

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 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

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)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 6, 2019, the registrant had 27,468,904 shares of common stock, no par value, outstanding.

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**CYCLERION PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED SEPTEMBER 30, 2019**  
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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 and IW-6463;
- our interpretation of the data from the praliciquat Phase 2 clinical trial in patients with diabetic nephropathy, including regarding the clinical site whose results appear to be inconsistent with the overall study population;
- the potential of further evaluation of praliciquat for diabetic nephropathy;
- the potential commercial opportunities of praliciquat, including the potential for a future out-license of praliciquat by us;
- our ability to identify a licensee and to negotiate and execute an out-license or similar agreement with respect to praliciquat;
- the impact on our business of our recent workforce and expense reduction initiatives;
- our plans with respect to the development, manufacture or sale of our product candidates and the associated timing thereof, including the design and results of pre-clinical and clinical studies;
- the safety profile and related adverse events of our product candidates;
- the efficacy and perceived therapeutic benefits of our product candidates 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

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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 Consolidated and Combined Balance Sheets

(In thousands except share and per share data)

(Unaudited)

	September 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 117,034	\$ —
Related party accounts receivable	1,440	—
Prepaid expenses	2,164	867
Other current assets	68	12
Total current assets	<u>120,706</u>	<u>879</u>
Restricted cash	7,726	—
Property and equipment, net	12,114	6,497
Operating lease right-of-use asset	69,158	—
Other assets	—	25
Total assets	<u>\$ 209,704</u>	<u>\$ 7,401</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 4,818	\$ 2,781
Related party accounts payable	187	—
Accrued research and development costs	3,543	5,261
Accrued expenses and other current liabilities	7,298	9,804
Current portion of operating lease liabilities	3,250	—
Total current liabilities	<u>19,096</u>	<u>17,846</u>
Operating lease liabilities, net of current portion	71,411	—
Stockholders' equity (deficit)		
Common stock, \$0.0 par value, 400,000,000 shares authorized and 27,468,445 issued and outstanding at September 30, 2019 and no shares issued or outstanding at December 31, 2018	—	—
Accumulated deficit	(59,572)	—
Net parent investment	—	(10,445)
Paid-in capital	178,768	—
Accumulated other comprehensive income (loss)	1	—
Total stockholders' equity (deficit)	<u>119,197</u>	<u>(10,445)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 209,704</u>	<u>\$ 7,401</u>

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

Cyclerion Therapeutics, Inc.

Condensed Consolidated and Combined Statements of Operations and Comprehensive Loss

(In thousands except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue from related party	\$ 1,398	\$ —	\$ 3,026	\$ —
Cost and expenses:				
Research and development	22,295	21,499	74,458	65,264
General and administrative	7,119	7,787	27,019	19,086
Total cost and expenses	29,414	29,286	101,477	84,350
Loss from operations	(28,016)	(29,286)	(98,451)	(84,350)
Interest and investment income	699	—	1,498	—
Net loss	\$ (27,317)	\$ (29,286)	\$ (96,953)	\$ (84,350)
Net loss per share:				
Basic and diluted net loss per share	\$ (1.00)	\$ (1.07)	\$ (3.54)	\$ (3.08)
Weighted average shares used in calculating:				
Basic and diluted net loss per share	27,434	27,380	27,380	27,380
<b>Other comprehensive loss:</b>				
Net loss	\$ (27,317)	\$ (29,286)	\$ (96,953)	\$ (84,350)
Other comprehensive loss:				
Foreign currency translation adjustment	1	—	1	—
Total other comprehensive loss	1	—	1	—
Comprehensive loss	\$ (27,316)	\$ (29,286)	\$ (96,952)	\$ (84,350)

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

Cyclerion Therapeutics, Inc.

Condensed Consolidated and Combined Statements of Stockholders' Equity (Deficit)

(In thousands except per share data)

(Unaudited)

	Common Stock		Net Parent Company Investment	Paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total Stockholders' equity (deficit)
	Shares	Amount					
<b>Balance at December 31, 2017</b>	—	\$ —	\$ (8,567)	\$ —	\$ —	\$ —	\$ (8,567)
Net loss	—	—	(84,350)	—	—	—	(84,350)
Net transfers from Ironwood	—	—	75,973	—	—	—	75,973
Ironwood allocation - share-based compensation	—	—	8,824	—	—	—	8,824
<b>Balance at September 30, 2018</b>	—	\$ —	\$ (8,120)	\$ —	\$ —	\$ —	\$ (8,120)
<b>Balance at December 31, 2018</b>	—	\$ —	\$ (10,445)	\$ —	\$ —	\$ —	\$ (10,445)
Net loss	—	—	(37,381)	—	(59,572)	—	(96,953)
Net transfers from Ironwood	—	—	38,687	—	—	—	38,687
Ironwood allocation - share-based compensation	—	—	3,989	—	—	—	3,989
Separation-related adjustments	—	—	7,752	—	—	—	7,752
Reclassification of net parent company investment	—	—	(2,602)	2,602	—	—	—
Distribution of common stock by Ironwood upon separation	15,562	—	—	—	—	—	—
Issuance of common stock - private placement, net of fees	11,817	—	—	164,622	—	—	164,622
Issuance of common stock upon exercise of stock options, RSUs and employee stock purchase plan	67	—	—	372	—	—	372
Issuance of common stock awards	22	—	—	—	—	—	—
Share-based compensation expense related to issuance of stock options and RSUs to employees and employee stock purchase plan	—	—	—	11,172	—	—	11,172
Foreign currency translation adjustment	—	—	—	—	—	1	1
<b>Balance at September 30, 2019</b>	<u>27,468</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 178,768</u>	<u>\$ (59,572)</u>	<u>\$ 1</u>	<u>\$ 119,197</u>

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



Cyclerion Therapeutics, Inc.

Condensed Consolidated and Combined Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2019	2018
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (96,953)	\$ (84,350)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	2,047	1,062
Loss (gain) on disposal of property and equipment	76	—
Share-based compensation expense	15,161	8,824
Changes in operating assets and liabilities:		
Related party accounts receivable	(1,440)	—
Prepaid expenses	(1,297)	551
Other current assets	(49)	(154)
Operating lease assets	2,108	—
Other assets	25	44
Accounts payable	1,942	1,142
Related party accounts payable	187	—
Accrued research and development costs	(1,719)	(997)
Operating lease liabilities	3,395	—
Accrued expenses and other current liabilities	(3,535)	(473)
<b>Net cash (used in) operating activities</b>	<b>(80,052)</b>	<b>(74,351)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(6,714)	(1,622)
Proceeds from sale of property and equipment	99	—
<b>Net cash (used in) investing activities</b>	<b>(6,615)</b>	<b>(1,622)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Gross proceeds from private placement	175,000	—
Costs associated with private placement	(10,378)	—
Proceeds from exercises of stock options and ESPP	365	—
Transfers from Ironwood	46,439	75,973
<b>Net cash provided by financing activities</b>	<b>211,426</b>	<b>75,973</b>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1	—
Net increase in cash, cash equivalents and restricted cash	124,760	—
Cash, cash equivalents and restricted cash, beginning of period	—	—
Cash, cash equivalents and restricted cash, end of period	<u>\$ 124,760</u>	<u>\$ —</u>
<b>Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated and combined balance sheets</b>		
Cash and cash equivalents	\$ 117,034	\$ —
Restricted cash	7,726	—
Total cash, cash equivalents and restricted cash	<u>\$ 124,760</u>	<u>\$ —</u>

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

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

**1. Nature of Business**

**Nature of Operations**

Cyclerion Therapeutics, Inc. (“Cyclerion” 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.

