 combined financial statements appearing elsewhere in this Quarterly Report.

### **Results of Operations**

Historically, our operations have been managed in the normal course of business as part of Ironwood. Accordingly, certain shared costs have been allocated to us and reflected as expenses in the stand-alone combined financial statements, as described in greater detail in the notes to the condensed combined financial statements appearing elsewhere in this Quarterly Report. We considered the allocation methodologies used to be a reasonable and appropriate reflection of the historical Ironwood expenses attributable to us for purposes of the stand-alone financial statements. The expenses reflected in the condensed combined financial statements may not be indicative of expenses that will be incurred by us in the future. The following discussion summarizes the key factors we believed are necessary for an understanding of our condensed combined financial statements.

	Three Months Ended March 31,			
	2019	2018	Change	
	(in thousands)		\$	%
Cost and expenses:				
Research and development	\$ 26,404	\$ 21,514	\$ 4,890	23%
General and administrative	10,977	3,769	7,208	191%
Total cost and expenses	37,381	25,283	\$ 12,098	48%
Loss from operations	(37,381)	(25,283)		
Net loss	\$ (37,381)	\$ (25,283)		

*Research and Development Expense.* The increase in research and development expense of approximately \$4.9 million for the three months ended March 31, 2019, compared to the three months ended March 31, 2018, was primarily related to an increase of approximately \$4.6 million in external research costs associated with clinical advancements for our product candidates, including costs associated with initiation of STRONG-SCD, a Phase 2 clinical trial for olinciguat; an increase of approximately \$0.7 million in operating costs, including facilities, allocated to research and development; an increase of approximately \$0.5 million related to workforce reduction charges associated with the organizational design of the group; offset by a decrease of approximately \$0.9 million in compensation, benefits and other employee-related expenses.

*General and Administrative Expense.* General and administrative expenses increased approximately \$7.2 million for the three months ended March 31, 2019, compared to the three months ended March 31, 2018, primarily as a result of an increase of approximately \$4.1 million in non-recurring costs associated with the Company's Separation; an increase of approximately \$1.8 million in compensation, benefits and other employee-related expenses allocated from Ironwood; an increase of approximately \$0.8 million related to allocated professional service costs; and an increase of approximately \$0.5 million in allocated costs related to facilities and information technology infrastructure.

### Liquidity and Capital Resources

Historically, the primary source of liquidity for our business was cash flow allocated to Cycleron from Ironwood. Prior to the Separation, transfers of cash to and from Ironwood have been reflected in Net Parent Investment in the historical combined balance sheets, statements of cash flows and statements of changes in Net Parent Investment. We have not reported cash or cash equivalents for the periods presented in the condensed combined balance sheets as Ironwood funded our cash needs through the date of the Separation.

After giving effect to the completion of the separation on April 1, 2019, and the closing of the private placement on April 2, 2019, our cash and cash equivalents were approximately \$165 million, which is equal to the aggregate cash investment in the private placement, after the payment of certain separation-related expenses. Subsequent to the separation, we no longer participate in Ironwood's centralized cash management or benefit from direct funding from Ironwood. Our ability to fund our operations and capital needs will depend on our ongoing 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.

### Going Concern

The financial statements have been prepared assuming that we will continue as a going concern. We have experienced negative cash flows from operations for all historical periods presented and expect these losses to continue into the foreseeable future as we begin to operate as a separate, publicly traded company and continue the development and clinical testing of our lead product candidates, olinciguat, pralicyguat and IW-6463, as well as our discovery research programs for serious and orphan liver and lung diseases. These conditions raise substantial doubt about our ability to continue as a going concern as of March 31, 2019. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Subsequent to March 31, 2019, certain events have occurred, and have been documented in Note 10 Subsequent Events of the accompanying financial statements, which have caused us to re-evaluate our ability as a going concern. On

April 1, 2019, Ironwood completed the previously announced separation of its soluble guanylate cyclase 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 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. As a result of the Separation, we became an independent public company and commenced regular way trading under the symbol "CYCN" on the Nasdaq Global Select Market on April 2, 2019. On April 2, 2019, we issued 11,817,165 shares of our common stock, or the Private Placement Shares, to accredited investors for gross proceeds of \$175 million (net proceeds of \$165 million) pursuant to the Amended and Restated Common Stock Purchase Agreement. We received the funds associated with the sale of Private Placement Shares on April 2, 2019, and as a result, the substantial doubt surrounding our ability to continue as a going concern (as discussed in Note 1) has been alleviated. As of April 2, 2019, though we expect negative cash flows to continue through 2019 as we continue the development and clinical stage testing of our product candidates and our discovery research programs, we expect to be able to fund operating expenses and capital expenditure requirements through the first quarter of 2021.

