Cyclerion Therapeutics Reports Second Quarter 2019 Financial Results and Progress on Four Clinical Studies with Data Readouts Anticipated in the Next 12 Months

August 12, 2019

– Two praliciguat Phase 2 studies for diabetic nephropathy and heart failure with preserved ejection fraction (HFpEF) on track for data readouts in Q4 2019 –

– Phase 2 study of olinciguat in sickle cell disease on track for data readout in mid-2020 –

– Phase 1 study of central nervous system penetrant sGC stimulator, IW-6463, on track for data readout in Q4 2019 –

– Webcast investor event focused on praliciguat cardiometabolic programs to be held on September 17 in New York City ahead of anticipated clinical results –

CAMBRIDGE, Mass., Aug. 12, 2019 (GLOBE NEWSWIRE) -- Cyclerion Therapeutics, Inc. (Nasdaq: CYCN), a clinical-stage biopharmaceutical company focused on the development of soluble guanylate cyclase (sGC) stimulators for the treatment of serious and orphan diseases, today provided general corporate and pipeline updates and reported financial results for the second quarter of 2019.

“Since Cyclerion launched as an independent public company in April, we have made excellent progress advancing our five programs targeting the soluble guanylate cyclase pathway. We look forward to an exciting and data-rich year ahead with four anticipated clinical readouts,” said Peter Hecht, Ph.D., chief executive officer of Cyclerion. “Each of our programs has the potential to provide a differentiated treatment option for serious diseases that are not well managed today, and each is supported by compelling science.”

Development Stage Programs and Recent Business Highlights

- **Praliciguat Phase 2 studies in patients with cardiometabolic diseases remain on track for two data readouts in Q4 2019.**
  - The ongoing Phase 2 study of praliciguat in patients with diabetic nephropathy is a randomized, placebo-controlled, dose-ranging study in 156 patients to evaluate safety and efficacy following 12 weeks of praliciguat treatment. Enrollment is complete. The primary measure of efficacy is the change in urine albumin to creatinine ratio (UACR). Effects on metabolic parameters will also be assessed as secondary endpoints.
  - The ongoing Phase 2 study of praliciguat in patients with HFpEF (CAPACITY study) is a randomized, placebo-controlled study in 196 patients to evaluate safety and efficacy following 12 weeks of praliciguat treatment. Enrollment is complete. The primary measure of efficacy is change in peak oxygen uptake (VO2 max) as assessed by cardiopulmonary exercise testing (CPET), a quantitative measure of exercise capacity. Secondary efficacy measures include change in exercise capacity as assessed by the six-minute walk test, and change in patient-reported quality of life as assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ).

- **Olinciguat Phase 2 study (STRONG SCD) in patients with sickle cell disease (SCD) remains on track for data readout in mid-2020.**
  - Olinciguat is being studied in a randomized, placebo-controlled, dose-ranging Phase 2 study in patients with sickle cell disease (STRONG SCD) that is expected to enroll up to 88 patients. STRONG SCD is designed to evaluate safety, tolerability, and pharmacokinetics of olinciguat, as well as to explore effects on daily symptoms and biomarkers of disease activity when dosed over a 12-week treatment period.

- **IW-6463 first-in-human Phase 1 study remains on track for data readout in Q4 2019.**
  - IW-6463 is a central nervous system (CNS) penetrant sGC stimulator in development for serious neurodegenerative diseases. The objectives of the ongoing single and multiple ascending dose Phase 1 study are to evaluate safety, tolerability and pharmacokinetics, including confirming the ability of IW-6463 to cross the blood-brain barrier. The study will also evaluate exploratory measures of target engagement.

- **Scientific and clinical meeting presentations:**
  - Cyclerion presented data on praliciguat, olinciguat and IW-6463 at several scientific conferences during the quarter, including:
    - 13th Annual Sickle Cell Disease Research and Educational Symposium – June 7-9; Fort Lauderdale, Florida
    - 79th Scientific Sessions of the American Diabetes Association (ADA) – June 7-11; San Francisco, California

    - 24th European Hematology Association (EHA) Congress – June 13-16; Amsterdam, the Netherlands
    - 9th International Conference on cGMP – June 14-16; Mainz, Germany
  - Presentations included preclinical data exploring the effects of praliciguat on metabolic parameters, new mechanistic data for praliciguat, new insights into sickle cell disease patient-reported outcomes (PRO) tools and a series of preclinical studies evaluating the pharmacology of IW-6463.
  - The conferences afforded an opportunity for continued engagement with patient and physician communities. For example, Cyclerion presented an overview of olinciguat and the STRONG SCD study and sponsored a town hall for men living with sickle cell disease in conjunction with the Sickle Cell Disease Research and Educational Symposium.

Upcoming Investor Event

- Cyclerion will host a webcast event, featuring external opinion leaders and Cyclerion management, to provide additional insights into the praliciguat cardiometabolic development programs ahead of data readouts: September 17, in New York, New York.