Cyclerion GmbH, a wholly owned subsidiary, was incorporated in Zug, Switzerland on May 3, 2019. Cyclerion GmbH is an operational entity with one employee who is the Company’s Chief Innovation Officer. The functional currency is the Swiss franc.

**The Separation**

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

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

On April 2, 2019, the Company issued 11,817,165 shares (“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, dated as of February 25, 2019, by and among the Company and the selling stockholders listed therein (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 Company did not operate as a separate, stand-alone entity for the full period covered by the interim consolidated and combined financial statements. The Company’s consolidated balance sheet as of September 30, 2019 and consolidated statement of operations and comprehensive loss for the three months ended September 30, 2019 consist of the consolidated balances of Cyclerion as prepared on a stand-alone basis. The Company’s combined balance sheet as of December 31, 2018 and consolidated and combined statements of operations and comprehensive loss for the nine months ended September 30, 2019 and the three and nine months ended September 30, 2018, as well as our statements of cash flows for the nine months ended September 30, 2019 and 2018, respectively, have been prepared on a “carve out” basis for the periods and dates prior to the Separation on April 1, 2019.

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

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

These unaudited condensed consolidated and combined financial statements of Cyclерion reflect the assets, liabilities, and expenses directly attributable to Cyclерion, 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 Cyclерion, as discussed further below. As such, these allocations may not be indicative of the actual amounts that would have been recorded had Cyclерion operated as an independent, publicly traded company for the periods presented.

During the nine months ended September 30, 2019, the Company recorded approximately \$7.8 million in Separation-related adjustments in its condensed consolidated and combined statements of stockholders' equity (deficit). The Separation-related adjustments primarily related to differences between assets and liabilities transferred to Cyclерion as a result of the Separation and assets and liabilities reported in the Company's combined balance sheet as of March 31, 2019.

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

Prior to the Separation, Cyclерion's combined financial statements included an allocation of expenses related to certain Ironwood corporate functions, including senior management, legal, human resources, finance, information technology and quality assurance. These expenses were allocated to Cyclерion 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 Cyclерion operated as an independent, publicly traded company for the periods presented.

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

### **Going Concern**

At each reporting period, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company's evaluation entails analyzing prospective operating budgets and forecasts for expectations of the Company's cash needs and comparing those needs to the current cash and cash equivalent balances. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by the Company's plans or when its plans alleviate substantial doubt about the Company's ability to continue as a going concern.

The Company has experienced negative operating cash flows for all historical periods presented and it expects these losses to continue into the foreseeable future as the Company continues the development and clinical testing of the product candidates, olinciguat, and IW-6463, and its discovery research programs, as well as the close-out of the recently completed praliguat studies. On April 2, 2019, the Company issued 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. The funds associated with the sale of Private Placement Shares were received by the Company on April 2, 2019.

After considering the Company's current research and development plans and the timing expectations related to the progress of its programs, and after considering its existing cash and cash equivalents as of September 30, 2019, the Company did not identify conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these financial statements were issued.

## 2. Summary of Significant Accounting Policies

### Principles of Consolidation

The accompanying condensed consolidated and combined financial statements include the accounts of Cycleron and its wholly owned subsidiary as of September 30, 2019.

### 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 consolidated and 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 consolidated and combined financial statements, and the amounts of expenses during the reported periods. On an ongoing basis, the Company's management evaluates its estimates, judgments and methodologies. Significant estimates and assumptions in the condensed consolidated and 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.

### Fair Value of Investment Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

### Foreign Currency Translation Adjustment

The functional currency of the Company's foreign subsidiary is its local currency, the Swiss franc. The assets and liabilities of the Company's foreign subsidiary are translated into U.S. dollars at exchange rates in effect at the balance sheet date. Income and expense items are translated at the average exchange rates prevailing during the period. The cumulative translation effect for the Company's foreign subsidiary is included as a foreign currency translation adjustment in stockholders' equity (deficit) and as a component of comprehensive loss.

The Company's intercompany accounts are typically denominated in the functional currency of the foreign subsidiary. Gains and losses resulting from the remeasurement of intercompany balances are recorded in the consolidated statements of operations.

### Related Party Accounts Receivable

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices. The Company's receivables primarily relate to amounts earned under a development agreement with Ironwood. The Company believes

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that credit risks associated with Ironwood are not significant. To date, the Company has not had any significant write-offs of bad debt and the Company did not have an allowance for doubtful accounts as of September 30, 2019.

### **Impairment of Long-Lived Asset**

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.

### **Leases**

Effective January 1, 2019, the Company adopted Accounting Standards Codification ("ASC") Topic 842, *Leases* ("ASC 842") using the optional transition method. The adoption of ASC 842 represents a change in accounting principle that aims to increase transparency and comparability among organizations by requiring the recognition of right-of-use assets and lease liabilities on the balance sheet for both operating and finance leases. In addition, the standard requires enhanced disclosures that meet the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases. The reported results for the nine months ended September 30, 2019 reflect the application of ASC 842 guidance, while the reported results for prior periods were prepared in conjunction with ASC 840, *Leases* ("ASC 840").

The recognition of right-of-use assets and lease liabilities related to the Company's operating leases under ASC 842 has had a material impact on the Company's condensed consolidated and combined financial statements.

As part of the ASC 842 adoption, the Company has used certain practical expedients outlined in the guidance. These practical expedients include:

- Account policy election to use the short-term lease exception by asset class;
- Election of the practical expedient package during transition, which includes:
  - An entity need not reassess whether any expired or existing contracts are or contain leases.
  - An entity need not reassess the classification for any expired or existing leases. As a result, all leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases under ASC 842, and all leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases under ASC 842.
  - An entity need not reassess initial direct costs for any existing leases.

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

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

Lease cost is recognized on a straight-line basis over the lease term, and includes amounts related to short-term leases.