## Cash Flows

The following is a summary of cash flows for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,			
	2019	2018		Change
	(in millions)		\$	%
Net cash used in operating activities	\$ (34.3)	\$ (26.4)	\$ (7.9)	30%
Net cash used in investing activities	(1.8)	(0.2)	(1.6)	800%
Net cash provided by financing activities	36.1	26.6	9.5	36%

### Cash Flows from Operating Activities

Net cash used in operating activities totaled approximately \$34.3 million for the three months ended March 31, 2019. The primary uses of cash were our net loss of \$37.4 million and changes in assets and liabilities of approximately \$5.3 million resulting from a decrease in accrued expenses and other current liabilities and approximately \$0.1 million resulting from an increase in prepaid expenses. These uses of cash were primarily offset by non-cash items of approximately \$4.5 million, including approximately \$4.0 million in share-based compensation expense and approximately \$0.5 million in depreciation and amortization expense of property and equipment, and changes in liabilities of approximately \$4.0 million resulting primarily from increases in accounts payable, accrued research and development costs and other liabilities of approximately \$2.9 million, \$1.0 million, and \$0.1 million, respectively.

Net cash used in operating activities totaled approximately \$26.4 million for the three months ended March 31, 2018. The primary uses of cash were our net loss of \$25.3 million and changes in liabilities of approximately \$5.3 million resulting primarily from decreases in accrued research and development costs and accrued expenses and other liabilities of \$2.2 million and \$3.1 million, respectively. These uses of cash were primarily offset by non-cash expenses of approximately \$2.9 million, including approximately \$2.5 million in share-based compensation expense and approximately \$0.4 million in depreciation and amortization expense of property and equipment, and changes in liabilities of approximately \$1.3 million resulting from an increase in accounts payable.

### Cash Flows from Investing Activities

Cash used in investing activities for the three months ended March 31, 2019 totaled approximately \$1.8 million, resulting primarily from payments for leasehold improvements.

Cash used in investing activities for the three months ended March 31, 2018 totaled approximately \$0.2 million, resulting from the purchase of property and equipment, primarily computer software and laboratory equipment.

## Cash Flows from Financing Activities

As Ironwood managed our cash and financing arrangements for the periods presented, all excess cash generated through earnings was deemed remitted to Ironwood and all sources of cash were deemed funded by Ironwood.

Cash provided by financing activities for the three months ended March 31, 2019 was approximately \$36.1 million, as compared to approximately \$26.6 million for the three months ended March 31, 2018, primarily as a result of cash transferred to us from Ironwood based on changes in our cash used for operations.

## Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, following the distribution, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase as we:

- leverage our programs to continue advancing our product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and our operations as a public company; and
- maintain, expand and protect our intellectual property portfolio.

We believe that our initial cash capitalization received as a result of the closing of the private placement will enable us to fund our operating expenses and capital expenditure requirements through the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Certain Relationships and Related Person Transactions—Private Placement” section of the registration statement on Form S-1, filed with the SEC on April 18, 2019.

Because of the numerous 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 future funding requirements will depend on, and could increase 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;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the 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 the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with 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” section of the registration statement on Form S-1, filed with the SEC on April 18, 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, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common shareholder. 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 or liabilities or obligations pertaining to uncertain tax positions from our summary of contractual commitments and obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of March 31, 2019, we had no uncertain tax positions.

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

As of March 31, 2019, we have several ongoing studies in various clinical trial stages. Our most significant clinical trial expenditures are to 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**

The condensed combined financial statements reflect our operating results and financial position as it was operated by Ironwood, rather than as an independent company. We will incur additional ongoing operating expenses to operate as an independent company. These costs will 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 will also incur non-recurring expenses and non-recurring capital expenditures.