Second Quarter 2019 Financial Results

- **Basis of presentation:** Cyclerion's unaudited consolidated balance sheet as of June 30, 2019, and results of operations for the second quarter ended June 30, 2019, consist of the consolidated balances of Cyclerion as prepared on a stand-alone basis. For prior periods, Cyclerion was a wholly owned subsidiary of Ironwood Pharmaceuticals, Inc. Accordingly, Cyclerion's financial statements for prior periods have been prepared and derived from Ironwood's financial statements and accounting records. These prior period condensed combined financial statements reflect the assets, liabilities and expenses directly attributable to Cyclerion, 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 Cyclerion. As such, these allocations may not be indicative of the actual amounts that would have been recorded had Cyclerion operated as an independent, publicly traded company for the prior periods presented.
- **Research and development expense:** Research and development expenses were $25.8 million for the three months ended June 30, 2019, compared to $22.3 million for the three months ended June 30, 2018. The increase of approximately $3.5 million was primarily related to external research costs associated with clinical development of Cyclerion's product candidates, including costs associated with supporting clinical pharmacology studies for olinciguat and Phase 1 clinical activities for IW-6463.
- **General and administrative expense:** General and administrative expenses were $8.9 million for the three months ended June 30, 2019, compared to $7.5 million for the three months ended June 30, 2018. The increase of approximately $1.4 million was primarily due to an increase in non-cash stock-based compensation driven by the conversion of employee equity awards resulting from Cyclerion's separation from Ironwood, as well as the differences stemming from the method used to allocate expense from Ironwood prior to the separation. This increase was partially offset by a decrease in professional service costs.
- **Net loss:** Net loss was $32.3 million for the three months ended June 30, 2019, compared to $29.8 million for the three months ended June 30, 2018.
- **Cash position:** On April 2, 2019, approximately $165 million net proceeds were received from a private placement financing that are expected to fund operations through at least the first quarter of 2021. Cyclerion ended the second quarter of 2019 with approximately $148.8 million of cash, cash equivalents and restricted cash. There was no cash specifically attributable to Cyclerion prior to the second quarter of 2019.

About Cyclerion Therapeutics

Cyclerion Therapeutics 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 is advancing its portfolio of five differentiated sGC stimulator programs with distinct pharmacologic and biodistribution properties that are uniquely designed to target tissues of greatest relevance to the diseases they are intended to treat. These programs include olinciguat in Phase 2 development for sickle cell disease, praliciguat in Phase 2 trials for heart failure with preserved ejection fraction (HFpEF) and for diabetic nephropathy, IW-6463 in Phase 1 development for serious and orphan central nervous system diseases, and two late-stage discovery programs targeting serious liver and lung diseases, respectively.

For more information about Cyclerion, please visit https://www.cyclerion.com/ and follow us on Twitter (@Cyclerion) and LinkedIn (www.linkedin.com/company/cyclerion).

Forward Looking Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties, including statements about the anticipated timing of release of data from our clinical trials; the progression of our clinical programs into commercial products; the business and operations of Cyclerion; and our future financial performance and expense levels. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "likely," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Each forward-looking statement is subject to risks and uncertainties that

could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include those related to the possibility that we may not achieve the expected benefits of the separation from Ironwood, and that this separation could harm our business, results of operations and financial condition; the risk that we may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent company; the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates; the risk of a delay in the enrollment of patients in our clinical studies; the risk that any one or more of our product candidates will not be successfully developed, approved or commercialized; our lack of independent operating history and the risk that our accounting and other management systems may not be prepared to meet the financial reporting and other requirements of operating as an independent public company; the risk that the separation from Ironwood may adversely impact our ability to attract or retain key personnel; and the other risks and uncertainties listed under the “Risk Factors” section and elsewhere in our Registration Statement on Form S-1 filed on April 18, 2019, with the Securities and Exchange Commission (SEC), and in subsequent reports that we file with the SEC. Investors are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and we undertake no obligation to update these forward-looking statements, except as required by law.

Cyclerion Therapeutics, Inc.

Condensed Consolidated and Combined Statements of Operations

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue from related party	$ 1,628	$ -	$ 1,628	$ -
Cost and expenses:				
Research and development	25,759	22,251	52,163	43,765
General and administrative	8,923	7,530	19,900	11,299
Total cost and expenses	34,682	29,781	72,063	55,064
Loss from operations	(33,054)	(29,781)	(70,435)	(55,064)
Interest and investment income	800	-	800	-
Net loss	$ (32,254)	$ (29,781)	$ (69,635)	$ (55,064)
Net loss per share:				
Basic and diluted net loss per share	$ (1.18)	$ (1.09)	$ (2.54)	$ (2.01)
Weighted average shares used in calculating:				
Basic and diluted net loss per share	27,393	27,380	27,380	27,380

Cyclerion Therapeutics, Inc.

Condensed Consolidated and Combined Balance Sheets

(In thousands)

(Unaudited)

	June 30, 2019	**December 31, 2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 141,030	$ -
Related party accounts receivable	1,857	-
Prepaid expenses	1,778	867
Other current assets	28	12
Total current assets	144,693	879
Restricted cash	7,726	-
Property and equipment, net	12,754	6,497
Operating lease right-of-use asset	70,330	-
Other assets	-	25
Total assets	$ 235,503	$ 7,401
LIABILITIES AND STOCKHOLDERS’ EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 6,863	$ 2,781

Related party accounts payable	1,920	$ -
Accrued research and development costs	5,250	5,261
Accrued expenses and other current liabilities	7,017	9,804
Current portion of operating lease liabilities	866	-
Total current liabilities	21,916	17,846
Operating lease liabilities, net of current portion	72,397	-
Stockholders' equity (deficit)		
Common stock, $0.0 par value, 400,000,000 shares authorized and 27,411,189 issued and outstanding at June 30, 2019 and no shares issued or outstanding at December 31, 2018	-	-
Accumulated deficit	(32,254)	-
Net parent investment	-	(10,445)
Paid-in capital	173,448	-
Accumulated other comprehensive income (loss)	(4)	-
Total stockholders' equity (deficit)	141,190	(10,445)
Total liabilities and stockholders' equity (deficit)	$ 235,503	$ 7,401

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