### **Revenue**

Upon executing a revenue generating arrangement, the Company assesses whether it is probable the Company will collect consideration in exchange for the good or service it transfers to the customer. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), it performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. The Company must develop assumptions that require significant judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The

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assumptions that are used to determine the stand-alone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

The Company generates revenue from a development agreement with Ironwood, pursuant to which the Company provides certain research and development services with respect to certain of Ironwood's products and product candidates. Such research and development activities are governed by a joint steering committee composed of representatives of both companies. Services performed are invoiced at a mutually agreed upon rate and the initial term of the agreement is two years from the date of Separation and automatically renews for one year unless either party notifies the other at least six months prior to the expiration.

### **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; 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.

### **Income taxes**

In accordance with ASC 270, Interim Reporting, and ASC 740, Income Taxes, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and nine months ended September 30, 2019 and 2018, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of September 30, 2019 and December 31, 2018, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

Prior to the Separation, income taxes included current and deferred income taxes of Ironwood allocated to the Company's stand-alone financials. In accordance with the tax matters agreement with Ironwood, Cycleron is responsible for its own portion of income taxes beginning after the Separation date.

### **Subsequent Events**

The Company considers events or transactions that have occurred after the balance sheet date of September 30, 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 13, *Subsequent Events*).

### **New Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Except as discussed elsewhere in the notes to the consolidated and combined financial statements, the Company did not adopt any new accounting pronouncements during the nine months ended September 30, 2019 and 2018, that had a material effect on its consolidated and 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

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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 consolidated and 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.

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments* (“ASU 2019-04”) and ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* (“ASU 2019-05”) to provide additional guidance on the adoption of ASU 2016-13. ASU 2019-04 added Topic 326, Financial Instruments—Credit Losses, and made several amendments to the codification and also modified the accounting for available-for-sale debt securities. ASU 2019-05 provides targeted transition relief by providing an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. ASU 2016-13, ASU 2019-04 and ASU 2019-05 are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of these ASUs will have on the Company’s financial position and results of operations.

In 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 first quarter of 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 first quarter of 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. 2018-13, *Fair Value Measurement (“ASU 2018-13”): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement* (“ASU 2018-13”) which amends the disclosure requirements for fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2018-13 may have on the Company’s financial position and results of operations.

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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 consolidated and combined financial statements upon adoption.

### **3. Related Party - Agreements and Transactions with Ironwood**

#### *Relationship with Ironwood*

Ironwood became a related party when Mark Currie, Ironwood's former Chief Scientific Officer and the Company's President, joined Ironwood's board in April 2019 following the Separation.

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, facilities and Separation-related costs.

A portion of these costs benefited Cycleron and have been allocated to Cycleron using a pro-rata method based on project related costs, headcount, or other measures that management believes are consistent and reasonable. 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 corporate costs allocated to Cycleron, prior to the Separation, and included in the combined statements of operations were approximately \$6.8 million, \$7.5 million and \$18.3 million for the three months ended March 31, 2019 and the three and nine months ended September 30, 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 prior to the Separation. Disbursements were made through centralized accounts payable systems operated by Ironwood. Cash receipts were transferred to centralized accounts, also maintained by Ironwood. As cash is disbursed and received by Ironwood, it was accounted for by Cycleron through net parent investment. All obligations were financed by Ironwood and financing decisions were determined by central Ironwood treasury operations until the Separation.

#### *Other Transactions with Ironwood*

As part of the Separation from Ironwood, the Company entered into transition services agreements and a development agreement with Ironwood.

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



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expenses that was not material and approximately \$0.1 million for activities related to the transition services agreements for the three and six months ended September 30, 2019.

Under the development agreement, the Company provides certain research and development services to Ironwood at mutually agreed upon rates and the amounts earned are recorded as revenue from related party. Such research and development activities are governed by a joint steering committee composed of representatives of both Ironwood and the Company. The Company recorded approximately \$1.4 million and \$3.0 million in revenue from related party for services provided under the development agreement for the three and six months ended September 30, 2019, respectively.

In accordance with the Separation Agreement, there were certain other transactions and adjustments post-Separation between the Company and Ironwood. The total amount due from Ironwood at September 30, 2019 was approximately \$1.4 million, primarily from the development agreement, and is reflected as related party accounts receivable. The total amount due to Ironwood at September 30, 2019 was approximately \$0.2 million. During the three months ended September 30, 2019, Cycleron paid Ironwood approximately \$1.3 million associated with tenant improvement reimbursement provisions in accordance with the Separation Agreement.

Ironwood has obtained 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. Prior to the Separation, 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 for the three months ended March 31, 2019 and approximately \$0.5 million and \$1.6 million for the three and nine months ended September 30, 2018, respectively, and is reflected in the Company's condensed consolidated and 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.

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 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.

#### 4. Fair Value of Financial Instruments

The Company's cash equivalents are generally classified within Level 1 of the fair value hierarchy. The following table presents information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of September 30, 2019 using: (in thousands)			
	Level 1	Level 2	Level 3	Total
<b>Cash equivalents:</b>				
Money market funds	\$ 20,958	\$ —	\$ —	\$ 20,958
Repurchase Agreements	92,506	—	—	92,506
Total cash equivalents	\$ 113,464	\$ —	\$ —	\$ 113,464

## 5. Property and Equipment

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

	September 30, 2019	December 31, 2018
Laboratory equipment	\$ 16,297	\$ 17,753
Software	2,232	2,593
Construction in progress	33	741
Computer and office equipment	1,890	901
Leasehold improvements	22,624	0
Gross property and equipment	43,076	21,988
Less: accumulated depreciation and amortization	(30,962)	(15,491)
Property and equipment, net	<u>\$ 12,114</u>	<u>\$ 6,497</u>

As of September 30, 2019, and December 31, 2018, Company's property and equipment was primarily located in Cambridge, Massachusetts.

Depreciation and amortization expense of the Company's property and equipment was approximately \$0.7 million and \$0.4 million for the three months ended September 30, 2019 and 2018, respectively, and approximately \$2.0 million and \$1.1 million for the nine months ended September 30, 2019 and 2018, respectively. Fixed asset purchases included in accounts payable and accrued expenses was approximately \$0.1 million and \$1.2 million at September 30, 2019 and 2018, respectively.

## 6. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued incentive compensation	\$ 3,419	\$ 4,889
Salaries	1,687	1,513
Accrued vacation	1,271	1,048
Professional fees	885	1,019
Workforce reduction charges	—	565
Other	36	770
	<u>\$ 7,298</u>	<u>\$ 9,804</u>

## 7. Commitments and Contingencies

### *Other Funding Commitments*

As of September 30, 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*

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

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The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, clinical sites and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreements. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal. Accordingly, the Company did not have any liabilities recorded for these obligations as of September 30, 2019 or December 31, 2018.