As an independent company, our information technology operating costs may be higher than the costs allocated in the historical combined financial statements. In addition, we will incur non-recurring expenses and capital expenditures to establish independent information technology systems.

We continue to establish our accounting, legal, human resources and other administrative infrastructure. We have entered into a transition services agreement with Ironwood that will provide us with certain services and resources related to corporate functions for an initial term of up to two years (as applicable). This transition services agreement will help us to operate our business independently prior to establishing stand-alone infrastructure. During the transition from Ironwood, we will incur non-recurring expenses to expand our infrastructure.

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 during these periods would have depended on various factors, including organizational design, outsourcing and other strategic decisions related to corporate functions, information technology and back office infrastructure.

### **Transactions with Related and Certain Other Parties**

Prior to or concurrently with the completion of the Separation, we entered into certain agreements with Ironwood resulting from and relating to the Separation, including a separation agreement, two transition services agreements, a development agreement, a tax matters agreement, an intellectual property license agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail under “Certain Relationships and Related Person Transactions” appearing in the registration statement on Form S-1, filed with the SEC on April 18, 2019.

### **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 combined financial statements appearing elsewhere in this Quarterly Report.

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

#### **Interest Rate and Other Risks**

During the three months ending March 31, 2019, Cyclerion participated in Ironwood's centralized treasury management including centralized cash management and overall financing arrangements. Cyclerion did not report cash and equivalents on its balance sheet due to its participation in Ironwood's centralized treasury management. No debt or interest expense was allocated to Cyclerion because Cyclerion was not the legal obligor of the debt and the borrowings were not directly attributable to Cyclerion's business.

#### **Effects of Inflation**

We do not believe that inflation and changing prices over the three months ended March 31, 2019, and 2018 had a significant impact on our results of operations.

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

#### **Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, or the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit 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 us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control**

There were no changes during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II — OTHER INFORMATION**

### **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 the registration statement on Form S-1 filed with the SEC on April 18, 2019. There have been no material changes from the factors disclosed in such registration statement, although we may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

### **Item 6. Exhibits**

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

## EXHIBIT INDEX

Exhibit Number	Exhibit Description
2.1	<a href="#">Separation Agreement, dated March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K filed on April 2, 2019 (File No. 001-38787))</a>
3.1	<a href="#">Restated Articles of Organization of Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))</a>
3.2	<a href="#">Amended and Restated Bylaws of Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 4.2 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))</a>
10.1	<a href="#">Tax Matters Agreement, dated March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed on April 2, 2019 (File No. 001-38787))</a>
10.2+	<a href="#">Employee Matters Agreement, dated March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cycleron Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed on April 2, 2019 (File No. 001-38787))</a>
10.3+	<a href="#">Cycleron Therapeutics, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.3 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))</a>
10.4+	<a href="#">Cycleron Therapeutics, Inc. 2019 Equity Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 4.4 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))</a>
10.5+	<a href="#">Cycleron Therapeutics, Inc. Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 4.5 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))</a>
10.6+	<a href="#">Cycleron Therapeutics, Inc. Amended and Restated 2005 Stock Incentive Plan (incorporated by reference to Exhibit 4.6 to Registration Statement on Form S-8 filed on March 29, 2019 (File No. 333-230615))</a>
10.7	<a href="#">Amended and Restated Common Stock Purchase Agreement, dated as of February 25, 2019, by and between Cycleron Therapeutics, Inc. and the investors party thereto (incorporated by reference to Exhibit 10.19 on Amendment No. 1 to Form 10 filed on March 4, 2019 (File No. 001-38787))</a>
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1*	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
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.

\* The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

+ Management contract or compensatory plan or arrangement.

**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 Huyett  
Name: William Huyett  
Title: *Chief Financial Officer (Principal Financial and Accounting Officer)*

Date: May 13, 2019

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: May 13, 2019

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 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: May 13, 2019

By: /s/ William Huyett

Name: William 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 Cyclarion Therapeutics, Inc. for the period ended March 31, 2019 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 Cyclarion Therapeutics, Inc.

Date: May 13, 2019

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 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 Cycleron Therapeutics, Inc. for the period ended March 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Cycleron Therapeutics, Inc.

Date: May 13, 2019

By: /s/ William Huyett

Name: William Huyett

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

---