### **8. Leases**

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

On April 1, 2019, the Company entered into a direct operating lease (the "HQ Lease") for its existing premises located at 301 Binney Street, Cambridge, MA consisting of approximately 114,000 rentable square feet of office and lab space on the first and second floors. The HQ Lease is for a term of 123 months with two five-year extension options and certain expansion rights. The HQ Lease includes a letter of credit of \$7.7 million posted with the landlord as a security deposit, which is collateralized by a money market account recorded as restricted cash on the Company's condensed consolidated balance sheets as of September 30, 2019. Cyclcrion has also entered into customary non-disturbance arrangements with the building landlord's mortgagee and with the property ground lessor recognizing Cyclcrion's leasehold interest in this property.

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

The Company recorded the liability associated with the HQ Lease at the present value of the lease payments not yet paid, discounted using the discount rate for the HQ Lease established at the commencement date. As the HQ Lease does not provide an implicit rate, the Company had to estimate the incremental borrowing rate, or IBR, as of the commencement date. The IBR is defined under ASC 842 as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments in a similar economic environment. The Company determined its IBR to be 10.9%, which was used to discount the remaining lease payments over the remaining lease term and recorded a lease liability of \$71.3 million on April 1, 2019. This lease liability will be amortized over the remaining lease term in an amount equal to the difference between the cash rent paid and the monthly interest calculated on the remaining lease liability. As of September 30, 2019, the Company had a current lease liability of \$3.3 million and a noncurrent lease liability of \$71.4 million recorded in its condensed consolidated balance sheets related to the HQ Lease.

The Company has a tenant improvement allowance from the landlord of approximately \$2.3 million for certain permitted costs related to the buildout of the premises. The Company is deemed to be the owner of these tenant improvements during the lease term. These \$2.3 million of improvements are included in the Company's property, plant and equipment balances in its condensed consolidated balance sheets as of September 30, 2019 and are depreciated over the shorter of their useful life or the related lease term. The Company received the payment for the tenant allowance in the third quarter of 2019.

On April 1, 2019, the Company recorded a right-of-use asset in the amount \$71.3 million. The right-of-use asset is being amortized over the remaining lease term in an amount equal to the difference between the calculated straight-line expense of the total lease payments less the monthly interest calculated on the remaining lease liability. As of September 30, 2019, the Company had a long-term lease asset of \$69.2 million recorded in its condensed consolidated balance sheets related to the HQ Lease.

Lease cost is recognized on a straight-line basis over the lease term. For the three and six months ended September 30, 2019, the Company recognized a total of approximately \$3.0 million and \$6.3 million of lease cost.

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Supplemental cash flow information related to leases for the periods reported is as follows:

	<b>Nine Months Ended September 30, 2019</b>
Right-of-use assets obtained in exchange for new operating lease upon lease commencement (in thousands)	\$ 71,266
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	\$ 2,834
Cash received for tenant improvements included in the measurement of lease liabilities (in thousands)	\$ 2,289
Weighted-average remaining lease term of operating leases (in years)	9.8
Weighted-average discount rate of operating leases	10.9%

Future minimum lease payments under non-cancelable operating leases under ASC 842 as of September 30, 2019 are as follows (in thousands):

	<b>Operating lease payments</b>
2019 (remaining three months)	\$ 2,743
2020	11,212
2021	11,537
2022	11,872
2023	12,217
2024 and hereafter	73,847
Total future minimum lease payments	123,428
Less: present value adjustment	48,767
Operating lease liabilities at September 30, 2019	74,661
Less: current portion of operating lease liabilities	3,250
Operating lease liabilities, net of current portion	\$ 71,411

On March 31, 2019, the Company entered into a short-term sublease of approximately 24,000 rentable square feet with Ironwood to provide temporary working space for a portion of its workforce while the buildout of the Company's new premises was being completed. The sublease was for an initial one-month term with several one-month extension options. The Company subleased the space for approximately 1.5 months, vacating the space and terminating the sublease in mid-May 2019. The Company incurred approximately \$0.2 million in rent expense related to the sublease, which is included in the total lease cost of \$6.3 million, for the six months ended September 30, 2019. See also Note 13, *Subsequent Events*.

At December 31, 2018, no leases were directly attributed to Cycleron.

## 9. Share-based Compensation Plans

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

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

Cycleron also mirrored two of Ironwood's existing plans, the Amended and Restated 2005 Stock Incentive Plan ("2005 Equity Plan") and the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan ("2010 Equity Plan").

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These mirror plans were adopted to facilitate the exchange of Ironwood equity awards for Cycleron equity awards upon the Separation as part of the equity conversion. As a result of the Separation and in accordance with the EMA, employees of both companies retained their existing Ironwood vested options and received a prorata share of Cycleron options, regardless of which company employed them post-Separation. For employees that were ultimately employed by Cycleron, unvested Ironwood options and RSUs were converted to unvested Cycleron options and RSUs.

The conversion of equity awards resulting from the Separation impacted approximately 143 employees and was treated as a Type 1 modification under ASC Topic 718, *Share Based Payments*, as the awards are expected to vest under the original terms. Incremental compensation expense was measured as the excess, if any, of the fair value of the modified award over the fair value of the original award immediately before its terms were modified. The fair value of RSUs and restricted stock awards was measured using the fair value stock price immediately before and immediately after the modification date which resulted in no incremental compensation expense. The fair value of stock options was measured using the Black-Scholes option pricing method using the appropriate valuation assumptions immediately before and immediately after the modification date. As a result of the modification, Cycleron recognized a one-time incremental expense of approximately \$0.3 million for the vested stock options and will recognize an incremental expense of approximately \$7.5 million for the unvested stock options over their remaining vesting period.

The following table provides share-based compensation reflected in the Company's condensed consolidated and combined statements of operations and comprehensive loss for the three and nine months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 2,192	\$ 1,796	\$ 6,774	\$ 5,350
General and administrative	2,756	1,515	8,386	3,474
	<u>\$ 4,948</u>	<u>\$ 3,311</u>	<u>\$ 15,160</u>	<u>\$ 8,824</u>

**Stock Options**

A summary of stock option activity for the nine months ended September 30, 2019 is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2018	—	\$ —	—	\$ —
Aggregate impact of conversion related to spin-off	6,456,982	14.90	—	—
Granted	893,529	13.21	—	—
Exercised	(47,121)	8.18	—	—
Cancelled or forfeited	(396,560)	12.50	—	—
Outstanding as of September 30, 2019	<u>6,906,830</u>	<u>\$ 14.86</u>	<u>7.57</u>	<u>\$ 1,076</u>
Exercisable at September 30, 2019	<u>2,475,077</u>	<u>\$ 14.84</u>	<u>5.23</u>	<u>\$ 315</u>

During the three and six months ended September 30, 2019 the Company granted stock options to purchase an aggregate of 395,000 shares and 893,529 shares, respectively, at weighted average grant date fair values per option share of \$6.54 and \$8.04, respectively. The total grant date fair value of options granted during the six-month period ended September 30, 2019 was \$7.2 million.

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As of September 30, 2019, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested stock options held by Cyclierion's employees is \$29.4 million and the weighted average period over which that expense is expected to be recognized is 2.79 years.

The weighted-average Black-Scholes assumptions used in estimating the fair value of the stock options granted by Cyclierion following the Separation during the three and six months ended September 30, 2019, were as follows:

	Three Months Ended September 30, 2019	Six Months Ended September 30, 2019
Weighted average risk-free interest rate	1.52%	1.86%
Expected dividend yield	—	—
Expected option term (in years)	6.25	6.25
Expected stock price volatility	64.86%	65.07%

For the three and six months ended September 30, 2019, expected volatility was estimated using an average of the historical volatility of the common stock of a group of similar companies that were publicly traded. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

### Restricted Stock Units

The RSUs generally vest 25% per year on the approximate anniversary of the date of grant until fully vested, provided the employee remains continuously employed with the Company through each vesting date. Shares of the Company's common stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of all RSUs is based on the market value of the Company's common stock on the date of grant. Compensation expense, including the effect of estimated forfeitures, is recognized over the applicable service period.

A summary of RSU activity for the nine months ended September 30, 2019 is as follows:

	Number of Shares	Weighted- Average Grant Date Fair Value
Unvested as of December 31, 2018	—	\$ —
Aggregate impact of conversion related to spin-off	932,469	\$ 15.55
Granted	133,705	\$ 11.76
Vested	(19,662)	\$ 17.22
Forfeited	(154,542)	\$ 15.76
Unvested as of September 30, 2019	891,970	\$ 14.91

As of September 30, 2019, the unrecognized share-based compensation expense, net of estimated forfeitures, related to all unvested restricted stock units by the Company's employees is \$8.4 million and the weighted-average period over which that expense is expected to be recognized is 2.8 years.

### Restricted Stock Awards

Any of the Company's non-employee directors who served as non-employee directors of Ironwood received shares of the Company's unvested restricted stock in respect of any outstanding unvested awards of Ironwood restricted stock they held. Such

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restricted stock awards were subject to the vesting schedule set forth in the original Ironwood restricted stock award. On April 1, 2019, the Company made grants of its restricted stock to its non-employee directors who did not hold Ironwood restricted stock prior to the distribution. Such restricted stock awards have an equivalent value to the shares of the Company's restricted stock granted to its non-employee directors who held Ironwood restricted stock prior to the distribution, and have been pro-rated to reflect each non-employee director's period of service with the Company from the date of the distribution to the anticipated date of the first annual grant. These restricted stock awards fully vested on May 30, 2019.

A summary of the restricted stock for the nine months ended September 30, 2019 is as follows:

	Number of Shares	Weighted- Average Grant Date Fair Value
Unvested as of December 31, 2018	—	\$ —
Granted	21,942	\$ 14.81
Vested	(21,942)	\$ 14.81
Unvested as of September 30, 2019	—	\$ —

**10. Loss per share**

Basic and diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Prior to April 1, 2019, there were no Cycleron shares outstanding, as such, the shares outstanding immediately after the distribution and the private placement were used to calculate the net loss per share for all pre-separation periods presented.

Basic and diluted earnings per share are calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss (in thousands)	\$ (27,317)	\$ (29,286)	\$ (96,953)	\$ (84,350)
Denominator:				
Weighted average number of common shares outstanding (in thousands)	27,434	27,380	27,380	27,380

The following common stock equivalents were excluded from the calculation of diluted loss per share allocable to common stockholders because their inclusion would have been anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Stock Options	6,907	—	—	—
Restricted Stock Units	892	—	—	—
	<u>7,799</u>	<u>—</u>	<u>—</u>	<u>—</u>

## 11. Defined Contribution Plan

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

Subsequent to the Separation, Cycleron adopted a defined contribution 401(k) Savings Plan similar to the plan in place at Ironwood. The plan assets under the Ironwood defined contribution 401(k) Savings Plan were transferred to the Cycleron plan. Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. Cycleron contributions to the plan are at the sole discretion of the board of directors. Currently, Cycleron provides a matching contribution of 75% of the employee's contributions, up to \$6,000 annually.

Included in compensation expense for employees that are directly attributable to Cycleron is approximately \$0.1 million and \$0.4 million for the three months ended September 30, 2019 and 2018, respectively, and \$0.5 million and \$0.4 million for the nine months ended September 30, 2019 and 2018, respectively.

## 12. Ironwood Workforce Reduction

On June 27, 2018, as part of its plans to separate its sGC business from its commercial and gastrointestinal business, Ironwood initiated a reduction in its headquarters-based workforce by approximately 40 employees and substantially completed the reduction in its workforce during the year ending December 31, 2018.

On February 7, 2019, following further analysis of its strategy and core business needs, Ironwood commenced another reduction in its workforce by 35 employees, primarily based in its headquarters. Ironwood completed the reduction in its workforce during the first quarter of 2019. Even though employees expected to go to Cycleron were excluded from the workforce reduction, certain charges associated with the reduction were allocated to Cycleron.

Prior to the Separation, expenses related to these workforce reductions were allocated to Cycleron using a pro rata method based on internal project assignments and headcount that management believes are consistent and reasonable. Pursuant to the terms of the Separation Agreement entered into between the Company and Ironwood on March 30, 2019, the accrued liability related to these workforce reductions remained with Ironwood.

The following table summarizes the accrued liabilities activity allocated to Cycleron in connection with the reduction in workforce for the three and nine months ended September 30, 2019 (in thousands):

	Amounts accrued at December 31, 2018	Charges	Amount paid	Balance assumed by Ironwood	Amounts accrued at September 30, 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>	<b>\$ —</b>

## 13. Subsequent Events

On October 18, 2019, the Company entered into an agreement to sublease approximately 16,000 square feet primarily of lab space, representing a portion of the Company's current leased premises, to a third party. The annual sublease base rent, which begins six months after the sublease commencement date, is approximately \$1.5 million and increases 3% annually over the term of the lease which is 117 months with no extension options. The subtenant is also responsible for paying a pro rata share of operating expenses and certain other costs associated with the subleased premises. The sublease requires an initial security deposit equal to the three months of base rent, increasing to a total of six months base rent no later than nine months after the sublease commencement date. The Company also entered into a license and service agreement with the same third party for the use of a certain portion of the subleased space and for certain services to be provided by the subtenant in the subleased space.

On October 30, 2019, the Company began a reduction of its current workforce by approximately thirty (30) full-time employees in order to align its resources with its ongoing clinical and preclinical programs, innovation strategy and partnering efforts. The Company expects that this workforce reduction will take place primarily during the fourth quarter of 2019. The Company estimates that it will incur aggregate charges in connection with the workforce reduction of approximately \$3.0 million for employee severance and benefit costs primarily in the fourth quarter of 2019, nearly all of which are expected to result in cash expenditures.



## **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 consolidated and 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**

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.

Our 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.

Our 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 our common stock to Ironwood's stockholders. These historical combined financial statements may not be indicative of our future performance and do not necessarily reflect what our combined results of operations, financial condition and cash flows would have been had we operated as a separate, publicly traded company during the periods presented. The unaudited consolidated and combined financial statements prior to the Separation included herein do not reflect any changes that occurred in our financing or operations as a result of the Separation from Ironwood.

### **Financial Overview**

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

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

*Olinциguat* 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 dose-ranging Phase 2 study, STRONG-SCD, that is expected to enroll up to 88 patients from both US and ex-US sites. This study is designed to explore a broad range of tolerated doses and optimize our understanding of the therapeutic potential of olinциguat in SCD. 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 olinциguat 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 nine months ended September 30, 2018, costs associated with olinциguat include clinical studies on achalasia, although we are not presently conducting further development activities for that indication.

*Praliciгуat* is an orally administered, once-daily systemic sGC stimulator that was evaluated in two recently completed Phase 2 proof-of-concept studies: a dose-ranging study in 156 adult patients with diabetic nephropathy, and a study in 196 adult patients with heart failure with preserved ejection fraction (HFpEF), CAPACITY-HFpEF. On October 30, 2019, we released topline results from these studies.

In CAPACITY-HFpEF, the study did not meet statistical significance on its primary endpoint of improved exercise capacity from baseline as compared to placebo, measured by cardiopulmonary exercise testing. There was clear evidence of drug exposure and pharmacological activity as judged by expected reductions in blood pressure. Praliciгуat was generally well tolerated. We are discontinuing development of praliciгуat in HFpEF.

The study of praliciгуat for diabetic nephropathy also did not meet statistical significance on its primary endpoint of reduction in albuminuria from baseline as compared to placebo, measured by urine albumin creatinine ratio. However, there was a trend toward improvement across the total intention-to-treat study population. Praliciгуat was generally well tolerated. As previously announced, we intend to out-license praliciгуat for late-stage global development and commercialization.

*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.

*Discovery Research.* Our discovery efforts are primarily focused on identifying, designing and developing sGC stimulators for 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 these 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 summarizes 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 and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Product pipeline external costs:				
Praliciгуat	\$ 2,575	\$ 4,396	\$ 12,102	\$ 12,391
Olinциguat	2,891	1,651	10,794	4,887
IW-6463	1,559	740	3,797	2,157
Discovery research	364	693	999	1,652
Total product pipeline external costs	7,389	7,480	27,692	21,087
Personnel and related internal costs	9,517	8,818	29,540	27,936
Facilities and other	5,389	5,201	17,226	16,241
Total research and development expenses	\$ 22,295	\$ 21,499	\$ 74,458	\$ 65,264

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

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

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

- The 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 listed 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 our Separation from Ironwood are included in these expenses. We record all general and administrative expenses as incurred.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated and combined financial statements prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated and combined financial statements, and the amounts of expenses during the reported periods. Significant estimates and assumptions in our consolidated and combined financial statements include those related to 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

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liabilities. Actual results may differ materially from our estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

We believe that our application of accounting policies requires significant judgments and estimates on the part of management and is the most critical to aid in fully understanding and evaluating our reported financial results. Our significant accounting policies are more fully described in Note 2, *Summary of Significant Accounting Policies*, of the condensed consolidated and combined financial statements elsewhere in this Quarterly Report.

### 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 consolidated and combined financial statements appearing elsewhere in this Quarterly Report.

### Results of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Revenue from related party	1,398	—	3,026	—
Cost and expenses:				
Research and development	22,295	21,499	74,458	65,264
General and administrative	7,119	7,787	27,019	19,086
Total cost and expenses	29,414	29,286	101,477	84,350
Loss from operations	(28,016)	(29,286)	(98,451)	(84,350)
Interest and investment income	699	—	1,498	—
Net Loss	<u>\$ (27,317)</u>	<u>\$ (29,286)</u>	<u>\$ (96,953)</u>	<u>\$ (84,350)</u>

*Revenue from related party.* The increase in revenue from related party for the three and nine months ended September 30, 2019, compared to the three months and nine months ended September 30, 2018 is the result of services performed under the development agreement with Ironwood.

*Research and Development Expense.* The increase in research and development expense of approximately \$0.8 million for the three months ended September 30, 2019, compared to the three months ended September 30, 2018, was primarily related to an increase in employee-related expenses of approximately \$0.7 million as compared to the pre-Separation allocation from Ironwood and approximately \$0.2 million in facilities and operating costs allocated to research and development. This increase is partially offset by a net decrease of approximately \$0.1 million in external research costs associated with decreases in the praliciquat program of approximately \$1.8 million and costs associated with discovery of approximately \$0.3 million, partially offset by increases in the olinciguat program of approximately \$1.2 million relating to the STRONG-SCD Phase 2 study and approximately \$0.8 million in the IW-6463 program associated with our first-in-human study.

The increase in research and development expense of approximately \$9.2 million for the nine months ended September 30, 2019, compared to the nine months ended September 30, 2018, was primarily related to an increase of approximately \$6.6 million in external research costs associated with clinical advancements for our development candidates. This includes an increase of approximately \$5.9 million of costs associated with clinical progress on the STRONG-SCD Phase 2 study and supporting clinical pharmacology studies within the olinciguat program, and approximately \$1.6 million relating to clinical progress on our

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first-in-human study for the IW-6463 program, partially offset by decreases of approximately \$0.6 million associated with discovery and approximately \$0.3 million associated with the pralicigat program. Employee-related expenses, including stock-based compensation, increased by approximately \$1.6 million and facilities and operating costs increased by approximately \$1.0 million as compared to pre-Separation allocated costs from Ironwood.

*General and Administrative Expense.* General and administrative expenses decreased approximately \$0.7 million for the three months ended September 30, 2019, compared to the three months ended September 30, 2018, primarily driven by a decrease of approximately \$2.4 million in non-recurring costs associated with the Separation, partially offset by an increase of approximately \$1.4 million related to stock-based compensation and other employee-related expenses, and an increase of approximately \$0.3 million in costs related to facilities and operating costs.

General and administrative expenses increased approximately \$7.9 million for the nine months ended September 30, 2019, compared to the nine months ended September 30, 2018, primarily as a result of increases of approximately \$4.9 million of stock-based compensation, approximately \$1.5 million in salaries and other employee-related expenses, and approximately \$1.7 million in costs related to facilities and operating costs, partially offset by a decrease of approximately \$0.2 million in professional services expenses.

## Liquidity and Capital Resources

Prior to the Separation, the primary source of liquidity for our business was cash flow allocated to Cycleron from Ironwood. 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. Ironwood's cash has not been assigned to us for any of the periods prior to the Separation presented in the condensed consolidated and combined financial statements because those cash balances are not directly attributable to us. Post Separation, transfers of cash to and from Ironwood related to the transition service agreements, development agreement and provisions of the separation agreement, have been reflected in the consolidated and combined statement of cash flows.

After giving effect to the completion of the Separation on April 1, 2019, we raised approximately \$165 million net of direct financing expenses with the closing of the private placement on April 2, 2019. Subsequent to the Separation, we no longer participate in Ironwood's centralized cash management or receive direct funding from Ironwood.

On September 30, 2019, we had approximately \$117.0 million of unrestricted cash and cash equivalents. Our cash equivalents include amounts held in U.S. government money market funds and overnight repurchase agreements. We invest cash in excess of immediate requirements in accordance with our investment policy, which requires all investments held by us to be at least "AAA" rated or equivalent, with a remaining final maturity when purchased of less than twelve months, so as to primarily achieve liquidity and capital preservation.

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

Based on our development plans and clinical stage patient testing and our timing expectations related to the progress of our discovery research programs, we expect that our existing cash and cash equivalents as of September 30, 2019, will be sufficient to fund our planned operating expenses and capital expenditure requirements through at least the first quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, particularly as the process of testing drug candidates in clinical trials is costly and the timing of progress in these trials is uncertain.

## Cash Flows

The following is a summary of cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,			
	2019	2018	Change	
	(in thousands)			
Net cash used in operating activities	\$ (80,052)	\$ (74,351)	\$ (5,701)	8%
Net cash used in investing activities	(6,615)	(1,622)	(4,993)	308%
Net cash provided by financing activities	211,426	75,973	135,453	178%

### **Cash Flows from Operating Activities**

Net cash used in operating activities totaled approximately \$80.1 million for the nine months ended September 30, 2019. The primary uses of cash were our net loss of \$97.0 million and changes in assets of approximately \$0.6 million. The changes in assets resulted primarily from increases in related party accounts receivable of approximately \$1.4 million and prepaid expenses of approximately \$1.3 million, partially offset by a decrease in the operating lease right of use asset of approximately \$2.1 million. These uses of cash were partially offset by non-cash items, including share-based compensation of approximately \$15.2 million and depreciation and amortization expense of property and equipment of \$2.0 million, in addition to changes in liabilities of approximately \$0.3 million. Changes in liabilities included increases in operating lease liabilities of approximately \$3.4 million, accounts payable of approximately \$1.9 million, and related party accounts payable of \$0.2 million, partially offset by decreases in accrued expenses and other current liabilities of approximately \$3.5 million and accrued research and development expenses of \$1.7 million.

Net cash used in operating activities totaled approximately \$74.4 million for the nine-month period ended September 30, 2018. The primary uses of cash were our net loss of \$84.4 million and changes in assets of approximately \$0.6 million resulting primarily from an increase in prepaid expenses and other current assets. These uses of cash were partially offset by non-cash items of approximately \$10.0 million including approximately \$8.8 million in share-based compensation expense and approximately \$1.1 million in depreciation and amortization expense of property and equipment, and changes in liabilities of approximately \$0.3 million resulting primarily from increases in accounts payable and accrued expenses and other current liabilities of approximately \$1.1 million and approximately \$0.5 million, respectively, offset by a decrease in accrued research and development costs of approximately \$1.0 million and decrease in accrued expenses and other liabilities of approximately \$0.5 million.

### **Cash Flows from Investing Activities**

Cash used in investing activities for the nine months ended September 30, 2019 totaled approximately \$6.6 million, resulting from purchases of property and equipment of \$6.7 million, primarily leasehold improvements, partially offset by proceeds from the sale of property and equipment of \$0.1 million.

Cash used in investing activities for the nine months ended September 30, 2018 totaled approximately \$1.6 million, resulting primarily from the purchase of property and equipment, primarily laboratory equipment.

### **Cash Flows from Financing Activities**

Cash provided by financing activities for the nine months ended September 30, 2019 was approximately \$211.4 million, primarily as a result of \$164.6 million in net proceeds from the private placement, approximately \$46.4 million of cash transferred to us from Ironwood prior to Separation when Ironwood managed our cash and financing arrangements, and approximately \$0.4 million from proceeds from the exercises of stock options and the employee stock purchase plan

Cash provided by financing activities for the nine months ended September 30, 2018 was approximately \$76.0 million, 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 as we advance the preclinical activities and clinical trials of our product candidates. In addition, as a result of the Separation, we expect to continue incur additional costs associated with operating as a public company. Our expenses will also increase as we:

- continue advancing our product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- may potentially hire additional clinical, quality control and scientific personnel;
- enhance our operational, financial and management systems and
- maintain, expand and protect our intellectual property portfolio.

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We believe that our existing cash, cash equivalents and restricted cash as of September 30, 2019 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 many risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase or decrease significantly as a result of, many factors, including the:

- scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- costs, timing and outcome of regulatory review of our product candidates;
- costs of future activities, including medical affairs, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- cost and timing of necessary actions to support our strategic objectives;
- costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

A change in any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing of the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements with third parties. As discussed under the “Risk Factors” 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, liabilities or obligations pertaining to uncertain tax positions from our summary of contractual commitments and obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of September 30, 2019, we had no uncertain tax positions.

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

As of September 30, 2019, we have several ongoing studies in various clinical trial stages. Our most significant clinical trial spending is with clinical research organizations, or CROs. The contracts with CROs generally are cancellable, with notice, at our option and do not have any significant cancellation penalties.

## **Transition from Ironwood and Costs to Operate as an Independent Company**

Prior to the Separation, our financial statements reflect our operating results and financial position as it was operated by Ironwood, rather than as an independent company. We have incurred additional ongoing operating expenses to operate as an independent, publicly traded, 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 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 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 consolidated and combined financial statements appearing elsewhere in this Quarterly Report.

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

### **Interest Rate Risk**

We are exposed to market risk related to changes in interest rates. We invest our cash in money market instruments and overnight repurchase agreements. The goals of our investment policy are preservation of capital while anticipating and maintaining liquidity and fiduciary control of our cash and investments. We also seek to obtain favorable yields from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in money market accounts. Due to the primarily short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 1% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.



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We do not believe our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the potential instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits.

**Foreign Currency Risk**

We have operations in Switzerland and transact certain other business which may be subject to fluctuations in foreign currency exchange rates. We do not believe, however, that we are materially exposed to market risk related to changes in foreign currency exchange rates.

**Effects of Inflation**

We do not believe that inflation and changing prices had a significant impact on our results of operations during the three and nine months ended September 30, 2019.

**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**

Prior to the Separation, the Company's financial results were included within the consolidated results of Ironwood and Cycleron was not directly subject to Section 404 of the Sarbanes-Oxley Act. The Company is now subject to the reporting requirements of Section 404 of the Sarbanes-Oxley Act and is an emerging growth company ("EGC") and a smaller reporting company ("SRC"). As long as we remain an EGC or SRC, we will be exempt from Section 404(b) of the Sarbanes-Oxley Act, which requires auditor attestation to the effectiveness of internal control over financial reporting. We are, however, subject to Section 404(a) of the Sarbanes-Oxley Act, and beginning with the year ending December 31, 2020, must include a management assessment of the effectiveness of our internal control over financial reporting. To achieve compliance with Section 404 within the prescribed periods, we are engaging in a process to document and evaluate our internal controls, including reporting systems and control processes.

**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. The following updated risk factors should be considered in addition to those included in the Form S-1.

*We may not succeed in our pursuit of an out-license agreement for the development and commercialization of praliciguat for diabetic nephropathy, which would materially adversely affect our financial condition and results of operations.*

We are evaluating alternatives, including seeking an out-license for the purpose of pursuing further development and commercialization of praliciguat for diabetic nephropathy. There is no certainty that we will find a commercial or financial partner to fund and undertake development and commercialization, and failure to find such a partner may result in the discontinuation of

development of praliguat for diabetic nephropathy. We may also incur costs to wind down our activities related to this product candidate. Failure to find a partner for the continued development and commercialization of praliguat for diabetic nephropathy would materially adversely affect our financial condition and results of operations.

***The market price for our common stock is particularly volatile.***

The market for our common stock is characterized by significant price volatility when compared to seasoned issuers, and we expect that our stock price will continue to be more volatile than those of a seasoned issuer. Several factors cause the volatility in our share price. We are a speculative or “risky” investment due to our short operating history, lack of revenues and the uncertain success (including of regulatory approval) of any of our product candidates. For example, on October 30, 2019 we announced that topline results from our Phase 2 proof-of-concept trials of praliguat in patients with diabetic nephropathy and in HFpEF did not meet statistical significance on their respective primary endpoints. After this announcement, the market price of our common stock decreased substantially. As a consequence of this risk, more risk-averse investors may, under the fear of losing all or most of their investment in the event of further negative news or lack of progress, be more inclined to sell their shares of our common stock more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Plaintiffs have, in the past, initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of such litigation. Securities litigation could result in substantial costs and liabilities and could divert management’s attention and resources.

***The reported results of our Phase 2 proof-of-concept trials of praliguat in patients with diabetic nephropathy and in HFpEF are based on topline data. While we intend to follow our previously announced strategy to discontinue internal development of praliguat in diabetic nephropathy, we believe that positive trends on primary and secondary endpoints indicate a profile that merits further investigation. However, topline data may ultimately differ from actual results once additional data are received and fully evaluated.***

The reported results of our Phase 2 proof-of-concept trials of praliguat in patients with diabetic nephropathy and in HFpEF that we have publicly disclosed, and that are discussed herein, consist of topline data. Topline data are based on a preliminary analysis of currently available efficacy and safety data, and therefore the reported results, findings and conclusions related to such clinical trials are subject to change following a comprehensive review of the more extensive data that we expect to receive related to these clinical trials. Topline data are based on important assumptions, estimations, calculations and information currently available to us, and we have not received or had an opportunity to fully and carefully evaluate all of the data related to our Phase 2 proof-of-concept trials of praliguat, including with respect to diabetic nephropathy, for one clinical trial site where data was found to be inconsistent with the overall study population. Topline results may differ from future results, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. In addition, third parties, including regulatory agencies and potential third-party licensees, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently. If the topline data that we have reported related to our Phase 2 proof-of-concept trials of praliguat differ from actual results, our ability to potentially obtain approval for or out-license and commercialize praliguat may be harmed, which could harm our business, financial condition, operating results or prospects.

***Research and development of biopharmaceutical products is inherently risky. We may encounter substantial delays in our clinical studies, or we may fail to reach statistical significance on one or more primary endpoints, or to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.***

Our current product candidates are at an early stage of development. Our business depends heavily on successful preclinical development, clinical testing, regulatory approvals and commercialization of our lead product candidates. On October 30, 2019, we announced that our topline results from our Phase 2 proof-of-concept trials of praliguat in patients with diabetic nephropathy and in HFpEF did not meet statistical significance on their respective primary endpoints. In light of this topline data, we intend to discontinue development of praliguat in patients with HFpEF and to pursue an out-license of praliguat for diabetic nephropathy. Our other lead product candidates, olinciguat and IW-6463, as well as any other of our current product candidates or product candidates that we may discover in the future, will require substantial additional development and testing, as well as regulatory approvals, prior to commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical and clinical studies that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate benefit-risk profile for its intended use in its intended patient population. In some instances, significant variability in safety or efficacy appear in different clinical studies of the same product candidate due to numerous factors, including changes in study protocols, differences in the number and characteristics of the enrolled patients, variations in the dosing regimen and other clinical study parameters or the dropout rate among study participants. Product candidates in later stages of clinical studies often fail to demonstrate adequate safety and efficacy despite promising preclinical testing

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and earlier clinical studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical studies. Most product candidates that begin clinical studies are never approved for commercialization by regulatory authorities.

*Any collaboration or license arrangements that we enter into in the future may not be successful, which could impede our ability to develop and commercialize our product candidates.*

We intend to seek collaboration or license arrangements for the commercialization, and/or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration or license arrangements. For example, we intend to out-license praliciguat for diabetic nephropathy. We will face significant challenges in seeking appropriate partners. Moreover, collaboration and license arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement such arrangements. The terms of any collaborations, licenses or other arrangements that we may establish may not be favorable to us.

Any future collaboration or license arrangements that we enter into may not be successful. The success of such arrangements will depend heavily on the efforts and activities of our partners. Collaboration and license arrangements are subject to numerous risks, which may include risks that:

- partners have significant discretion in determining the efforts and resources that they will apply to collaborations;
- a partner with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaboration and license arrangements may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- partners may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaboration or license arrangements; and
- a partner's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

**Item 6. Exhibits**

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

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.1+	<a href="#">Cyclerion Therapeutics, Inc. Executive Severance Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 25, 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.

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\* 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: November 12, 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 Cyclarion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

By: /s/ Peter M. Hecht

Name: Peter M. Hecht

Title: Chief Executive Officer (Principal Executive Officer)

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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 Cyclarion Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

By: /s/ William Huyett

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

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

I, Peter M. Hecht, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Cycleron Therapeutics, Inc. for the period ended September 30, 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: November 12, 2019

By: /s/ Peter M. Hecht

Name: Peter M. Hecht

Title: Chief Executive Officer (Principal Executive Officer)

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

Date: November 12, 2019

By: /s/ William Huyett  
Name: William Huyett  
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

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